FAITH DM | Feeding America Intervention Trial For Health Diabetes Mellitus

Manual of Operations and Procedures (MOP)

Table of Contents

1 Introduction

1.1 Overview of the FAITH-DM Trial

The Feeding America Intervention Trial for Health—Diabetes Mellitus (FAITH-DM) is a randomized, controlled study of the implementation of a diabetes intervention in food pantry settings. Every effort has been made to enhance the feasibility of implementation while maintaining the rigor of a randomized, controlled trial. The intervention will be implemented in three food banks: Alameda County Community Food Bank (Oakland, CA), Gleaners Community Food Bank of Southeastern Michigan (Detroit, MI), and the Houston Food Bank, (Houston, TX). These food banks were chosen through a competitive application process after demonstrating their capacity to reach the population of interest (English- and Spanish-speaking adults with diabetes receiving food at food pantries) and carry out the study procedures according to the instructions laid out in this manual.

This research is critically important. In the pilot study recently completed, we observed significant improvements in self-management skills and competencies such as self-efficacy and medication adherence, and a trend toward improved glycemic control (HbA1c) and decreased risk of severe hypoglycemic events. Participants were highly satisfied with the diabetes-appropriate food distributed as part of the intervention. This work suggested that food pantries are a feasible site to engage vulnerable individuals in diabetes self-management efforts. We are excited to be able to determine the efficacy of this model.

Funding for FAITH-DM was provided by Feeding America and the Laura and John Arnold Foundation.

The study is listed on www.clinicaltrials.gov with identifier: NCT02569060.

FAITH-DM received approval from the Western Institutional Review Board (Protocol Number: FADiabetes2015, WIRB#: 2015169).

1.2 Overview of the Manual of Operations (MOP)

A MOP is a handbook that details a study's conduct and operations. It transforms the study protocol into a guideline that describes a study's organization, operational data definitions, recruitment, screening, enrollment, randomization, follow-up procedures, data collection methods, data flow, and quality control procedures. The MOP is intended to serve as a study "cookbook" that facilitates adherence to study procedures. It is a reference guide for how each element of the study should be carried out.

Implementing a trial is a complex undertaking. The MOP is a dynamic document that will be updated throughout the study to reflect any refinements to the study protocol, forms, or procedures. It should be easily accessible, in electronic and/or printed form, at all study sites. Each page of the MOP contains the version number and date in order to allow easy tracking of revisions. As pages are

revised, an updated version number and associated date will replace the original page(s) in the MOP. All previous versions should be archived.

1.3 MOP Contents and Organization

This MOP includes the following information:

a) Study Protocol
b) Study Organization and Responsibilities
c) Study Timeline
d) Study Intervention Overview
e) Recruitment and Participant Retention Plan
f) Study Flow
g) Screening and Eligibility Criteria and Processes
h) Informed Consent and HIPAA
i) Study Intervention
j) Study Measurements and Procedures
k) Safety Reporting
l) Study Compliance
m) Data Collection and Study Forms
n) Data Management
o) Quality Control Procedures
p) Reports
q) Data Safety and Monitoring Board
r) Study Completion and Closeout Procedures
s) Study Policies
t) Appendices: contain additional information and sample forms

2 Study Protocol

For adults with diabetes mellitus, diabetes self-management education (DSME) is critical to achieving long-term control of blood sugar levels (glycemic control) and preventing diabetes-associated complications. This education is often difficult to access for highly vulnerable and marginalized adults in the United States. Furthermore, we know that the appropriate foods for a diabetic diet are often out of reach for food insecure households. The purpose of this study is to determine the extent to which food banks and food pantries can help reach this population with effective DSME, food, and access to primary health care, with the ultimate goal of reducing diabetes complications and mortality. The randomized, controlled trial design will allow us to definitively answer this question. Our primary outcome of interest is HbA1c improvement in the intervention group compared to a wait-listed control group of food pantry clients living with uncontrolled type 2 diabetes.

2.1 Study Organization and Responsibilities

Feeding America National Offices
Responsibilities:

- WIRB Approval
- Study design
- Survey design and distribution
- Food bank selection
- Educational content development
- Food box content development
- Training of Food Bank staff
- Training for blood glucose and HbA1c testing
- Technical assistance for regulatory oversight, including CLIA certification
- Progress reporting to donor
- Compliance with donor requirements
- Results reporting through Feeding America network

UCSF Center for Vulnerable Populations
Responsibilities:

- UCSF IRB Approval
- Study design
- Survey design and distribution
- Food bank selection approval
- Educational content development
- Training of Research Assistants
- Data analysis
- Progress reporting to FANO
- Results dissemination via scientific journals and presentations
- PI (Dr. Seligman) will also assume responsibility of Lab Director if required by local (Alameda County, CA) CLIA and NDGHA regulations

Food Bank 1
Responsibilities:

FAITH-DM Manager

- Assistance to enrolled clients
- Blood glucose and HbA1c screening and monitoring
- Diabetes education
- Relationships with health care providers
- Preparation and distribution of food boxes
- Regulatory compliance for blood glucose and HbA1c testing (CLIA, medical waste, NDGHA)

Research Assistants

- Pilot all forms on 2-3 participants
- Obtain informed consent in English and Spanish
- BG and HbA1c screening and monitoring
- Randomization
- Survey administration in English and Spanish
- Data collection (including utilization data)
- Data entry, management, and transmission
- Participant follow-up and retention
- Report standard food box and diabetes food box contents every 3 months

Food Bank 2
Responsibilities:

See List for Food Bank 1

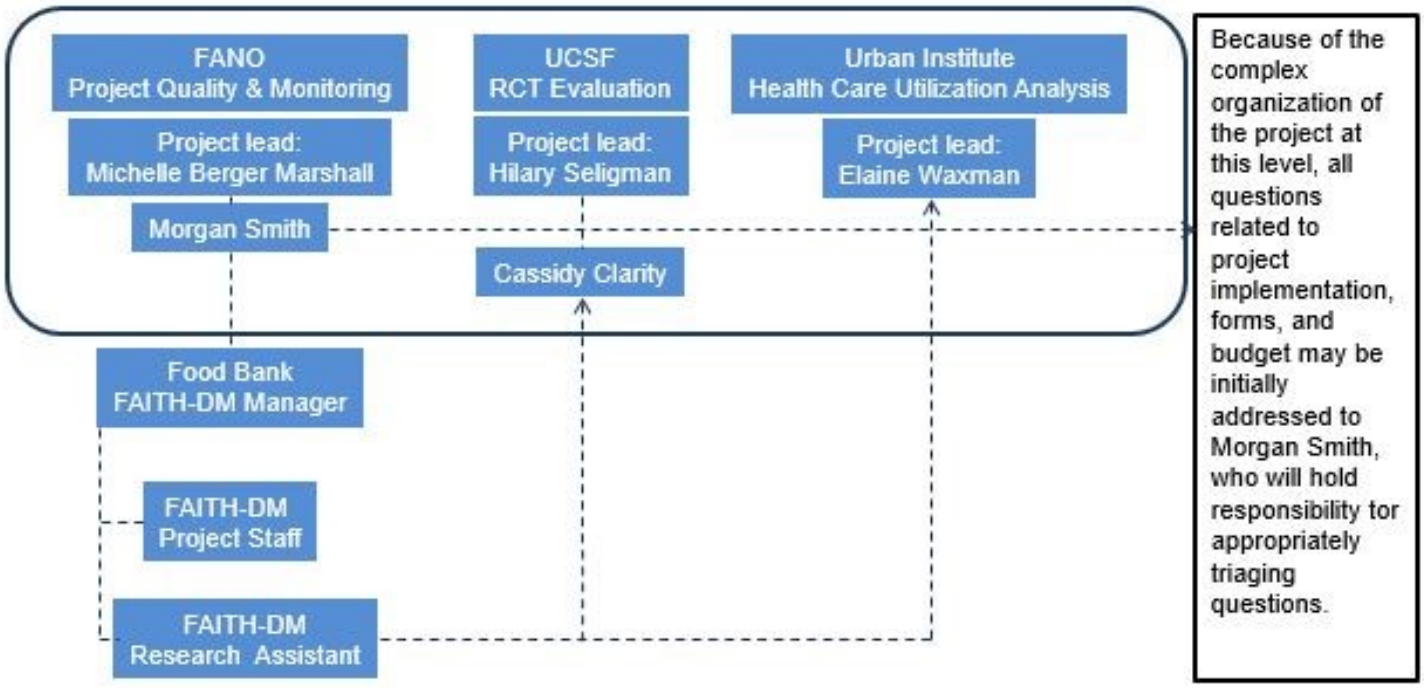
Food Bank 3
Responsibilities:

See List for Food Bank 1

Urban Institute
Responsibilities:

- Urban Institute IRB Approval
- Design health care utilization evaluation plan and delineate data needed from provider and participant surveys
- Train Research Assistants in proper procedures for sending de-identified data to Urban for utilization analysis
- Provide consultation to RAs on provider questions regarding health care utilization data
- Receive de-identified provider surveys and construct data set using project identifiers
- Conduct health care utilization analyses, using de-identified provider data set and de-identified participant survey data set received from UCSF
- Disseminate results via scientific journals and presentations (health care utilization analysis only)

2.2 Division of Supervision Responsibilities



2.3 Coordinating Center Study Staff Roster

Name	Organization	Principle Role	Address	Email
Courtney Lyles, PhD	CVP	UCSF Analyst/Statistician	Box 1364, San Francisco, CA 94143	Courtney.Lyles@ucsf.edu
Michelle Berger Marshall, RD	FANO	FANO Director	35 East Wacker Drive, Suite 2000 Chicago, IL 60601	mbergermarshall@feedingamerica.org
Justin Morgan	Urban Institute	Intern		JMorgan@urban.org
Kim Prendergast, RD, MPP	FANO	FANO Consultant	35 East Wacker Drive, Suite 2000 Chicago, IL 60601	kprendergast@feedingamerica.org
Sophie Rosenmoss	CVP	UCSF Project Coordinator	Box 1364, San Francisco, CA 94143	sophie.rosenmoss@ucsf.edu
Hilary Seligman, MD	CVP	FAITH-DM Principle Investigator	Box 1364, San Francisco, CA 94143	Hilary.Seligman@ucsf.edu

Morgan Smith, RN, PHN, CDE	FANO	Project Manager	5715 Baltimore Dr., Unit 149 La Mesa, CA 91942	mosmith@feedingamerica.org
Elaine Waxman, PhD	Urban Institute	Lead, Health Care Utilization Analysis		EWaxman@urban.org

2.4 Coordinating Center

Coordinating center responsibilities will be shared between FANO and UCSF's Center for Vulnerable Populations. These responsibilities include:

- Development and maintenance of the MOP (UCSF and FANO)
- Development of the randomization scheme and procedures (UCSF)
- Development of the data flow and data management procedures including data entry, error identification and correction (UCSF and FANO)
- Adverse event monitoring and reporting to Coordinating Center (FANO)
- Adverse event reporting to UCSF Committee on Human Research and/or Western Institutional Review Board, and/or the Urban Institute IRB as appropriate (UCSF)
- Central communication with study sites, scheduling of meetings and training sessions, responding to and documenting ad hoc communications (FANO)
- Site visits to ensure adherence to the protocol and procedures (FANO)
- Quality control procedures (UCSF)
- Reports (e.g. enrollment, adverse events, participant status, site performance, quality control) (UCSF and FANO)
- Distribution of all changes, reports, procedures and documents to participating study sites (FANO)
- CITI Certification (FANO and UCSF, as necessary)

2.5 Study Sites

Sites participating in FAITH-DM include: Alameda County Community Food Bank (ACCFB), Gleaners Community Food Bank of Southeastern Michigan (GCFB), and the Houston Food Bank (HFB)

The roles and responsibilities of the food banks include:

- Maintenance of study binder with updated MOP
- Participation in protocol finalization and preparation of study materials
- Compliance with protocol, MOP, IRBs (UCSF Committee on Human Research, Western IRB, Urban Institute IRB) and Federal and state regulations
- Accountability for administration of study intervention
- CITI certification (as necessary)

- Membership in Steering Committee
- Recruitment, screening, enrollment, and follow-up/retention of participants
- Protection of participants' rights
- Data collection from enrollment through study completion, including: survey data, HbA1c, and health care utilization data (requiring medical chart abstraction)
- Transfer of data to Coordinating Center and resolution of all queries
- Communication of questions, concerns, and/or observations to the Coordinating Center (FANO, Morgan Smith)
- Development and maintenance of MOUs with collaborating health care sites
- Communication with primary care providers
- Development of expertise in administration of all intervention components, including diabetes education
- Maintenance and quality control of point-of-care HbA1c machines and glucometers, including CLIA Certification and other regulatory requirements (as necessary)
- Assembly and distribution of food packages
- Communication and reporting per project guidelines and timeframes with FANO and UCSF staff (e.g., progress reports, budget reports, food box content reports, etc.)

2.6 Steering Committees

The Steering Committee is composed of representatives from FANO, UCSF, and staff from each of the three food banks, including the FAITH-DM Manager and the Research Assistant(s). It is responsible for the overall direction of the study.

The following areas fall under the purview of the Steering Committee:

- Review of overall design and implementation of the study
- Conduct of the study
- Approval of essential study documents, including the protocol, protocol amendments, MOP, and data collection forms
- Review of data collection practices and procedures
- Monitoring recruitment and retention of study participants
- Changes in study procedures as appropriate
- Allocation of resources based on priorities of competing study demands
- Review of study progress in achieving goals and taking necessary steps to ensuring the likelihood of achieving those goals

It is FANO and UCSF’s responsibility to make sure the Steering Committee has the necessary data to make decisions related to these responsibilities.

2.7 Timeline

Timeline

	IRB Finalization, Kick-Off call, distribution of MOP	Hire Research Assistants, Kickoff Meeting	Food Bank Planning, Training	Screening & Enrollment	INT - Food Boxes & Written educational materials distributed	Educational Classes Offered as needed per site	Participant nudges for Control group & intervention group	3-month HbA1c tests	INT Follow-up surveys and HbA1c testing – T6	Control Group Surveys and HbA1c testing – T6	Control Group receives food boxes	Control group final survey and HbA1c testing – T12	Intervention group follow-up HbA1c and survey – T12; HCUS (extension activities)	**Target #'s participants recruited this month per food bank**	**Total Numbers Recruited per food bank**	**Total Intervention Group at end of the month (Estimate) per food bank**	**# of participants receiving diabetes food boxes (assuming full participation of control group)**
July 2015	X	X	X														
August	X	X	X														
September			X														
October			X	X	X	X	X							10	10	5	5
October Notes				Classes ideally offered twice this month													
November				X	X	X	X							20	30	15	15
December				X	X	X	X	X						25	55	28	28
January 2016				X	X	X	X	X						25	80	40	40
February				X	X	X	X	X						25	105	53	53
March				X	X	X	X	X						20	125	63	63
April			X	X	X	X	X	X	X	X	X			30	155	73	78
April Notes		First intervention group concludes; Team Retreat in Houston (4/20-4/21/16); begin sending and retrieving HCU surveys to all PPT providers															
May				X	X	X	X	X	X	X	X			30	185	78	93
June				X	X	X	X	X	X	X	X			30	215	81	109
July				X	X	X	X	X	X	X	X			25	240	81	121
August				X	X	X	X	X	X	X	X	X		20	260	78	131
August Notes		Screening & enrollment concludes (or earlier if goal #'s are achieved)															
September					X	X	X	X	X	X	X	X	X			66	129

October					X	X	X	X	X	X	X	X	X			54	127
November					X	X	X	X	X	X	X	X	X			44	122
December					X	X	X	X	X	X	X	X	X			29	109
January 2017					X	X	X	X	X	X	X	X	X			14	94
February					X		X	X	X	X	X	X	X			14	77
February Notes		Final Food Boxes and Group Classes (Intervention Group); send final HCU surveys to both INT & CONT PPTs' Providers															
March							X	X	X	X	X	X	X				67
April							X	X			X	X	X				52
May							X	X			X	X	X				37
June							X				X	X	X				22
July							X				X	X	X				10
August											X	X	X				10
August Notes		Final Food Boxes Distributed (Control Group)															
September												X	X				
October													X				
October Notes		Research Assistants finish all data collection & uploads; final PCP HCUS surveys (INT only at T12); final transmissions to UCSF; **final site grant reports DUE**															
November	Data analysis by UCSF and Urban Institute; manuscript preparation (UCSF, UI, & FANO)																
December																	
December Notes		**FAITH-DM concludes**															

2.8 Communications Plan

The communication plan includes:

Steering Committee

- Monthly meetings by phone
- Ad hoc phone meetings between monthly meetings as necessary
- Email communication as necessary

FANO Staff (Morgan Smith), FAITH-DM Managers, and Research Assistants:

- Weekly meetings by phone during implementation, with frequency reduced to twice or once monthly after follow-up period is completed
- Email communication as necessary
- Quarterly brief written progress reports (including project information: food box contents, DSME activities, clinic referrals, etc.)
- Annual project and budget reporting (exact dates and forms TBD)

All changes to the study protocol will be clearly documented by email communication and revision of the MOP.

3 Study Intervention

There are four components of the intervention. Each is described below.

1. Testing and monitoring of blood glucose levels
2. Primary care coordination
3. Diabetes-appropriate food packages
4. Diabetes self-management education (DSME) and support (SMS)

3.1 Testing and monitoring of blood glucose

Sites will follow all local, county, state, and federal regulations to develop and operate a testing, screening, and monitoring program that meets compliance requirements. For specific regulatory guidelines, refer to **section 7.5**.

3.1.1 Testing for diabetes and diabetes control among food pantry clients

In order to identify food bank clients who may be eligible for study participation, food bank project staff will offer free diabetes screening events at food pantry sites during the recruitment phase of the study. Diabetes screening will be provided at no cost for any food pantry client who is interested in and verbally consents to the screening, and is over 18 years of age. Food bank staff will conduct all screening activities, emphasizing with food pantry clients that screening tests are ***not*** diagnostic and that clients should speak directly with their health care providers for diabetes risk assessment, evaluation, and treatment.

For food pantry clients with no reported history of diabetes, or no known history of diabetes, diabetes screening will first include a random blood glucose (RBG) test using a Point-of-Care (POC) glucometer and a finger stick capillary whole blood sample. Clients who have an elevated RBG screening result (defined as ≥ 160 mg/dL in non-fasting individuals and ≥ 140 mg/dL in fasting individuals) will also receive a screening glycosylated hemoglobin A1C (HbA1c) test using a POC device.

All screening tests will be performed by trained study or food bank staff, or by trained food bank volunteers. All study staff and volunteers with human subjects contact must have appropriate CITI certification and quality and safety training. Screening staff will complete the information on the Screening Log (***Appendix B***) for **every** food pantry client who receives a blood glucose and/or HbA1c test. If uncertain, staff can ask the client for specific information in order mark the appropriate boxes under "age", "gender", and "race/ethnicity" (otherwise, staff can complete that information based on their assessment of the client.

For food pantry clients who self-report a history of diabetes, screening will consist of a POC HbA1c test using a finger stick capillary whole blood sample performed by trained personnel.

All clients who participate in screening will receive written results of their screening tests (see Client Screening Results Form in ***Appendix J***), along with basic information about their results and local community health care resources.

Additionally, any food pantry client who receives an HbA1c test will receive an educational handout (***see Appendix AK***) with information about the category in which their result falls:

- HbA1c result less than 5.7%: normal HbA1c range
- HbA1c result 5.7% to 6.4%: pre-diabetes range
- HbA1c result 6.5% to 7.4%: diabetes, controlled
- HbA1c result equal to or greater than 7.5%: diabetes, poorly controlled

Food pantry clients who have screening HbA1c test results ≥ 7.5% will then be further assessed by study staff for eligibility and, if appropriate, enrollment into the study.

3.1.2 Testing random blood glucose levels

We will test food pantry clients' current glycemic status using a point-of-care (POC) glucometer that measures random blood glucose (RBG). We have chosen a glucometer that is inexpensive, reliable, and FDA-approved for use on multiple people. Specific instructions for using the GE100 Blood Glucose Monitor can be found in **section 7.2**.

3.1.3 Testing Glycosylated Hemoglobin (HbA1c) Levels

We will measure HbA1c levels for food pantry clients who report a diabetes history or who have a screening RBG result ≥ 160 mg/dL non-fasting or ≥ 140 mg/dL fasting. We will use a point-of-care (POC) HbA1C device using a small sample (1 large drop, 5 microliters [µL]) of capillary whole blood. Instructions for using the PTS Diagnostics HbA1c+NOW®™ system can be found in **section 7.3**.

3.1.4 Monitoring blood glucose control among study participants

Our primary outcome of interest is change in HbA1c over time for study participants. Hemoglobin A1c testing provides a reliable estimate of general blood glucose control over an approximate three-month time frame. We include regularly scheduled HbA1c testing for all study participants throughout the course of the study following the timeframes outlined below. All HbA1c testing will be conducted by trained food bank staff or volunteers, who will use the same POC HbA1c devices described above (and in specific detail in **section 7.3**). We will conduct monitoring tests with study participants at the food pantries where participants will be going to receive food bank services. Study staff can use the "Participant Follow-Up Testing Results" form (***Appendix AU***) to record all follow-up and monitoring participant test results. All test results will be entered into the MS Access database; the database has fields for recording test results performed outside of the windows identified below.

	Intervention Group	**Control Group**
T0 (baseline)	At enrollment	At enrollment
T3 (month 3)	2 – 4 months (3±1)	N/A
T6 (month 6)	5 – 7 months (6±1)	5 – 7 months (6±1)
T9 (month 9)	N/A	8 – 10 months (9±1)
T12 (month 12)	11 – 13 months (12±1)**	11 – 13 months (12±1)**

* 1 month = 30 DAYS ALWAYS

** Alternatively, T12 HbA1c windows can be manually calculated as 5-7 months ***after*** the completion date of a participant's T6 follow-up activities. This revision will accommodate participants who complete their T6 activities at month 5 (earliest part of the window) and maintain a 5-7 month separation between the T6 and T12 follow-up activities.

Study staff can complete "extra" HbA1c testing for study participants outside of their intervention windows (e.g., between T0 and T6 for CONT group, or between T6 and T12 for INT group) **if** a participant requests a test during a pantry visit. Staff should not complete more than 1 extra HbA1c test for a participant during their waiting period. Staff should not promote extra HbA1c testing for study participants—the primary purpose for completing extra testing during these periods is to provide a positive experience for study participants. Extra HbA1c test results should be entered in the Access database in one of the "extra test" fields.

If a participant does not complete their follow-up HbA1c test at T6 or T12, study staff can still complete an HbA1c test with the participant when they are next seen at a pantry or study activity.

Any HbA1c test completed beyond the follow-up windows should be entered in the MS Access database as an "extra" test.

3.2 Primary care coordination

MOUs with clinics require clinic staff to actively reach out to food bank-referred clients and schedule a new patient appointment within 3 months. Food bank staff / RA will need to be able to verify with the clinic that the attempt was made and that the client has an appointment for care.

A sample MOU document is included in ***Appendix O***.

Based on lessons learned from the Feeding America / BMSF Diabetes Pilot Project, it is recommended that food banks complete the following activities in order to build and sustain effective food bank – clinic partnerships:

- Identify clinic point person ("clinic champion") who will be the main contact for FAITH-DM staff
- Meet with clinic staff to brief providers on the FAITH-DM trial, health care utilization analysis, food bank resources, and food insecurity screening; attend weekly "huddles" or monthly staff meetings to inform, update, and remind clinic staff about the project and partnership

Participating clinic providers will receive a packet from FAITH-DM with:

- Background info on FAITH-DM RCT
- Overview of referral process and communication strategy for FB participants referred to clinic for care (fax process, appointment verification, etc.)
    - Clinic patients cannot be directly referred into FAITH-DM RCT
- Overview of study health care utilization plan (consent to share protected health information [PHI], HIPAA, data requests)
- Institutional Review Board (IRB) certification: Western IRB protocol # 20151569
- Contact info / signatures of UCSF MD, FANO, and participating food bank
- General information on how to:
    - Conduct food insecurity screening with patients (***Appendix P***)
    - Refer food insecure clinic patients into local hunger safety net

3.2.1 Referrals to a primary care provider (PCP)

- If food pantry client is not (and will not be) enrolled in FAITH-DM, provide resource hand out
    - For clients who report no PCP, complete "Screening and Referral Form" and fax form to appropriate provider
- If participant is enrolled in FAITH-DM, study staff will ask: "Is there a doctor, other health care provider, or clinic you usually go to in order to help you manage your diabetes?"
- Intervention participants who answer "yes" (has PCP)
    - Retrieve PCP information
- Intervention participants who answer "no" (does not have PCP)
    - Provide written information to participant on PCP resources

    - Send active referral to PCP (FAX to PCP and/or phone call to PCP/clinic) using the appropriate HCUA provider letter (see **section 7.7**).
- Control participants who answer "yes" (has PCP)
    - Retrieve PCP information
- Control participants who answer "no" (does not have PCP)
    - Provide resource handout

- All study participants will again be asked at T6 and at T12 if they have a PCP; for **both** intervention group and control group participants who report no PCP at T6 or T12, provide:
    - Written information to participant on local PCP resources
    - Active referral to PCP (FAX to PCP and/or phone call to PCP/clinic) using the appropriate HCUA provider letter (see **section 7.7**).

See ***Appendix AI*** for the "Screening and Referral Form" to use when sending a food pantry client's screening results to a clinic. The client must sign this form, giving food bank staff permission to share screening results with the clinic and/or provider.

Food banks must also maintain a HIPAA compliant fax to send/receive client information to/from health care partners in order to maintain security and protect client/patient medical information. To meet HIPAA standards, food banks should ensure that a dedicated FAITH-DM fax is located in a secure area (away from public areas). Staff should use the HIPAA-compliant fax cover sheet (***Appendix AB***) whenever faxing forms and information connected with the FAITH-DM study. Additionally, site staff should follow best practices to maintain protection of participant data:

- Only authorized personnel are to have access to the fax machine and incoming faxes
- Destination numbers should be verified before transmission
- Verified numbers used frequently should be pre-programmed to reduce number entry errors
- Recipients should be notified that they have been sent a fax
- Any patient data should be in the fax body and not in any of the data fields
- Faxes are to be sent to secure destinations; i.e., the fax machine of the recipient must be in a secure location, accessible only by those authorized to receive the information
- Maintain records of fax transmissions in the MS Access database for study participants

3.2.2 Referrals from primary care

Clinics can refer patients into the local hunger safety net through standard food bank protocols. Enrollment into the study for these participants will proceed through the standard process outlined in the MOP. We cannot accept referral of clinic patients directly into the study.

3.2.3 Communication with health care provider

Communication with the health care provider will be informed by the Health Care Utilization Analysis Plan (see **section 7.7**).

3.3 Diabetes-appropriate food boxes

Through the 6-month intervention, FAITH-DM participants will receive 11 bi-monthly food packages (twice monthly). The main goal of the food packages will be to increase participants' access to foods appropriate for diabetes self-management. The food packages will aim to provide approximately 25% of a participant's food needs for the month, equating to about 11 meals from each food package. Additionally, the food packages will serve as a model for healthy food choices for people living with diabetes.

Food group servings for the baseline food package will include a box with non-perishable items (canned, boxed, or other shelf-stable vegetables, fruits, grains, meats, beans, etc.), as well as supplemental perishable items (e.g. fresh vegetables and fruits, bread, dairy, meat, poultry) in a bag intended to serve a household of 1-2 people. In order to address varying household sizes, guidelines for distribution of food packages will be as follows:

Household Size (# persons)	Food Package Guidelines
1 - 2	1 standard box of non-perishables and 1 standard bag of perishables
3 - 4	1 standard box of non-perishables and 2 standard bags of perishables
5 or more	2 standard boxes of non-perishables and 2 standard bags of perishables

Food Box Criteria:

Based on USDA guidelines for number of servings of different food groups for an adult male

- Sufficient food items and variety to create 11 meals
- Focus on vegetables and fruits, whole grains, low-fat dairy, lean meat
- Ideal breakdown of food package by servings
    - 30- 40% non-starchy vegetables
    - 10 - 20% fruit
    - 25% grains and other carbohydrates (includes corn and potatoes)
    - 25% lean protein and dairy

Food Group	What equals a choice?	Number of choices per food package

Vegetables - non-starchy vegetables including a variety of types. Canned should be low-sodium or "no salt added".	Fresh vegetables: 1 head, 1 bunch or 1 pound = 1 choice Canned vegetables (no salt added), 15 oz = 1 choice Spaghetti sauce, 15 oz = 1 choice Frozen Vegetables, 16 oz = 1 choice	9 (Ideally 4-5 fresh/ perishable and 4-5 shelf-stable)
Fruits - include a variety of fruits. Canned should be no-sugar added or packed in 100% juice. No fruit juice.	Fresh fruit: 1 bunch, 1 pound, or 4 pieces = 1 choice Frozen Fruit, 12 - 16 oz = 1 choice Canned Fruit, 15 oz = 1 choice	3 (Ideally 2 perishable and 1 shelf-stable)
Proteins - Meat & Non-Meat - Focus on lean meats	Canned Beans, 15 oz = 1 choice Dried beans, 1 pound = 1 choice Peanut Butter, 18 oz = 2 choices Dozen eggs = 1 choice Frozen meat, fish, poultry, 1 lb = 2 choices Canned chicken, tuna, salmon, 5 oz, 1 can = 1 choice Tofu, 14 oz package = 1 choice	6 Ideally 2-3 perishable and 3-4 shelf-stable
Dairy - Low fat dairy	1/2 gallon milk, 1% or skim = 1 choice Shelf Stable milk, 1% or skim quart = 1 choice 4 yogurts, 6 oz each = 1 choice Cottage Cheese, 8 oz = 1 choice Mozzarella, Cheddar, Swiss cheese, 8 oz = 1 choice	2
Grains and other starches - at least 50% whole grains; ready-to-eat cereal < 8g sugar and 3g fiber per serving	Whole grain bread, 1 loaf = 1 choice 6 rolls or bagels = 1 choice Package Tortillas, whole grain = 1 choice Brown Rice, 1 bag, 16 oz = 1 choice Pasta, 16 oz = 1 choice Oatmeal, 18 oz = 1 choice Ready to Eat Cereal, 12 - 16 oz = 1 choice Corn, 15 oz = 1 choice Potatoes, yams, 1lb bag = 1 choice	5 2 perishable and 3 shelf-stable
Other	Coffee, tea, spices, low-sodium condiments, non-stick pan spray, salad dressing Olive oil and/or canola oil to be given out 2 times during the intervention	1-2 items

Example Food Package

Box
Diced tomatoes, no salt added (2-15.5 oz. cans)
Peas, no salt added (1-15.5 oz. can)
Green Beans, no salt added (1-15.5 oz. can)
Mixed vegetables, no salt added (1-15.5 oz. can)
Applesauce, no sugar added (1-15.5 oz. can)
Black beans (1-15.5 oz. can)
Pinto beans (dry, 1 lb.)
Salmon (1-14.75 oz. can)
Peanut Butter (1-18 oz. jar)
Box pasta, whole wheat (dry, 1 lb)
Bag Brown Rice (dry, 1 lb)
Box of high fiber cereal (dry, 18 oz.)
Olive Oil
Italian Seasoning

Perishables
Salad mix (10 oz.)
Broccoli (1-2 heads)
Carrots (1 lb.)
Snap peas (1 lb.)
Oranges (1 lb.)
Grapes (1 lb.)
Chicken thighs, frozen (1 lb.)
Eggs (1 dozen)
Milk, 1% or skim (1/2 gal.)
Cheddar cheese (8 oz.)
Bread, whole grain (1 loaf)
Tortillas, whole grain (1 pkg.)

3.4 Diabetes self-management education (DSME) and support (SMS)

A major component of the intervention is to provide study participants with diabetes self-management education and support that is culturally appropriate and tailored to meet their needs relative to their socio-economic status, literacy level, and food security challenges. We have drawn from evidence-based practice and adapted existing diabetes education curricula to develop a structured intervention that is designed to be flexible to accommodate individual, community, and site variations.

The FAITH-DM educational intervention is modeled on the American Association of Diabetes Educators "AADE7™ Self-Care Behaviors". These seven self-care behaviors include:

- Healthy Eating
- Being Active
- Monitoring
- Taking Medications
- Problem-Solving
- Healthy Coping
- Risk-Reduction

The FAITH-DM curriculum was primarily adapted from the "Type 2 Diabetes BASICs" curriculum (Park Nicollet International Diabetes Center), with additional content adapted from educational materials used in the "Improving Diabetes Care and Outcomes on the South Side of Chicago" project (Peek M., Chin M., University of Chicago). The FAITH-DM curriculum addresses the AADE7™ through a combination of group classes, 11 packets of written education materials to accompany the

food box distributions, and one-on-one interactions to reinforce those messages. A "Train the Trainer" model will be used to build capacity among the health educators at each site who will be implementing the intervention with study participants.

The three DSME components of the education and support intervention described below include:

- Formal DSME Group Classes (2 sessions with monthly drop-in sessions): **section 3.4.1**
- Brief one-on-one interactions to reinforce DSME messages: **section 3.4.2**
- Passive education materials (11 bi-monthly packets of written educational materials to accompany the food box distributions): **section 3.4.3**

*** **Note:** Intervention group and control group participants **receive different elements** of the study DSME program (see below). Food bank education staff will need to maintain a process to ensure participants receive the correct educational components based on their group assignment (the study MS Access database will support this process). This group difference will allow us to assess the effectiveness of DSME components at the study's end.

All outreach and communication related to diabetes programming for participants in the intervention group should be targeted to the individual (using project reminder cards for group classes, phone calls, 1-on-1 in-person meetings, etc.). Food bank education staff should **NOT** use global outreach strategies (general announcements, flyers, posters, mass mailings, etc.) to promote any diabetes education components to the general food bank population.

Overview of DSME Components by Participant Group		
DSME Component	**Intervention Group**	**Wait List Control Group**
Group Classes (includes monthly drop-in sessions)	Yes	No
1-on-1 Interactions	Yes	Yes, after waiting period
ACP "Living with Diabetes" Guide	Yes, at enrollment	Yes, after waiting period
Bi-monthly passive education materials with food packages	Yes	Yes, after waiting period

3.4.1 DSME Group Classes

For the purposes of this study our assumptions are that a majority of study participants will be linked to a primary medical home to receive ongoing diabetes clinical care and chronic disease management, and a majority of study participants will (or should) be receiving basic DSME from existing clinic services at their primary medical home. However, based on our experience in the diabetes pilot project, we know that many participants may not receive DSME as part of their primary care, or clinic-based DSME messages may not be appropriate or relevant for this population.

Rationale behind FAITH-DM DSME Group Classes: Based on prior experience attempting to conduct group DSME classes with food pantry clients, we have learned that it is difficult to run formal class series that meet more than 3-4 times. We have thus decided to tailor our DSME program to focus on elements of diabetes self-management that are particularly important and specific to low-income populations facing food insecurity, with the understanding that existing health care clinic services will address traditional DSME messages and support. While we plan on addressing information on all AADE7™ Self-Care Behaviors, we will conduct a 2-class series emphasizing: healthy eating, problem solving, healthy coping, and risk reduction (prevention of diabetes-related complications), with a third open monthly forum session for further group discussion, support for the challenges of living with diabetes, reinforcement of problem-solving skills, and troubleshooting by participants.

Key Metrics for DSME Program Selection and Adaptation

1. Relevance for participant population
2. Flexibility to be tailored to heterogeneity of participant group
3. Cost
4. Translation into Spanish
5. Materials for participant distribution and training of facilitators

Intervention participants will be asked to sign up for a group DSME Class series at the time of their enrollment into the study. Prior to a participant's first class session, food bank staff will send out reminder postcards and make reminder phone calls. Template postcards will be provided and a script for reminder phone calls will be given to staff and volunteers making those calls. (See ***Appendix AD*** for a sample of the post card with text.)

To help maximize attendance at Sessions 1 and 2, sites will offer supplies to participants in attendance to support their diabetes self-management. Supplies will include items such as water bottles, measuring cups, re-usable grocery bags, cookbooks, medication pill boxes, foot mirrors, pedometers, and stress balls. Grant awards include funding for these items.

<u>Group classes (including the monthly drop-in sessions) are only offered to participants randomized to the intervention group.</u>

Group Classes

Group classes will be offered twice each month (or as needed) at varied days, times, and locations to maximize attendance. Classes will be conducted in English and Spanish by trained health educators. Each class session lasts 2 – 2.5 hours, and a class series will include 2 sessions with follow-up drop-in sessions for ongoing support. Class structure will emphasize participant involvement, group discussion and interaction, participant teachback, use of visual aids, and repetition of clear, simple messaging around key self-management strategies.

Class sessions will be scheduled so that all study participants can complete session 1 within 1 month of their enrollment date, and session 2 within 2 months of their enrollment date.

Session 1: Introduction to Diabetes – provide participants with basic information needed for diabetes self-management including disease overview, healthy eating strategies, physical activity, blood sugar monitoring, and treatment plans. Primary AADE7™ behaviors addressed: Healthy Eating, Physical Activity, and Monitoring.

Session 2: This session will focus on living with diabetes given the challenges of food insecurity and other common issues for food pantry clients. Primary AADE7™ behaviors addressed: Problem Solving, Healthy Coping, and Risk Reduction.

Drop-in Open Forum Sessions: These sessions will be offered once monthly (in both English and Spanish and in as many geographic areas as needed) and facilitated by food bank nutrition education staff. The goal of the drop-in classes is to create a space for participants to receive ongoing support, practice problem-solving skills, develop health care connections, etc. The forum sessions are also opportunities for sites to respond directly to participant needs and interests. A secondary objective in offering open forum sessions is to help foster a participant support structure whereby food pantry participants can benefit from one another's experiences, skills, and strategies on diabetes self-management. Each session should last 60-90 minutes.

Drop-in sessions are for study participants in the intervention arm, and participants should be encouraged to attend all sessions while they remain in the study. Monthly reminder calls and flyers during food distributions are useful strategies for increasing attendance. Additionally, food bank staff should encourage study participants to attend the sessions with a family member or a support person.

These monthly sessions can focus on a variety of topics related to diabetes self-management education and support. Food bank staff can draw from existing nutrition education programming and adapt materials to target study participants. Example session topics include:

- Healthy eating and MyPlate
- Healthy eating: rethink your drink
- Healthy eating: grocery store tour
- Healthy eating: label reading and carbohydrate counting
- Healthy eating on a budget
- Physical activity: walking program

- Goal setting and action plans

Additionally, sites are encouraged to build on existing connections with local community health care providers to involve clinicians as guest speakers during monthly sessions. Clinicians and practitioners can be invited to participate in 1-2 sessions during a 12-month period. Examples of topics and providers include:

- Stress management (social worker, therapist)
- Depression and healthy coping (social worker, therapist)
- Diabetes and eye health (ophthalmologists)
- Diabetes and dental health (dentist)
- Diabetes and foot health (podiatrist)
- Diabetes medications overview (RN/CDE, MD)
- Physical activity alternatives (yoga instructor, zumba instructor, dance instructor)
- Smoking cessation (local provider)

More detail about the lesson plans, participant handouts, and facilitator guides can be found in ***Appendix AC***. Formal content for drop-in sessions need not last longer than 30 minutes. Participant peer support is an important aspect of drop-in sessions and can last the majority of the time.

Participants in the control group will not have access to the group classes or drop-in sessions following their six-month waiting period (but they will receive passive diabetes education materials along with each food package they pick up).

3.4.2 Brief 1-on-1 interactions

1-on-1 interactions are offered to participants in the intervention group (T0-T6) and to control group participants (T6-T12).

In order to reinforce DSME messages participants receive in the group class series or through the bi-monthly passive education materials, health educators and food pantry staff will conduct brief 1-on-1 interactions and check-ins with participants over the course of the intervention. These interactions will take place during food distributions when participants pick up their bi-monthly food boxes.

These interactions will assist participants in acquiring and reinforcing diabetes self-care knowledge and developing and strengthening diabetes self-management skills by providing a support structure for participants. The interactions are opportunities for study staff to listen to participant feedback, challenges, and successes, as well as to provide participants with information on other existing community-based resources. In order to meet this obligation, study staff should be accessible and open to questions and informally check in with participants during food box distributions. Being proactive, friendly, and enthusiastic is critical to the success of this informal intervention component.

Health educators at sites will utilize materials from the diabetes education curriculum to interact with participants and respond to comments and questions relative to the AADE7™ Self-Care Behaviors. Sample questions and prompts to initiate interactions with participants include:

- What have you been working on to help take care of your diabetes?
- What challenges have you had with your diabetes?
- How do you like the diabetes food packages included in the FAITH-DM project? What changes would you like to see with the food packages?
- What questions do you or your family have about taking care of your diabetes?
- What challenges have you had with keeping to your plan to eat healthy?
    - Educators can utilize existing food bank nutrition education resources and expertise
    - Focus on Healthy Eating messages (MyPlate, label reading, portion control, "rethink your drink", etc.)
- Review bi-monthly passive diabetes education materials
    - Highlight any local resources that relate to current topics

Because these are 1-on-1 interactions, participants may have questions or comments specific to their individual health status and diabetes self-management plan. Food bank staff and volunteers should respond to specific questions within their own scope of knowledge and practice (as applicable per individual training and credentials). Participants should <u>always</u> be encouraged to contact their primary care provider for information related to their individual care, treatment plan, and diabetes self-management activities.

3.4.3 Bi-Monthly Written Materials and Handouts

Study participants in the intervention arm will receive at enrollment the "Living with Diabetes" guide published by the American College of Physicians (ACP) and specifically developed for low-literacy audiences. The guide is available in both English and Spanish.

Study participants in the control arm will receive the ACP "Living with Diabetes: guide at the completion of their six-month waiting period and when they begin picking up the bi-monthly diabetes food packages.

<u>All study participants will receive written diabetes educational materials twice monthly with each food box</u>. These materials will also be available in English and Spanish, and will focus on a specific AADE7™ Self-Care Behavior. A distribution schedule and list of included educational resources can be viewed in ***Appendix I***.

Along with these "passive" diabetes education materials, participants will receive diabetes-appropriate recipes with each food box they pick up. These recipes will be developed or evaluated by study staff (Registered Dietitians and/or Certified Diabetes Educators). Recipe selection and distribution each month will likely vary at all three study sites due to community differences, food bank resources, and

seasonal availability and variety of fresh produce, but will be in alignment with Healthy Eating principles outlined in the AADE7™.

3.4.4 Other diabetes education interventions

While study staff should make every effort to ensure FAITH-DM study participants receive the correct diabetes education components based on their group assignment, it is likely that some study participants may have access to other diabetes programs outside of FAITH-DM. In order to adhere to the study protocol, and to account for other clinic- or community-based diabetes programming, food bank and FAITH-DM staff should do the following:

1. Communicate to the Coordinating Center (Morgan Smith, FANO) any knowledge of other diabetes education programs that may actively target food pantry clients
2. If other diabetes education programs do exist and it is unethical not to allow study participants access to these programs, both the intervention groups and control groups **must** have equal access to the programs (e.g., FAITH-DM staff should **not** be referring ONLY control group participants only to a commuity-based DSME program)

Food banks and FAITH-DM staff should refrain from conducting or participating in other diabetes education programming or other diabetes interventions (either as a lead site or a partner site) for the duration of their participation in the FAITH-DM study. Any food bank participation in non-FAITH-DM diabetes programming needs to be communicated to the Coordinating Center (Morgan Smith, FANO).

3.5 Tracking participation in intervention elements

The MS Access database has several fields to track participant engagement in the study intervention (dates of food package pick-up, percent of food package pick-up, participation in diabetes education classes, etc.). Study staff should maintain consistent processes to record participant engagement during study activities, and update participant records in Access in a timely manner.

The MS Access database has several open “notes” fields for adding additional information, which may include important data and participant feedback that can be included in study analyses to help interpret final results. In order to help capture this information, study staff should use the “Barriers to Participation in FAITH-DM Activities” form (***Appendix AV***) for any intervention-specific data reported by a participant. The site RAs will use completed forms to enter this data into Access in the notes fields for study participants.

Additionally, site and study staff can use results from these forms as part of a continuous quality improvement process at the sites. However, any changes that may impact the study intervention, or how participants access the intervention, must be discussed with and approved by the Coordinating Center.

3.6 Length and time windows for intervention

For participants in the intervention group, access to the food package and DSME intervention components is only available during their 6-month intervention window (T0-T6). Intervention group participants should no longer have access to these elements after they reach their T6 time point in the study (they will have access to referrals for care, if needed, at T6 and T12, and have access to HbA1c testing and monitoring at T6 and again at T12).

For participants in the control group, access to the food package and the modified DSME intervention components is also only available during their 6-month intervention window (T6-T12). Control group participants should not have access to intervention components prior to T6, nor should they continue receiving any intervention components after T12. Control group participants will have access to referrals for care, if needed, at T6 and T12, and have access to HbA1c testing and monitoring at T6, T9, and again at T12 per existing study protocols.

Site adherence to these time windows will help achieve and maintain fidelity to the original study design. While sites may need to make minor, reasonable accommodations for individual participants (e.g., provision of a maximum of 2 food packages to be picked up within 1 month post T6 follow-up activities for intervention group participants), any deviation from these protocols should be logged in the MS Access database for the participant, and site staff should complete and submit a Protocol Deviation (***Appendix F***) form.

Any food bank services (e.g., food packages, education, support, referrals) provided or conducted after T12 activities for any study participant will be at the discretion of the food bank as these clients will no longer be enrolled in the study as active study participants.

4 Recruitment and Retention Plan

In order to meet recruitment targets, we will:

- Monitor recruitment and intervene quickly to change recruitment techniques that are proving unsuccessful; discuss on monthly calls
- Identify barriers to recruitment
- Use multiple recruitment strategies depending on the needs of each food bank or food pantry (see ***Appendix AJ*** for a sample recruitment flyer to post at pantry sites)
- If we are not meeting recruitment goals, we can employ additional outreach strategies such as English and Spanish language flyers and advertisements
- Recruitment-related team conference calls will occur weekly to start, then switch to monthly
- Our goal is to recruit approximately 240 people per site

4.1 Participant Retention

We will use the following practices to ensure the highest levels of retention in our study, as this is one of the most important steps we can take to ensure the validity of our findings.

At baseline:

- Whenever possible, recruitment into the study, informed consent, administration of the baseline survey, and randomization should occur **during a single, face-to-face visit**
- Stress the importance of adherence to entire study protocol during the informed consent interview and throughout the study
- Obtain the names and contact information for 2 individuals closely related to the participant (e.g., next of kin, friends, etc.). Such individuals can be contacted in the event that a participant does not return for follow-up visits. This information (as with all participant information) will be stored in the MS Access database.
- Establish rapport with the participants
- Treat participants and their caregivers with respect
- Assure a welcoming atmosphere where participants are seen
- Be considerate of the participant's time and confidentiality
- Identify and resolve issues in a timely manner

Throughout the study:

- Streamline assessments and procedures that are excessively burdensome and time consuming, especially completing the baseline and follow-up questionnaires in the most convenient time and place for participants
- Use reminder notes and calls to let the participant know you will be calling shortly for their follow-up assessment, or to increase adherence to intervention components such as education classes
- Be persistent. Document in MS Access database all attempts to contact participants, and keep trying.
- Use the contact information for a missing participant that has not withdrawn consent. The telephone numbers for friends and/or relatives in the MS Access Database should be accessed to locate the participant.
- Use global strategies for staying in contact with all participants, such as: monthly phone calls; birthday and holiday cards; & reminder postcards. FANO will provide pre-printed birthday, holiday, and diabetes class reminder cards to sites (see ***Appendix AD*** for samples).
- Encourage pantry staff and volunteers to interact with all study participants (especially those in the control group during their waiting period) during distributions and other events to maintain high levels of excitement, enthusiasm, and awareness of the project

Participant retention requires careful planning and continuous efforts and helps to ensure a successful study. Every effort should be made to retain study participants without coercion.

4.2 Study Flow

For a detailed, illustrated overview of the flow of participants through the study, see ***Appendix C***. For a general overview that can be used when describing the trial to staff, clinic partners, and pantry agencies, see ***Appendix AQ***. An overview of the study flow is below:

1. Screen for diabetes with HbA1c testing
2. Perform informed consent, HIPAA
3. Conduct baseline survey
4. Randomize the participant
5. Perform intervention, wait list intervention
6. Perform follow-up survey and HbA1c testing
7. Provide compensation at baseline and/or at follow-up survey (see **section 9.3**)

Study Approach to Screening and Enrollment
When enrolling new clients into the study, every effort should be made by study staff to complete all enrollment processes (HbA1c testing, consents, baseline survey, randomization, and study orientation) on-site and face-to-face with the new study participant.

If a food bank client is identified as eligible to participate in the study but does not have time to complete these enrollment processes, then study staff should not consent and enroll the client at that time. Instead, study staff should attempt to identify a time and food distribution location occurring within 2 weeks that is available to the client so that they can enroll into the study and complete all enrollment processes during one encounter.

Additionally, for study participants completing their follow-up and /or final HbA1c testing and surveys, study staff should attempt to complete testing and surveys in-person during one encounter.

If necessary, FANO and UCSF project staff can review challenges to this approach identified by the food banks and work to develop alternative screening, enrollment, and survey administration strategies that are responsive to issues identified at the participant / food pantry level. Food bank staff should communicate any screening, enrollment, and survey administration challenges directly to Morgan Smith, FANO Project Manager.

5 Screening and Eligibility Criteria

To help assure that study sites accrue participants with the required characteristics, this section provides a detailed discussion of the screening procedures, including checking random blood sugar and HbA1c levels, and eligibility and exclusion criteria.

5.1 Screening procedures

In order to identify potentially eligible participants, we will conduct diabetes screening with adults who utilize services at food pantries. We will use random blood glucose testing and Point-of-Care Hemoglobin A1C testing to screen adults for diabetes.

Prior to initiating screening activities, we will conduct a diabetes screening training seminar with study staff (Research Assistants) and food bank staff and volunteers in order to ensure safety and consistency of screening across all sites.

The diabetes screening training of RAs and food bank personnel will include information in the following areas:

- Diabetes pathophysiology, screening, evaluation, and treatment
- Client privacy and HIPAA regulations
- Universal precautions & sharps safety
- Medical waste handling
- Use of specific study equipment (e.g., GE100 glucometers, A1C+Now Testing System)

To ensure screening programs at the food bank sites are in compliance with all relevant local, county, state, and federal regulations, sites will apply for and obtain any necessary certifications prior to initiating diabetes screening (e.g., CLIA waiver certifications, sharps storage and transport, medical waste permitting; see **section 7.5**).

Food banks and food pantry sites are non-traditional locations for conducting diabetes screenings. In acknowledgement of this, we address the following to ensure food pantry clients have a safe, informative, and positive experience when participating in a screening event in the food pantry setting:

- Food pantries typically operate in community settings (e.g., senior centers, community centers, churches, etc.) with limited resources regarding space and supplies. We will conduct screenings at identified pantries that do have adequate space and resources (tables and chairs, room dividers, etc.).
- Screening stations will be located in food pantry areas where client privacy and confidentiality can be maintained (separate room or office, or on the periphery of the pantry).

Screening Protocol

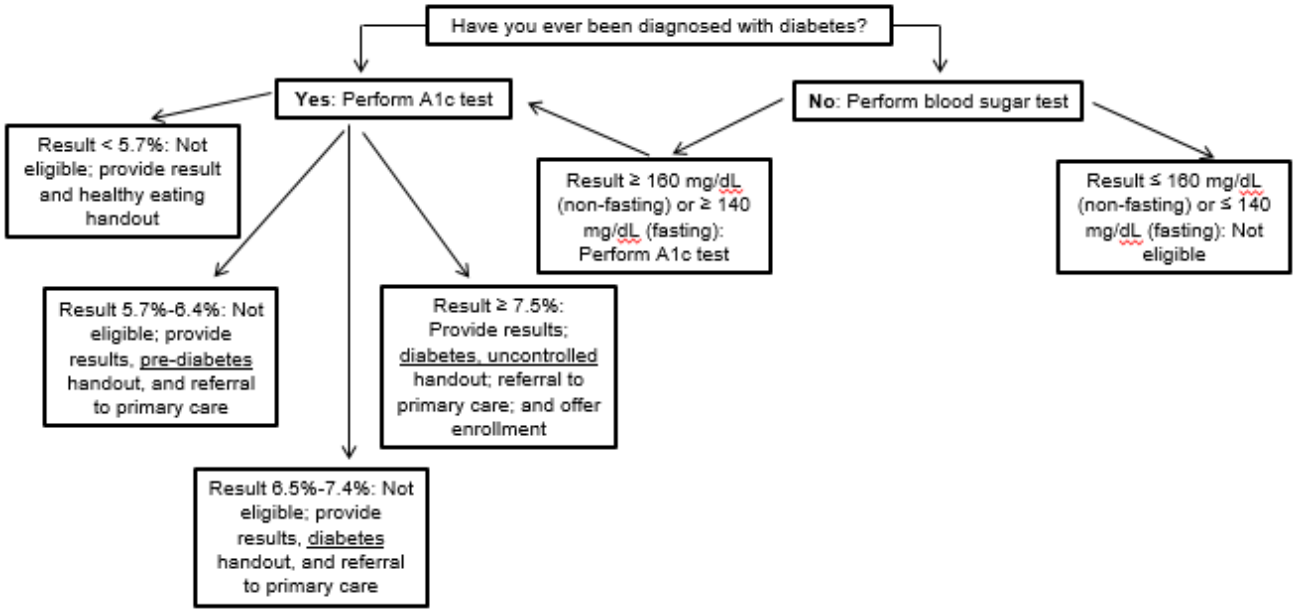
Any adult (aged 18 years or older) present at a food pantry site where diabetes screening is available can participate in the screenings. Food bank staff will promote the screening events at the food pantries through flyers, announcements, and other outreach activities targeting <u>existing</u> food pantry clients.

All food pantry clients participating in diabetes screening events will be informed by staff that screening results are **<u>NOT</u>** diagnostic. Staff will direct clients to contact their primary medical provider or a community health center to address all personal medical and health questions, and for further screening, evaluation, and treatment as needed. Staff will provide food pantry clients with contact information for local community health care organizations as part of the screening process.

<u>Each food bank site is only expected to conduct regular screening activities until that site reaches its target number of enrolled participants (240 per site)</u>. Once study recruitment and enrollment has ended, each site will only be required to continue testing and monitoring enrolled participants per the study timeline. Sites can continue to conduct general screening activities with pantry clients if they have the time, resources, and capacity. However, no new screening information should be tracked in ACCESS after enrollment has closed, and pantry clients screened after the enrollment has closed may not participate in study activities or interventions. Sites can develop their own protocols (e.g.,

referral processes for clients needing care, educational programming, food resources) for managing pantry clients and screening activities beyond what is required for this trial.

When an adult food pantry client provides verbal consent and agrees to participate in a diabetes screening test, we will use the following flow chart to identify what screening tests and procedures are used:



5.2 Eligibility and Exclusion Criteria

Study eligibility is determined by a set of specific inclusion and exclusion criteria. Individuals must meet all eligibility criteria. This section defines the criteria, method for determination, and the specific forms needed to document eligibility.

Our specific inclusion criteria include:

- Type II diabetes mellitus with HbA1c ≥ 7.5% using food bank point-of-care testing
- Food pantry client (defined as any individual engaging with a food bank or partner agency for food assistance, regardless if is their first visit or not, or if they are requesting direct food assistance, SNAP enrollment assistance, or general information on any food resources or programming)
- Reliable mode of contact (either phone or address) where they can be reached
- English or Spanish verbal fluency
- 18 years of age or older
- Intent to remain in the study area for at least the next 12 months
- Willingness to participate in intervention (including picking up bi-monthly food boxes and participating in diabetes education activities)

Exclusion criteria include:

- Type 1 diabetes
- Pregnant or less than 6 weeks post-partum*
- Cognitively impaired: dementia, mental illness, or active substance abuse severe enough to make client incapable of providing informed consent and could interfere with administration of the survey or participation in the intervention**
- Household member already enrolled in the study***

* Study participants who become pregnant after enrollment may remain in the study and participate in all study activities in their assigned group (intervention or control). Study staff will emphasize with any pregnant study participant the importance of staying connected with their healthcare providers (to receive regular pre-natal care and any pregnancy-specific diabetes self-management education and support).

** Refer to ***Appendix AS*** "Cognitive Impairment Assessment Tool" to assess cognitive impairment during participant enrollment; this form and process need only be used on clients where study staff suspect cognitive impairment.

*** Other household members with diabetes can share the food box, participate in the education, and have their HbA1c checked, but should not be enrolled in the study.

5.2.1 Prompts for speaking with ineligible clients

During the screening and enrollment process, it is likely that food bank staff will interact with clients who want to enroll in the project, but who do not qualify based on the study eligibility requirements. For example: a client who has an HbA1c result of 7.4%, or is planning on moving away in 11 months, or does not speak English or Spanish fluently would be excluded from study participation. The following prompts are to provide guidance to project staff to communicate this information to the client, with the goals of ensuring that the client understands and has a positive pantry experience.

- Emphasize that because this is a research study, enrollment requirements are very clear and are not flexible (potentially a difference from other pantry programs); adhering to the protocol will allow the researchers to learn what best helps participant with diabetes
- Provide information about other pantry or community resources for which the participant may be eligible
- If the client may become eligible in the future (e.g., has an increased HbA1c, or exits out of the 6-week post-partum period), then encourage the participant to return in the future for additional screening and assessment of eligibility
    - It may be important to stress that the enrollment period will have an end date, and there is no guarantee that enrollment will be possible at a later date
    - For clients with an elevated HbA1c level that is not high enough to qualify for the study (e.g., an HbA1c 6.5% - 7.4%), it is **essential** to provide the client with positive feedback

that they are doing a tremendous job in managing their diabetes well and that they should continue working hard to keep their HbA1c level under 7.5% (we do not want clients "sabotaging" their diabetes self-management in order to enter the study)

- Remind clients that the study is helping the food bank to learn more about community based interventions that help people living with diabetes; it is likely that the food bank will offer additional diabetes programming after the study ends that will have much less strict enrollment requirements

5.3 Informed Consent

Informed consent is a process in which an eligible individual is informed of all aspects of the research that are relevant to his or her decision and is then given the chance to choose whether or not to participate without any consequence to usual care.

US regulations 21 CFR 50 and 45 CFR 46 require that informed consent be documented by the use of an informed consent form approved by the responsible institutional review board (IRB) and signed and dated by the participant and research staff at the time of consent. Detailed instructions for obtaining informed consent are listed below and a quick guide to the informed consent process (Western Institutional Review Board, except from "A Guide for Researchers") can be found in ***Appendix T***. In addition, a copy of this study's informed consent form can be found in ***Appendix AE***.

The informed consent form and process has been approved by the Western Institutional Review Board.

5.3.1 The Informed Consent process for participants with adequate literacy

- **Review eligibility:** Before initiating the informed consent process, be sure to review the eligibility of the potential participant and make sure this information is accurately recorded on the screening and enrollment checklists.
- **Verbally explain the study and research activities:** Using the informed consent form as a guide, verbally go through each section (section headings are in bold) of the form with the potential participant, speaking clearly and allowing the potential participant to ask questions. The consent form and consent process must be completed in the potential participant's preferred language (either English or Spanish).
- **Provide the written consent:** When the verbal consent process is complete, provide the participant with the written form for them to read. The participant must be given sufficient time to read and consider what is required of them, the risks, benefits, and alternatives of participating before providing their consent.
- **Assess client comprehension:** In addition to fielding questions from the potential participant, the person obtaining the consent must assess the food bank client's comprehension by using the teach-back method whereby the person obtaining consent asks open-ended and non-directive questions that require the potential participant to explain in his or her own words the

basic study procedures. Research staff should make sure the potential participant can describe why the research is happening, what is being asked of him or her, and the risks and/or benefits to taking part in the study. Some sample questions include:

- If someone in your family asked you what this study was about, what would you tell them?
- How often might you need to pick up food boxes as part of this study?
- Where will you be picking up your food boxes during the study?
- If you had a question or problem during the study, who could you contact?
- What else might you receive for participating in this study?
- How many diabetes classes might you be expected to participate in during the study?

- **Obtain consent:** Once all questions are answered by both parties and the individual has agreed to participate in the study, the participant should sign and date the consent form where indicated. The research staff member who performed the consent procedures should sign and date the same consent form. The participant and research staff should also sign a second consent form for the participant to keep as a copy for their records.
- **Store and track signed forms:** Once the consent is complete, the original form should be stored in an informed consent binder at the individual site. This material is sensitive and access should be restricted to trained FAITH-DM study personnel only (**see section 17.4**). Documentation that the consent was or was not completed should be noted on the appropriate tracking forms in the MS Access database.

5.3.2 The Informed Consent process for participants with limited literacy

If you are enrolling participants who cannot read the consent materials due to limited literacy skills:

- It is recommended that an impartial witness observe the consent process.
  - In the food pantry setting, impartial witnesses could include: other study staff or volunteers, food bank / pantry staff or volunteers, or host site staff / volunteers.
- Consent materials should be presented orally, including the HIPAA form (see next section)
- Sufficient time should be allowed for questions to be asked and answered, both by the participant and by the person obtaining consent, to ensure the subject comprehends the consent information.

- **Review eligibility:** Before initiating the informed consent process, be sure to review the eligibility of the potential participant and make sure this information is accurately recorded on the screening checklist.
- **Verbally explain the study and research activities:** Using the informed consent form as a guide, verbally go through each section (section headings are in bold) of the form with the potential participant, speaking clearly and allowing the potential participant to ask questions. The consent form and consent process must be completed in the potential participant's preferred language (either English or Spanish).

- **Assess client comprehension:** In addition to fielding questions from the potential participant, the person obtaining the consent must assess the food bank client's comprehension by using the teach-back method whereby the person obtaining consent asks open-ended and non-directive questions that require the potential participant to explain in his or her own words the basic study procedures. Research staff should make sure the potential participant can describe why the research is happening, what is being asked of him or her, and the risks and/or benefits to taking part in the study. Some sample questions include:
    - If someone in your family asked you what this study was about, what would you tell them?
    - How often might you need to pick up food boxes as part of this study?
    - Where will you be picking up your food boxes during the study?
    - If you had a question or problem during the study, who could you contact?
    - What else might you receive for participating in this study?
    - How many diabetes classes might you be expected to participate in during the study?
- **Obtain consent:** Once all questions are answered by both parties and the individual has agreed to participate in the study, the participant should sign and date the consent form where indicated. To document the consent process, Western Institutional Review Board's recommendations are consistent with guidance endorsed by the FDA (FDA 21 CFR 50.25). If the participant verbally agrees to participate in the study:
    - If capable of doing so, the participant signs or marks an X to signify consent.
    - The witness signs and personally dates the consent form. By doing so the witness attests that the consent information was accurately explained and that the participant apparently understood the information, and informed consent was given freely.
    - The research staff that performed the consent procedures should sign and date the same consent form. The participant, witness, and research staff should also sign a second consent form for the participant to keep as a copy for their records.

Important notes: It is the responsibility of the research staff obtaining consent to judge the participant's comprehension of the consent information including the understanding that participation is voluntary and that the participant has the right to withdraw at any time during the study. If any study staff doubts the participant's consent comprehension, he/she should not enroll the individual in the study.

5.3.3 Participant update process at T6

The IRB-approved consent forms include information on possible T12 activities that could occur in the event ancillary funding is obtained for the study. As a result of receiving this funding (**see section 17.3**) the MOP has been revised to reflect changes to study activities at T12. Western IRB approved of these changes and the updated research protocol on: 3/18/2016.

While these changes did not require a revision to original and existing informed consent processes, study staff will need to inform current and future study participants of all study activities and timelines accordingly:

- Use revised participant recruitment flyer and other materials to describe all participant activities and study timelines
- Verbally communicate all participant activities and study timelines when promoting study and recruiting participants
- Verify all participant activities and study timelines when completing informed consent process during participant enrollment ("If you are in the intervention group, we may contact you to perform HbA1c testing and follow-up 12 months after you enroll.")
- Disseminate informational sheet ("Participant FAITH-DM Study Update", ***Appendix AW***) to all study participants at their 6-month marks (in-person and/or via mailings)

5.4 HIPAA Authorization

The Health Insurance Portability and Accountability Act authorization form is a separate document from the informed consent, and must be reviewed and signed by the study participant at the time of consent. The HIPAA authorization form is an extension of the informed consent form that pertains to the study purpose and procedures. When signed, this document authorizes the release of specified personal identifiable health information for use in this study and allows communication with a participant's health care provider. The signed HIPAA authorization form must be faxed or securely sent to the health care provider before they can release any information about the patient.

5.4.1 Process for obtaining HIPAA authorization

The process for reviewing the HIPAA document and obtaining participant authorization is similar to the process for obtaining informed consent. It is usually easiest to append this document to the end of the informed consent form in order to review them in a single session with the potential participant. For this study, personal identifiable health information will be collected in the form of selected data from medical records.

We will collect information on healthcare use by each participant. Because part of the intervention involves a referral to primary care, we will also assess if an appointment with a primary care provider was made and kept. Furthermore, we seek to collect information on other health care utilization, including emergency department visits, hospitalizations, and primary care visits.

As with the informed consent, verbally discuss pages 6-7 of the HIPAA form, allow time for questions and review, employ the teach-back method, and if the participant agrees, obtain his/her signature. If the subject has limited literacy skills, refer to **section 5.3.2**.

Completed HIPAA documents should be kept with the associated informed consent documents in the secure site-specific binder. Again, documentation that HIPAA authorization was or was not provided should be made in the MS Access database. The HIPAA form can be found in ***Appendix X***.

5.5 Medical Records Release Form

The Medical Records Release Form (***Appendix AO***) should be completed at the same time as the informed consent form and the HIPAA authorization form during participant enrollment. This form needs to be completed and signed by the participant in order to access clinic medical records as part of the Health Care Utilization Analysis. While the informed consent and HIPAA authorization forms are mandatory for participants, the medical records release form is optional. If a participant refuses to sign this form, they can still participate in the study, but we cannot request any of the participant's medical records from their provider. However, because the HCUA is an important part of this study, study staff should provide support and encouragement to participants to ensure they understand the form and request, and complete it as part of the enrollment process. Encouragement entails not only explaining the benefits of the information obtained in the study, but also emphasizing that the decision to sign the medical release form in no way impacts a person's participation in the study. **As such, encouragement excludes any action or statement that can be interpreted as coercive to the participant.** Coercive actions include, but are not limited to, putting undue pressure on the participant or implying that the participant will not receive FAITH-DM food boxes and/or any applicable intervention components, or regular food bank services if he or she does not sign the release form. Study staff should document in the MS Access database whether or not the medical records request form was completed for each participant.

When filling in the dates of requested information on the bottom of the first page of the Medical Release Form, please fill in the following dates specified in the "From" and "To" blanks.

- From: The date **6 months prior** to the day of enrollment of the participant
- To: The date the participant will have been in the study for **1 year from the day of enrollment**

Prior to asking the participant to sign the Medical Release Form, please **mark all fields** under "Specific type of information to be disclosed" with a check or X mark (with the exception of the "other" field, which you should leave blank).

6 Blinding and Unblinding (Masking and Unmasking)

This study is not blinded. However, to reduce bias in allocation, the randomization process will be completed by UCSF staff prior to enrollment of the first participant. The baseline survey should always be administered prior to determining the randomization status of the participant.

7 Study Measurements and Procedures

To ensure that assessments and measures are conducted consistently across study participants and sites, this section describes detailed procedures for:

- Universal precautions and safety
- Random blood glucose testing (including Quality Control testing)
- Point-of-care HbA1c testing (including Quality Control testing)
- Regulatory requirements for testing (CLIA certificates of waiver, medical waste permits and plans, licenses and certifications, county and/or state specific regulations, etc.)
- Survey administration
- Health care utilization plan

7.1 Universal precautions and safety

Safety of study staff, food bank staff, volunteers, and clients are top study priorities. While the risk of injury and/or infections disease transmission associated with our community screening program is negligible, risk still exists. To further reduce risk and maintain a safe screening environment, all study staff, food bank personnel, and food bank volunteers who conduct screening and testing activities will complete training on universal precautions and screening safety (or demonstrate evidence that they successfully participated in a comparable training program) prior to screening clients. Training will include information on: hand hygiene, proper use of personal protective equipment (e.g., nitrile gloves), surface sanitizers, single-use lancet devices, sharps containers (including use, transport, and storage), proper testing techniques with clients, and on developing site-specific sharps and accidental needle stick protocols.

7.2 Random blood sugar testing

We will use GE100 Blood Glucose Monitoring System (Bionime Corporation) glucometers to conduct all random blood glucose testing with food pantry clients and study participants. The GE100 Blood Glucose Monitoring System received U.S. FDA 510K approval for use by healthcare personnel to test multiple patients.

Random blood glucose testing can be conducted by trained study staff and food bank personnel. Testing will follow manufacturer guidelines for glucometer use, maintenance, cleaning, and quality assurance (see Glucometer User Manual in ***Appendix M***).

<u>Materials List for Random Blood Glucose Testing</u>

- GE100 Blood Glucose Meter
- GE100 Blood Glucose Test Strip (check expiration date on strips; do not use expired strips)
- Hand sanitizer
- Nitrile gloves
- Alcohol prep pad (minimum 70% alcohol)
- Single-use lancet device
- Cotton balls
- Bandage
- Dental bib (disposable barrier)
- Surface sanitizer (Sani Cloth Super Wipes)
- Trash can with liner

- Sharps container
- Dex4 Glucose Tabs

7.2.1 Procedure to conduct a blood glucose test

1. Have client sit at health screening table.
2. Introduce yourself and provide client with background on screening.
3. Ask client: “have you ever been told by a doctor that you have diabetes?”
4. Always maintain client privacy. If necessary, ask other food bank clients to stand away from the screening area.
5. Clean hands with hand sanitizer.
6. Set up testing supplies.
7. Put on exam gloves.
8. Ask if client has a preference for which finger to use in order to access blood sample.
   a. Do not use any site on a finger that is an open wound, has scar tissue, has evidence or infection, or has any other contraindication (e.g., previous diabetes-related amputation, scleroderma); select a different finger for testing.
9. Ask client to hang hand below table and open and close their fist 3-4 times in order to increase blood flow to the fingers.
10. Open alcohol swab and clean finger at site where sample will be obtained. The side of the finger provides a blood sample with less pain than the center of the finger pad.
11. Allow finger to air dry or blot with clean cotton ball to dry site.
12. Take one GE100 Blood Glucose Test Strip from the vial. Close the vial cap immediately.
13. Insert the test strip into Test Strip Port of the GE100 Glucose Meter with the indication symbol facing up; the meter confirms the insertion of a strip with a beep (if volume is turned on).
14. A blood drop icon will appear on the meter display window and will be accompanied by a beep (if the volume is turned on). Apply the blood sample within 2 minutes.
15. A minimum of 1.0µL of blood is needed for testing with the GE100 Blood Glucose Monitoring System. Blood sample size above 3.0µL might contaminate the test strip port and the meter. Blood sample size below 1.0µL might cause inaccurate test results or might not start the meter. In this case, repeat the test with a new test strip.
16. Place lancet device against prepared site on client’s finger and push down quickly and firmly.
17. Assess puncture site; if necessary provide light pressure around puncture site to form a drop of blood on the client’s skin (avoid touching blood or puncture site).
18. Touch and hold the drop of blood to the edge of the sample port until you hear a “beep” (if volume is turned on) and the view window is filled with blood. If the view window is not completely filled with blood the test will not start. If this happens, discard the test strip and repeat with a new GE100 Blood Glucose Test Strip.
19. Countdown mode will begin on the display window. After 5 seconds, test result will appear.
20. Apply cotton ball to client’s finger and ask client to apply pressure at puncture site.
21. Apply bandage to client’s finger at puncture site (if necessary).

22. Discard used lancet into red sharps container. Never reach in or try to remove any material from the sharps container.
23. Record every blood glucose test on study screening form and on client results form. Explain results to client.
24. Discard all other used testing supplies (alcohol prep pad, cotton ball, bib, used test strip, etc.) into trash. Never push down on trash or reach into trash to remove objects.
25. Use alcohol wipes (at least 70% alcohol) to clean and disinfect the GE100 Blood Glucose Monitoring System. Staff should be careful to ensure that the entire meter, including the top, sides, and bottom, are wiped off, while ensuring that "liquid" alcohol is not dripped directly into the electrical components of the meter. The Monitoring Systems should then be allowed to "air dry" prior to being used on the next client.
26. Remove exam gloves by pulling gloves off using the wrist section and inverting the gloves as they are removed from your hands. Dispose gloves in trash.
27. Use hand sanitizer to clean hands.
28. At the end of each screening event and as needed during screening activities, put on a new set of gloves and use Sani-Cloths to sterilize table, pens, glucometers, and all other supplies at testing station.

7.2.2 Performing a Quality Control Test with the GE100 Blood Glucose Monitor

Always follow manufacturer guidelines and instructions when using the GE100 meter. It is necessary to perform a Quality Control ("QC") Test to ensure the meter is functioning properly.

When to Perform a QC Test:

- If meter is dropped or appears damaged
- When using a new shipment or lot of test strips
- If meter was left out in extreme heat or cold
- If meter was exposed to any liquid (including any cleaning solutions that may have entered meter's testing port)
- After any confirmed "Hi" or "Lo" test result on a patient
- Whenever test result seems to be an error
- After replacing the meter battery
- Every 2 weeks, if not already preformed for other reasons.

A Quality Control Log should be kept to ensure the QC procedures have been completed at least every 2 weeks (see ***Appendix Q***). All QC logs should be saved and stored with other project documents.

Performing a Quality Control Test with the GE100 Blood Glucose Meter

1. Take one GE100 Blood Glucose Test Strip from the vial and close the vial cap immediately.
2. Insert the GE100 Blood Glucose Test Strip with the indication symbol facing up, into test strip port.
3. While the blood drop icon is flashing on the display window, press and hold the Main button for at least 3 seconds until the "CS" symbol appears.

4. You will see the blinking “drop” icon and “CS” icon on the screen, prompting you to apply GE100 Control Solution.
5. Shake the bottle of GE100 Control solution well before opening cap. Place cap on a flat surface.
6. Place a drop of the control solution onto the top of the cap.
7. Gently touch the sample entry of the strip with the GE100 Control Solution from the top of the cap. The screen will display the count time starting from 5 (you will hear a beep if the volume is turned on).
8. Tightly replace the cap on the GE100 Control Solution bottle.
9. The Control Solution result will appear. Compare your Quality Control Test result to the Control Solution Range printed on the GE100 Blood Glucose Test Strip vial label.
10. Record the QC result and any comments on the GE100 Quality Control Log (***Appendix Q***).
11. All QC logs should be saved and stored with other project documents.
12. When a meter fails a QC test, refer to the user manual for troubleshooting steps and then perform a second QC test. If after troubleshooting, a meter still does not pass a QC test, replace the meter.

QC Testing Notes

- Control Solution Test should be conducted between 59-104°F (15-40°C).
- Before the drop icon and “CS” appears, do not touch the GE100 Control Solution to the sample entry on the strip. The GE100 Blood Glucose Meter is preforming an internal check. Touching the Control Solution to the sample entry before prompted will result in an error message, drop icon, and beeps (if volume is turned on).
- Do not drip the GE100 Control Solution into the sample port of the strip directly. The reagent on the strip might leak into the bottle of GE100 Control Solution and cause degeneration of GE100 Control Solution. Doing this could also contaminate the meter via the test strip port.
- Do not touch anything to the tip of the GE100 Control Solution bottle.

Maintenance of the GE100 Blood Glucose Meter

Keep the GE100 Blood Glucose Meter and Test Strip free of dust, water, and any liquids. Store the meter in the carrying case when not in use. If meter is dropped or damaged, perform a quality control test with the control solution before doing a blood glucose test.

Cleaning the GE100 Blood Glucose Meter

Clean the outside of the GE100 Blood Glucose Meter with a damp cloth and mild soap/detergent. Do not get the test strip port wet. The meter should be cleaned with 70% alcohol, as described earlier, between client uses.

Cleaning the GE100 Blood Glucose Meter Test Strip Port

If Test Strip Port is stained with blood, control solution or any other liquid, use a dry tissue or cotton swab to clean it immediately. Do not use anything wet to clean it. Perform a quality control test to ensure that the GE100 Blood Glucose Meter is working properly.

7.3 Point-of-care HbA1c testing

We will use the PTS Diagnostics A1CNow®+ System to conduct all point-of-care (POC) HbA1c testing with food pantry clients and study participants. HbA1c testing will be conducted by trained study staff or food bank personnel. Testing will follow manufacturer guidelines for device use, maintenance, storage, cleaning, and quality assurance (see A1CNow®+ System User Guide in ***Appendix N***).

Materials List for HbA1c Testing

- A1CNow®+ System Monitor
- A1CNow®+ System Blood Collector, Sampler Body, and Cartridge
- Hand sanitizer
- Nitrile gloves
- Alcohol prep pad (minimum 70% alcohol)
- Single-use lancet device
- Cotton balls
- Bandage
- Dental bib (disposable barrier)
- Surface sanitizer (Sani Cloth Super Wipes)
- Trash can with liner
- Sharps container

7.3.1 Procedure to conduct an HbA1c test

1. Prior to starting an HbA1c test, ensure you have access to a stable, level surface at room temperature and out of direct sunlight.
2. Have client sit at health screening table.
3. Introduce yourself and provide client with background on screening.
4. Ask client: “have you ever been told by a doctor that you have diabetes?”
5. Always maintain client privacy. If necessary, ask other food bank clients to stand away from the screening area.
6. Clean hands with hand sanitizer.
7. Set up supplies. Ensure that lot numbers on Monitor, pouched test Cartridge, and pouched Sampler all match.
8. Put on exam gloves.
9. Ask if client has a preference for which finger to use in order to access blood sample.
    a. Do not use any site on a finger that is an open wound, has scar tissue, has evidence or infection, or has any other contraindication (e.g., previous diabetes-related amputation, scleroderma); select a different finger for testing.
10. Ask client to hang hand below table and open and close their fist 3-4 times in order to increase blood flow to the fingers.
11. Open alcohol swab and clean finger at site where sample will be obtained.
12. Allow finger to air dry or blot with clean cotton ball to dry site.
13. Open pouched Sampler Body and Blood Collector.

14. Place lancet device against prepared site and push down quickly and firmly. The side of the finger provides a blood sample with less pain than the center of the finger pad.
15. Assess puncture site; if necessary provide light pressure around puncture site to form a drop of blood on the client's skin (avoid touching blood or puncture site).
16. Gently touch tip of Blood Collector to puncture site to completely fill Collector. Wipe away excess blood from Collector (if necessary). A blood sample size of 5 microliters (µL) is required to run a test. A large blood drop is approximately 5 µL.
17. Apply cotton ball to client's finger and ask client to apply pressure at puncture site.
18. Fully insert Blood Collector with sample into Sampler Body.
19. Shake Sampler Body well 6-8 times.
20. Stand Sampler Body on table while preparing test Cartridge.
21. Insert Cartridge into Monitor. Ensure that codes match and Monitor is placed on a level surface, at room temperature, and out of direct sunlight. Sample must be applied to Cartridge within 2 minutes.
22. Wait for "SMPL" to display on Monitor.
23. Remove base of Sampler Body and dispense sample into Cartridge.
24. Do not handle Monitor again until test is complete (approximately 5 minutes).
25. Once test is complete, Monitor will display quality control test result ("QCOK" indicates the Monitor is functioning properly with no detected errors), HbA1c result, and number of tests remaining for Monitor. Refer to User Guide for list of error codes if "QCOK" is not displayed.
26. Apply bandage to client's finger at puncture site (if necessary).
27. Discard used lancet into red sharps container. Never reach in or try to remove any material from the sharps container.
28. Record HbA1c result on study form (screening log and enter in MS Access database at site or immediately after screening event) and on client results form. Explain results to client.
29. Discard all other used testing supplies (used test Cartridge, used Blood Collector and Sampler Body, alcohol prep pad, cotton ball, bib, etc.) into trash. Never push down on trash or reach into trash to remove objects.
30. Remove exam gloves by pulling gloves off using the wrist section and inverting the gloves as they are removed from your hands. Dispose gloves in trash.
31. Use hand sanitizer to clean hands.
32. At the end of each screening event and as needed during screening activities, put on a new set of gloves and use Sani-Cloths to sterilize table, pens, Monitor, and all other supplies at testing station.

7.3.2 Performing a Quality Control Test with the A1C+Now Monitor

Each A1CNow+ Monitor performs over 50 internal chemical and electronic quality control checks, including potential hardware and software errors (e.g. cartridge alignment, programming), and potential reagent strip errors (e.g. insufficient sample volume, invalid calculations). The Monitor has been programmed to report an error code if these quality checks are not passed.

Control testing solutions are <u>not</u> included with testing kits. When ordering new test kits, you must order and purchase both the high and low control solutions in addition to the kits.

Follow manufacturer instructions for properly conducting a QC test with the A1C+Now System. Record the QC result and any comments on the A1C+Now Quality Control Log (***Appendix R***). All QC logs should be saved and stored with other project documents. When a monitor fails a QC test, refer to the user manual for troubleshooting steps and then perform a second QC test. If after troubleshooting, a monitor still does not pass a QC test, replace the monitor.

Quality control testing should be performed at the following times:

- With each new shipment
- With each new lot
- With each new operator (conduct QC test before a newly trained staff begins using monitor with clients)
- Whenever problems (storage, operator, instrument, or other) are identified
- To ensure that storage conditions have not affected the product, run a control sample before running a patient sample if the test kit has been stored for more than a month and it has been at least a month since the last control testing

The measured value should be within the acceptable limits stated for the control material (refer to specific instructions and limit information included with control testing solutions). If the results obtained are outside the acceptable limit, please review the procedure and re-test the control material. If the measured value continues to fall outside the acceptable limit, please refrain from analyzing additional patient samples and contact Customer Service (1-877-870-5610).

Good laboratory practices include a complete quality control program. This entails proper sample collection and handling practices, ongoing training of testing personnel, ongoing evaluation of control results, proper storage of test kits, etc. A permanent record of control results should be retained see A1C+Now Quality Control Log in ***Appendix R***).

7.4 Ordering Information for testing supplies

Sites will be responsible for ordering and purchasing all supplies required to conduct testing, and each site has funding that should cover screening costs for the duration of the project. The following includes suggested information on where to purchase all supplies.

- GE100 meters and strips
    - Katie Enright, Katie.Enright@bionime.com
    - http://www.gediabetes.com/ge100/
- A1C+Now Testing System
    - System information: http://www.ptsdiagnostics.com/
    - Vendor information: http://www.whitmiremedical.com/
    - Vendor contact: Michael Falck, michael@whitmiremedical.com
    - Vendor pricing for Feeding America: $152.50 per box (20 tests), not including S/H
- General Testing Supplies

- Allegro Medical: http://www.allegromedical.com/
- Miscellaneous supplies (e.g., dental bibs, Dex4 glucose tablets)
  - Amazon.com

7.5 Regulatory requirements for testing

Conducting community-based screening and testing programs requires that organizations comply with a number of federal, state, and local regulations. FANO FAITH-DM project staff will provide technical assistance to food bank sites to support the sites in applying for and maintaining all required certifications in order to conduct testing. Food bank sites are ultimately responsible for ensuring that their organization is in compliance, and that any screening program is successfully meeting all regulatory requirements for the duration of the program. Sites cannot conduct any testing, screening, or monitoring until all regulatory requirements are met and maintained.

Regulatory requirements for conducting community-based screening and testing programs include the following:

7.5.1 CLIA Certificate of Waiver

Both of the devices we will use for testing (GE100 Blood Glucose Monitor, A1C+Now Monitor) are CLIA-waived devices. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) program is managed by Centers for Medicare and Medicaid Services (CMS), and implemented through state CLIA offices. All project sites need to apply for CLIA certificates of waiver for use of these testing devices through their state offices, following the state-specific processes and forms. Funding is included in the food bank grants to cover all state and federal fees associated with obtaining and maintaining a CLIA certificate of waiver.

7.5.2 Medical Waste Permitting

For the FAITH-DM study, the only medical waste that will be generated by the sites are sharps (single-use lancet devices). We anticipate that each site will generate under 10 pounds of sharps medical waste each month. Regulations addressing the use, storage, transport, and treatment of sharps and sharps containers vary by state. In Texas, generators who generate 50 pounds or less per month of medical waste are exempted from permit, registration, and notification requirements. Both California and Michigan require organizations apply for and maintain permits to transfer and store medical waste that includes sharps, regardless of the quantity generated monthly.

- To meet state requirements for Small Quantity Medical Waste generators and for Limited Quantity Hauling Exemptions, sites will submit applications and associated fees to their appropriate state or county offices.
- Sites will submit a “Medical Waste Management Plan” along with their application, and use a Medical Waste Tracking Log (***Appendix S***) to document waste management.

- All sites will utilize a USPS-approved medical waste mail back service (Sharps Compliance, Inc.: http://www.sharpsinc.com/) for purchase of sharps containers, shipping, tracking, and treatment of medical waste generated during screening activities.

7.5.3 Additional Screening Requirements

Sites will submit applications and program materials as required to address any additional local regulations relative to conducting screening and testing in the community setting.

- Non-Diagnostic General Health Assessment (NDGHA) application
    - Sites located in California need to complete and submit a NDGHA application annually to their local county health department in order to meet state screening requirements
    - The application must be submitted at least 30 days prior to any screening activities taking place, and must include all required information and documentation relative to program protocols, staff credentials, and screening locations, dates, and times
    - Sites must also include with their application materials the names and credentials (phlebotomist, RN, MA, PA, MD, etc.) of all staff that will be conducting screening.

7.6 Survey Administration

This section of the MOP covers instructions for the administration of surveys used in the course of this study. Surveys are administered by trained FAITH-DM research staff to consented food bank clients in the participant's preferred language. All surveys will be administered via the CASIC data collection software on a laptop provided by University of California San Francisco.

This study includes a baseline survey and two follow-up surveys. All participants will complete the same Baseline Survey (***Appendix U***). Intervention group participants will complete the Follow-Up Survey Intervention (***Appendix V1***) at T6. Control group participants will complete the Follow-Up Survey Control Survey (***Appendix V2***) at T6. As a result of study extension funding, both groups will also complete surveys at T12. The T12 INT survey (***Appendix W1***) is identical to the T6 INT survey, but does not include any satisfaction items. The T12 CONT survey (***Appendix W2***) is identical to the T6 INT follow-up survey.

The timing for completing the T6 and T12 follow-up surveys is outlined below and uses the same time windows for follow-up HbA1c testing.

SURVEY VERSION	GROUP	TIMING*
Baseline	All Participants	T0
T6 Follow-up (INT)	Intervention Group	T6 (5 – 7 months [6±1])
T6 Follow-up (CONT)	Control Group	T6 (5 – 7 months [6±1])
T12 Follow-up (INT)	Intervention Group	T12 (11 – 13 months [±1])**

T12 Follow-up (CONT)	Control Group	T12 (11 – 13 months [12±1])**

* 1 month = 30 DAYS ALWAYS
** Alternatively, T12 survey windows can be manually calculated as 5-7 months ***after*** the completion date of a participant's T6 follow-up activities. This revision will accommodate participants who complete their T6 activities at month 5 (earliest part of the window) and maintain a 5-7 month separation between the T6 and T12 follow-up activities.

If a participant does not complete their follow-up survey at T6 or T12, study staff can still complete it with the participant when they are next seen at a pantry or study activity. Participant surveys can also be completed over the phone if necessary.

7.6.1 Survey administration procedures

In order to maintain confidentiality, the survey should be conducted in an area away from other people, where the participant will feel comfortable discussing personal information with the research staff. The survey should last about 30 minutes and should be completed in one sitting; make sure the participant is aware of the duration of the survey before beginning. It is the research staff's responsibility to obtain full and accurate information from participants.

Strategies for starting baseline survey with a new participant:

- Emphasize the time commitment required to complete survey (approximately 30 minutes)
- Get a verbal commitment from the participant that they are able and willing to stay for the entire survey
- Only begin survey with participant who can commit to completing the survey now

Strategies and procedures for successfully administering the survey include:

- Read clearly and in a natural rhythm and tone; read as if you were speaking.
- If the answer provided seems inappropriate for the question asked, kindly acknowledge the response and then repeat the question, clarifying where needed.
- Each question must be asked of each participant in the same way and in the same order to ensure that comparable information is being obtained from all the participants in the study.
- Transition sentences appear throughout the survey to help you introduce a new topic. Read these out loud and in full as they often contain information for the participant on how to answer the following set of questions.
- "Don't read out loud" will often appear in multiple choice questions for the answers "don't know or refused". Study participants may not know the answer to a question and are allowed to refuse to answer any question, but don't read this aloud as an option; let the participant tell you.

See **section 12.3.1** for instruction on using CASIC.

7.6.2 Completing surveys when participant needs to leave

At times, a participant may need to leave before administration of a survey is complete. If the participant completed approximately less than half the survey, staff should inform the participant that they will need to restart the survey and complete it at a future date.

Instructions for when a client does not start a survey or completes less than half:

- If possible, schedule a day and time to complete the survey within the next two weeks
- Verify the participant's contact information, and the information for their additional contacts (participant, friend, family member) in order to place reminder calls
- Remind client of the program benefits / incentive available once survey is completed
- Save participant ID# used to enter baseline data into ACCESS database and to start CASIC survey
    - Do NOT open the randomization envelope; do NOT assign client to a study group
- In the event the participant does not start or complete the survey within the two week period:
    - The client will be considered lost to follow-up; add note to ACCESS
    - Notify Sophie Rosenmoss that client did not start/complete survey and was not randomized
    - Do not reuse the participant ID# and destroy the randomization envelope
    - If the participant was completing a follow-up survey, notify Sophie Rosenmoss that the survey was not completed within the two-week window

Instructions for when a participant completes approximately half of the survey or more:

- Site staff can save the survey and attempt to finish the remainder with the client within two weeks
- If completing a baseline survey, open the randomization envelope with the participant for group assignment before the participant leaves the site
    - If randomized to the intervention group, provide participant with resources and first food package per study protocols
    - If randomized to the control group, provide participant with 1st incentive ($15 gift card) and have participant sign for receipt of the gift card
- If completing a follow-up survey, provide participant with the correct incentive and have participant sign for receipt of the gift card
- Verify the participant's contact information, and the information for their additional contacts (participant, friend, family member) in order to place reminder calls
- If possible, schedule a day and time to complete the survey within the next two weeks, either in person or over the phone
- Conduct reminder calls to participant and contacts throughout this two week period to ensure they are able to complete survey at next visit (or over the phone)
- If, after two weeks the survey has not been completed, enter a note in ACCESS that the survey was "incomplete"
- Notify Sophie Rosenmoss that participant will not complete survey

7.6.3 CASIC instructions for completing surveys at a later date

When exiting and resuming an incomplete survey perform the following:

CASIC Online:

1. Simply exit survey using upper right hand corner exit button on pop-up survey window
2. Email Sophie to let her know of incomplete assessment and plans to complete or destroy
3. When resuming, click “Start assessment” and enter PPT ID as usual
4. You will be prompted to resume baseline survey, select this option
5. Complete survey as usual

CASIC Remote:
When managing an incomplete survey on CASIC Remote, the RA can select either option outlined below.

CASIC Remote surveys that are incomplete and uploaded to the server using the “upload data” button in the “synchronize subject data” tab cannot be resumed using CASIC Remote. They can only be resumed using CASIC Online, as the data no longer “lives” on the local drive after synchronization. You may resume a survey on CASIC Remote using the instructions below only if the survey data is not synchronized after exiting the survey. However, it is best practice to synchronize the subject data, incomplete and otherwise, at the end of each day. It is likely that these computers will be used for other survey administration during the timeframe that the incomplete survey remains outstanding. It is not possible to leave only the incomplete survey on the local drive and upload the other completed surveys, and it poses a risk of lost study data if surveys are not uploaded to the server in a timely manner, so it is best to upload the incomplete survey and resume using CASIC Online.

This may be less convenient for on-site administration, but since the RA will be working with the participant to re-schedule a time, they should take into account that they will need internet access to resume the survey. For this reason, it may be useful to complete the surveys by phone. In situations in which there are no other surveys on CASIC Remote on the computer in question and there is a reasonably short time period between first administration and completion of the incomplete survey, it may be appropriate to leave the study data from the incomplete survey on the local drive and resume and complete the survey using CASIC Remote.

Option 1: Synchronize subject data and resume survey using CASIC Online:

1. Simply exit survey using upper right hand corner exit button on pop-up survey window
2. Email Sophie to let her know of incomplete assessment and plans to complete or destroy
3. Navigate to the “Synchronize subject data” tab on the left hand navigation panel, select “Upload only” to upload the incomplete survey to the host
4. When resuming the survey using CASIC Online, click “Start assessment” and enter ppt ID as usual
5. You will be prompted to resume baseline survey, select this option
6. Complete survey as usual

Option 2: Leave subject data on the local drive and resume survey using CASIC Remote:

1. Simply exit survey using upper right hand corner exit button on pop-up survey window
2. Email Sophie to let her know of incomplete assessment and plans to complete or destroy
3. Do not synchronize subject data
4. When resuming the survey using CASIC Remote, click "Start assessment" and enter ppt ID as usual
5. You will be prompted to resume baseline survey, select this option
6. Complete survey as usual

7.6.4 Survey piloting procedures

Research assistants and any staff involved in survey administration should practice administering the surveys before completing with study participants. Piloting surveys will allow for feedback on improving study forms and surveys, and facilitate streamlined administration with initial participants.

- First, pilot survey on 1-2 colleagues to become familiar with the study format, questions, and response options.
- Practice using CASIC to enter practice study data.
- Second, pilot the study with 1-2 food pantry clients.
    - Use incentive gift cards to compensate clients for their time (1 - $15 gift card per survey)
    - Clients do NOT need to be consented for completing a pilot survey
    - Explain to clients that responses to pilot surveys will not be saved, and the client is free to answer survey questions with real or made-up responses

CASIC is programmed with participant ID numbers that have been identified for use in piloting and training purposes. Use these ID numbers when piloting surveys:

Site	Practice Participant ID Numbers
UCSF / FANO	10 - 29
ACCFB	30 - 49
GCFB	50 - 69
HFB	70 - 89

7.7 Health Care Utilization Analysis

This section contains information and processes specific to the Health Care Utilization (HCU) plan, including communicating with health care providers about the study and health care utilization data requests. A table at the end of this section identifies the different packets used when communicating with providers.

The HCUA is a critical component of the FAITH-DM study. The analysis will provide important information on how participating in the intervention may impact the ways in which a patient utilizes health care services for primary care and diabetes management.

Collection of health care utilization data from providers follows this format: HCU surveys are sent to providers two times over the course of the study: once at T6 for the entire previous 12 month period for both the control and intervention groups, and once at T12 for the previous 6 month period for the intervention group only.

7.7.1 HCUA Roles and Responsibilities

Site research assistants (RAs):

- Track primary care provider (PCP) information for study participants (at T0, T6, and T12) and enter data into MS Access database
- Communicate with PCPs regarding study activities by sending pre-drafted letters and HCU documents per the HCUA plan (see ***Appendix Y – Health Care Utilization Provider Letters [1-8]*** for all HCU Provider Letters)
- Track PCP completion of HCU surveys and provide follow-up and support as needed
- Compile completed surveys and ensure that documentation is de-identified before sending in batches to the Urban Institute
- Submit and track quarterly payments to clinic partners for data extraction and survey completion fees (per food bank – clinic MOU agreements)

Urban Institute:

- Provide technical assistance to site RAs in communicating HCUA to partner clinics and supporting clinics to complete HCU surveys per study protocols
- Communicate with site RAs to troubleshoot unanticipated challenges relative to completing provider surveys (e.g., participant uses a small, family practice for care which does not have a food bank MOU)
- Work with RAs to revise HCUA processes as needed at the site or clinic level to streamline acquisition of utilization data
- Develop and refine all HCU documents and surveys as needed
- Complete all data entry from submitted provider surveys and documents
- In the event site RAs submit de-identified copies of medical records, Urban Institute will complete data extraction and data entry for use in HCUA
- Manage all HCU-related data and conduct final data analyses

All RAs will be provided with contact information for the appropriate research personnel at the Urban Institute so that they can obtain assistance with any questions or issues that arise during the Health Care Utilization component of the study.

7.7.2 HCUA Activities at Baseline (T0)

The following sections outline HCUA activities that take place when a new participant enrolls in the study.

At enrollment, all participants will be asked to provide the name of their current primary care provider (individual provider and/or practice/clinic site) and to provide consent for communication with provider, including release of medical record information (see **section 5.3** for discussion of consent and HIPAA procedures, and ***Appendix AO*** for the Medical Records Release Template). The site personnel will request as much contact information for the provider as possible (phone number, address, or nearest cross streets the participant can identify). The RA may need to research and complete the provider contact information if the participant is unable to provide full contact information at the time of enrollment.

If the participant declines to provide consent for the release of medical records from the current provider, this should be documented and entered into the MS Access database. No further action to request information from the provider can be taken regarding release of medical record information. However, when a participant provides informed consent to enroll in the study, study staff does receive participant permission to contact the participant's care provider to inform provider of the participant's entry into the study.

7.7.2.1 Intervention group participants with an existing primary care provider

For intervention group participants who have a PCP, study staff will assemble a baseline provider communication packet that will include:

- Provider Letter (*HCU Letter 1 - T0 Current Pt INT*)
- Copy of the participant's signed HIPAA authorization form

This baseline letter provides background information on FAITH-DM, informs the provider that the participant has enrolled in FAITH-DM, identifies the participant's group assignment, discloses screening results (only for participants assigned to the intervention group), describes the HCUA process, and informs the provider that a care utilization survey will be sent at the participant's 6- and 12-month mark in the study. No action is requested of the provider at baseline.

The provider communication packet should be generated and sent (by fax or mail) within two weeks of the participant's enrollment in the study. A description of how the site can maintain a HIPAA compliant fax is contained in **section 3.2.1.**

7.7.2.2 Intervention group participants without a primary care provider

When the intervention participant does <u>not</u> have an existing source of primary care, he or she will receive an active referral per the process outlined in **section 3.2.1**. A modified baseline provider communication packet will be assembled and includes:

- Provider Letter (*HCU Letter 2 - T0 Newly Referred Pt INT*)
- Copy of the participant's signed HIPAA authorization form

The RA will need to verify the primary care provider information at the six-month participant survey (and is prompted by CASIC to do so).

The provider communication packet should be generated and sent (by fax or mail) within two weeks of the participant's enrollment in the study.

7.7.2.3 Waitlist control group participants with an existing primary care provider

For participants assigned to the waitlist control group and who state they have an existing primary care provider, the following communication packet will be sent to the provider:

- Provider Letter (*HCU Letter 3 - T0 Current Pt CONT*)
- Copy of the participant's signed HIPAA authorization form

The provider communication packet should be generated and sent (by fax or mail) within two weeks of the participant's enrollment in the study.

7.7.2.4 Waitlist control group participants without a primary care provider

If a waitlist control participant does not have an existing source of primary care, he or she will receive a provider resource handout (passive referral) per **section 3.2.1**.

No provider communication packet is required for this group at T0.

If the participant states they do not have a provider now, but they did receive primary health care services in the last six months, then the RA should complete the steps listed above for sending a communication packet (*HCU Letter 3 - T0 Current Pt CONT*) to their previous provider and offer a resource handout for the participant to establish care with a new provider. Contact information for the previous provider should be stored in Access to use when sending out HCU surveys at T6.

The RA will need to repeat the request for whether there is a current primary care provider at the point at which the participant becomes eligible to enroll in the intervention at six months (the 6-month participant survey includes a prompt in CASIC for this inquiry).

7.7.3 HCUA Activities at Six Months (T6)

The following sections outline the processes for how site staff communicate with providers at the six-month mark for each participant, including completion of the health care utilization survey (HCUS).

Site staff should still attempt to have the HCUS completed for any participant who at T6 has been identified as "lost to follow-up" or who dropped out of the study, **unless** the participant actively revoked their consent to participate in the study, **or** their consent to release medical records. Site staff cannot request HCUS completion for any participant who revokes these consents, and this should be recorded in the study MS Access database.

"Lost to follow-up" is defined as not completing follow-up activities after at least three no-shows to appointments during the participant's follow-up window. For participants lost to follow-up at T6, site staff can again attempt to engage with them during their T12 follow-up windows.

7.7.3.1 Study participants who had an existing provider at baseline

Site staff will complete the same provider packet at T6 for participants in both the intervention and control groups who identified a provider at baseline.

The T6 provider packet for these participants includes:

- Provider Letter (*HCU Letter 4 - T6 Current Pt*)
- Copy of signed HIPAA form
- Copy of signed Medical Records Release Form
- HCUS (***Appendix Z***)

Site personnel will complete the first page of the HCUS prior to sending the provider communication packet, including the participant's full name and date of birth so that the provider can verify that the participant data matches that reflected in the patient's records. If the provider has no record of the patient, they will be instructed to return the face sheet to the RA. The RA will also need to write in the participant ID number in the designated box at the top of each remaining page of the survey.

The top portion of each page will include space to specify the range of service dates the HCUS is requesting. Study staff should enter the date the participant reaches T6 as the **end date** for the record request and the **start date** should be entered as the corresponding date 12 months earlier (which equates to the 6-month period that occurred just prior to the participant's enrollment into the study). For example, if the participant reaches T6 in the study on November 1, 2016, the record request period will be identified as "November 1, 2015 through November 1, 2016."

After filling out the relevant dates we are requesting data on the HCUS, please use a highlighter to highlight on the first page the text "Period of Requested Data: _____ to _____." We want to emphasize these dates because they will be different compared to those specified on the Medical Records Release Form, which encompasses the entire span of the study and does not distinguish between the control and intervention groups.

All T6 provider packages should be faxed to or mailed to providers (based on individual processes outlined in each clinic's MOU with the food bank site). We expect providers to return completed surveys via fax to the RA. Please see **section 7.7.7** for instructions on how to send completed provider surveys to the Urban Institute.

7.7.3.2 Study participants without provider at T0 but have provider at T6

For participants who did not have a provider at baseline (T0), but do identify having a provider at the six-month mark (T6), site staff will send the same T6 packet identified above to the participant's new provider.

The T6 provider packet for these participants includes:

- Provider Letter (*HCU Letter 4 - T6 Current Pt*)
- Copy of signed HIPAA form
- Copy of signed Medical Records Release Form
- HCUS (***Appendix Z***)

The RA should follow the process outlined above for completing portions of the HCUS and sending the packet to providers.

7.7.3.3 Study participants without provider at T0 and who still do not have a provider at T6

For participants who did not have a provider at baseline (T0), and still do not identify having a provider at the six-month mark (T6), site staff will generate an active referral to a partner clinic per the process outlined in **section 3.2.1**.

In addition to the referral for care, site staff will send a modified T6 packet to the participant's new provider.

The T6 provider packet for these participants includes:

- Newly Referred Patient T6 Letter (*HCU Letter 5 - T6 Newly Referred Pt*)
- Copy of signed HIPAA form
- Copy of signed Medical Records Release Form
- HCUS (***Appendix Z***) – for use in the event the provider does have records for this participant

The RA should follow the process outlined above for completing portions of the HCUS and sending the packet to providers.

7.7.3.4 If a participant has switched providers between T0 and T6

It is possible that a participant may have switched primary care providers during the study intervention period. This could occur for several reasons: the participant may have moved and the prior provider location was no longer be convenient; the provider may have closed or changed the conditions under which it sees patients (e.g., the provider is no longer on the panel for the participant's insurance plan); the participant may have had a change in insurance or coverage status that affects his or her provider options; or the participant has decided to change for other reasons. It is important that the RA re-verify the primary care provider information for all participants at the six month survey point and note where any changes may have been made.

If there is more than one provider during the six-month period, then requests for records should be made to all primary care providers the participant has identified. Each provider will receive a T6 provider packet; however, the new provider should receive a modified version of the T6 letter that does not assume any prior communication with that provider (see: *HCU Letter 5 - T6 Newly Referred Pt*). The RA should make a note in the MS Access database that provider data is being requested from multiple providers. This information should be recorded on all survey forms for that participant

once they have been returned and logged into the database so that the analysis team is aware that two or more surveys will be entered for that period and special attention can be paid to reconciling the information for that participant.

7.7.4 HCUA Activities at Twelve Months (T12)

The following sections outline the processes for how site staff communicate with providers at the twelve-month mark for intervention group participants, including the completion of the second health care utilization survey (HCUS). These activities will be very similar to those conducted at T6. However, it is important to note that these activities will only be carried out for the intervention group. No further healthcare utilization activities will be conducted for the control group.

Site staff should still attempt to have the second HCUS completed for any INT participant who at T12 has been identified as "lost to follow-up" or who dropped out of the study, **unless** the participant actively revoked their consent to participate in the study, **or** their consent to release medical records. Site staff cannot request HCUS completion for any participant who revokes these consents, and this should be recorded in the study MS Access database.

"Lost to follow-up" is defined as not completing follow-up activities after at least three no-shows to appointments during the participant's follow-up window. For participants lost to follow-up at T6, site staff can again attempt to engage with them during their T12 follow-up windows.

7.7.4.1 Intervention group participants that had an existing provider at T6

Site staff will complete a provider packet very similar to the packet outlined in 7.7.3.1.

The T12 provider packet for these participants includes:

- Provider Letter *(HCU Letter 7 – T12 Current Pt INT)*
- Copy of signed HIPAA form
- Copy of signed Medical Records Release Form
- HCUS (***Appendix Z***)

Site personnel will complete the first page of the HCUS prior to sending the provider communication packet, including the participant's full name and date of birth so that the provider can verify that the participant data matches that reflected in the patient's records. If the provider has no record of the patient, they will be instructed to return the face sheet to the RA. The RA will also need to write in the participant ID number in the designated box at the top of each remaining page of the survey.

The top portion of each page will include space to specify the range of service dates the HCUS is requesting. Study staff should enter the date the participant reaches T12 as the **end date** for the record request and the **start date** should be entered as the corresponding date 6 months earlier (which equates to the 6-month period after the participant completed the intervention). For example,

if the participant reaches T12 in the study on April 1, 2017, the record request period will be identified as “November 1, 2016 through May 1, 2017.”

After filling out the relevant dates we are requesting data on the HCUS, please use a highlighter to highlight on the first page the text “Period of Requested Data: _____ to _____.” We want to emphasize these dates because they will be different compared to those specified on the Medical Records Release Form, which encompasses the entire span of the study and does not distinguish between the control and intervention groups.

All T12 provider packages should be faxed to or mailed to providers (based on individual processes outlined in each clinic’s MOU with the food bank site). We expect providers to return completed surveys via fax to the RA. Please see **section 7.7.7** for instructions on how to send completed provider surveys to the Urban Institute.

7.7.4.2 Study participants without provider at T6 but have provider at T12

For participants who did not have a provider at six months (T6), but do identify having a provider at the twelve-month mark (T12), site staff will send the same T12 packet identified above to the participant’s new provider.

The T12 provider packet for these participants includes:

- Provider Letter (*HCU Letter 7 – T12 Current Pt*)
- Copy of signed HIPAA form
- Copy of signed Medical Records Release Form
- HCUS (***Appendix Z***)

The RA should follow the process outlined above for completing portions of the HCUS and sending the packet to providers.

7.7.4.3 Study participants without provider at T6 and who still do not have a provider at T12

For participants who do not have a provider at T12, site staff will generate an active referral to the partner clinic per the process outlined in **section 3.2.1**

In addition to the referral for care, site staff will send a modified T12 packet to the participant’s new provider for intervention group participants only.

The T12 provider packet for these participants includes:

- Newly Referred Patient T12 Letter (*HCU Letter 8 – T12 Newly Referred Pt*)
- Copy of signed HIPAA form
- Copy of signed Medical Records Release Form
- HCUS (***Appendix Z***) – for use if the provider does have records for this participant

The RA should follow the process outlined above for completing portions of the HCUS and sending the packet to providers.

7.7.4.4 If a participant has switched providers between T6 and T12

Follow directions as outlined in section 7.7.3.4. For new providers, staff should send providers the *HCU Letter 8 – T12 Newly Referred Pt.*

7.7.5 Sending Follow-Up Prompts to Primary Care Providers Regarding Survey

The RA should monitor the results of all provider record requests on a weekly basis. If there has been no response to a record request after two weeks, a reminder letter will be generated and sent to the provider (*HCU Letter 6 - Provider Survey Reminder*). This mailing will include a friendly reminder about the survey, and enclose another copy of the consent to release records and the survey. The RA will log the date of the follow-up mailing in the MS Access database. If there has been no response after two more weeks, the RA will generate one final written reminder with a copy of the survey and consent.

If there has been no response to the first and second written reminders after four weeks, the RA will implement a phone contact protocol. If the provider / clinic on file for the participant has an MOU with the FAITH-DM site, the RA will follow the contact procedures previously identified by the provider site. If there is no MOU, the RA will make up to three telephone attempts to talk to the practice manager or medical records department to inquire whether the survey has been received and/or if the survey was sent in error (e.g., the provider has no record of this patient). If there is patient data that matches the participant, the RA will encourage the provider to complete the survey, offer assistance as needed, and review the opportunity for financial incentives upon completion. If after three contacts that result in direct communication, the RA is still unsuccessful in obtaining a baseline survey, the RA will note the attempts and the lack of response in the MS Access database.

Outstanding record requests will be reviewed quarterly with Urban Institute staff and the FAITH-DM project manager to determine if the FAITH-DM team can provide any additional assistance in securing a response or if the case should be deemed “nonresponse.”

7.7.6 Financial Incentives for Provider Survey Completion

The FAITH-DM sites have funds allocated to provide reimbursement to providers for each survey completed ($20). This information is included in the provider communication packet. Reimbursements should be generated quarterly by site personnel to ease the administrative burden for both the site personnel and providers (e.g., to avoid providers having to generate individual invoices for each record extraction).

7.7.7 Returning / Receiving the HCU survey

The provider communication packet will include instructions about how to return the survey to the site RA via fax. The site RA is responsible for logging receipt of a completed survey in the MS Access database. Similarly, provider requests for clarification on the survey or any follow-up prompts sent to the provider by the RA should be logged in the MS Access database so there is a complete picture of provider communication available to the site personnel. Once a quarter, the RA can tally the number of completed surveys by provider and generate the appropriate compensation from the food bank project funds, with a letter of thanks for their participation.

When the site RA receives the provider survey or any accompanying documentation the provider may have sent (e.g., printout of dates of service and diagnostic codes from their electronic health record), the RA must ensure that all PII must be removed before forwarding surveys to the Urban Institute. **This includes removing and shredding the provider face sheet with the personal data; making sure that the participant ID is included on the remaining survey pages but not associated with any PII (like name, date of birth, etc.) and blacking out the names or other identifying information from any attached records.**

In lieu of the shredded provider face sheet, the RA should subsequently complete an Urban Institute HCUS Cover Sheet for the purpose of sending the survey to the Urban Institute (see ***Appendix AX***). The cover sheet will ask for the participant ID, period of requested data, and date the survey was received, and will additionally include a space for any special notes or considerations about the survey that the RA wishes to communicate to the Urban Institute.

The RA should then make a copy of the survey / documentation with only the project identifier number displayed on each page and keep a copy for their files. At the end of every month, beginning with the month that provider surveys begin start arriving, the RA should assemble all completed provider surveys and send these in one mailing to the Urban Institute project contact via a verifiable, trackable delivery method, as described below. The UI project contact will provide the RA will email verification once the monthly survey package has been received and will verify the cost to the site of the mailing. Each quarter Urban Institute will generate a reimbursement check to the site for the costs of mailing the surveys.

Trackable Survey Delivery Methods

A trackable delivery method is defined as any mailing service that allows the sender to **confirm the receipt of your package** at the intended destination. Trackable delivery methods include:

- USPS Priority Mail with Delivery Confirmation
- USPS Priority Mail with Signature Confirmation
- USPS Express Mail (for overnight delivery requests) trackable delivery method
- Other trackable services such as UPS or FedEx that have delivery confirmation

Survey packages should be mailed to the following address:

Urban Institute
Attn: Justin Morgan
2100 M Street NW
Washington, DC 20037

See ***Appendix BA*** for detailed instructions when sending scanned, electronic HCUA data to the Urban Institute using encrypted USB devices.

7.7.8 Provider Packet Summary Table

The table below summarizes the different types of provider packets to be assembled at baseline and follow-up based upon the participant's enrollment in the intervention or control group and their reporting of a PCP:

	Intervention group	**Control group**
Existing PCP	At T0: *HCU Letter 1 - T0 Current Pt INT*, signed forms, information sheets At T6: HCUS, *HCU Letter 4 - T6 Current Pt*, signed forms At T12: HCUS, *HCU Letter 7 – T12* Current Pt, signed forms	At T0: *HCU Letter 3 - T0 Current Pt CONT*, signed forms, information sheets At T6: HCUS, *HCU Letter 4 - T6 Current Pt*, signed forms At T12: No provider communication
No existing PCP (at T0)	At T0: *HCU Letter 2 - T0 Newly Referred Pt INT*, signed forms, information sheets At T6: HCUS, *HCU Letter 4 - T6 Current Pt*, signed forms At T6: If participant still doesn't have PCP: *HCU Letter 5 - T6 Newly Referred Pt*, HCUS, signed forms, information sheets	At T0: No provider communication, but participant will be encouraged to see PCP At T6: If participant now has PCP: HCUS, *HCU Letter 4 - T6 Current Pt*, signed forms, information sheets At T6: If participant still doesn't have PCP: *HCU Letter 5 - T6 Newly Referred Pt*, HCUS, signed forms, information sheets

	At T12: HCUS, *HCU Letter 7 – T12 Current Pt*, signed forms At T12: If participant still doesn't have PCP: *HCU Letter 8 – T12 Newly Referred Pt*, HCUS, signed forms, information sheets	At T12: If participant now has a PCP, no provider communication At T12: If participant still doesn't have PCP, use "Screening and Referral Form" to complete active referral

8 Randomization

In randomized, controlled clinical trials, participants are assigned to a treatment group based upon a pre-determined randomization scheme developed by the study statistician (Courtney Lyles, UCSF). Randomization is used to reduce bias in assignment to treatment. In our case, clients will be randomized to receive the intervention immediately or after a 6-month delay.

- ***Randomization Plan:*** We will use a 6-block randomization scheme to ensure that the rolling enrollment process across multiple food bank sites will distribute participants equally into each study arm over time. This scheme will be generated using the website www.randomization.com for each food bank site separately, which will create a list of the order of randomization by sequential participant ID.
- ***Process Responsibilities:*** UCSF will be in charge of creating the randomization scheme for each site. This will include generating the randomization list, preparing sealed envelopes by participant ID, and mailing them to each site to open as recruitment progresses. In the event a participant ID is not used (e.g., a client withdraws consent upon learning what group he/she is randomized to), site study staff should note the participant ID number, destroy the number and envelope, and report the event and ID number to UCSF. UCSF staff will determine if any adjustments need to be made to maintain balance between assignments to intervention and control groups, and will instruct study staff accordingly.

Participant Identification Numbers by Study Site	
Site	**ID Numbers**
Houston	101-399
Detroit	401-699
Oakland	701-999

- ***Procedure for Randomizing a Participant:*** The research assistant at each food bank will enroll participants into the study. No staff member will know the randomly selected allocation of the participant until the HbA1c screening, informed consent process, and baseline survey is completed. At the conclusion of this baseline visit, the staff member will open the sealed envelope that corresponds to the participant ID number of the enrolled client and determine the arm assignment, either immediate intervention or waitlist intervention.
- ***Best Practices for Using Randomization Envelopes:*** Study staff that participate in enrollment activities should use the following best practices to ensure consistency in the randomization process, and to foster a satisfactory client experience.
    - Have all of your enrollment materials available when you are meeting with a new participant (e.g., consent forms, education materials, survey materials, and randomization envelopes)
    - It is especially important to have the participant's randomization envelope at your table (and in plain sight) during the entire enrollment process
    - Have only 1 randomization envelope at the table for each participant
        - In similar studies, some clients assigned to the waitlist control group have argued about their assignment, especially if the study staff leaves the area to retrieve the envelope after the consent and survey administration is completed (they may think staff selected the envelope based on their survey responses)
    - After the survey is completed, open the randomization envelope in front of the participant so they can observe the process

Randomization assignments must be documented in the Microsoft Access database.

9 Participant Timeline and Visit Schedule

A schedule of visits and evaluations that specifies what is to be done at each study phase and at each contact with the study participant is provided in ***Appendix E***.

9.1 Scope/Schema

This section outlines all in-person visits study participants have with the study staff. All dates listed below are relative to the day of enrollment for each participant (***see Appendix E***).

<u>Participants – Intervention Group</u>

- Day 1 (Month 1, Week 1) = T0 (by convention we identify the baseline visit as "T0")
    - Food bank client participates in diabetes screening (blood glucose and/or HbA1c testing) event at food pantry; study staff verifies that client meets eligibility requirements for study inclusion
    - Client agrees to participate in study and completes written consent form with study staff
    - Participant completes baseline survey with study staff (CASIC)
    - Participant randomly assigned to study intervention group by study staff

    - Participant receives 1st bi-monthly food box and passive education materials and receives information from food bank staff on group diabetes education classes
- Month 1, Week 2
    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
    - Participant attends Session 1 of group diabetes education class around this time
- Month 2, Week 1
    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
    - Participant attends Session 2 of group diabetes education class around this time
- Month 2, Week 2
    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 3, Week 1
    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
    - Participant attends monthly group drop-in diabetes education class around this time
- Month 3, Week 2 = T3
    - Participant completes 3-month HbA1c test with study staff
    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 4, Week 1
    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
    - Participant attends monthly group drop-in diabetes education class around this time
- Month 4, Week 2
    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 5, Week 1
    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
    - Participant attends monthly group drop-in diabetes education class around this time
- Month 5, Week 2
    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 6, Week 1 = T6
    - Participant completes 6-month HbA1c test with study staff
    - Participant completes T6 survey with study staff (CASIC)
    - Participant receives $30 gift card for completion of survey
    - Participant receives final bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
    - Participant attends monthly group drop-in diabetes education class
- Month 12 = T12

- Participant completes 12-month HbA1c test with study staff
- Participant completes T12 INT survey with study staff (CASIC)
- Participant receives $15 gift card for completion of survey
- Participant formally exits research study

Participants – Control Group

- Day 1 (Month 1, Week 1) = T0
  - Food bank client participates in diabetes screening (blood glucose and/or HbA1c testing) event at food pantry; study staff verifies that client meets eligibility requirements for study inclusion
  - Client agrees to participate in study and completes written consent form with study staff
  - Participant completes baseline survey with study staff (CASIC)
  - Participant randomly assigned to study control group by study staff
  - Participant receives $15 gift card for survey completion
- Month 1, Week 1 – Month 6, Week 2
  - Participant attends regular food pantry distributions and receives normal services per food pantry guidelines (does NOT receive diabetes food packages or education)
- Month 7, Week 1 = T6
  - Participant completes HbA1c test with study staff
  - Participant completes final survey with study staff (CASIC)
  - Participant receives $15 gift card for survey completion
  - Participant receives 1st bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 7, Week 2
  - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 8, Week 1
  - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 8, Week 2
  - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 9, Week 1
  - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 9, Week 2 = T9
  - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
  - Participant completes HbA1c test with study staff
- Month 10, Week 1
  - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 10, Week 2

    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 11, Week 1
    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 11, Week 2
    - Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
- Month 12, Week 1 = T12
    - Participant receives final bi-monthly food box, passive education materials, and 1-on-1 education
    - Participant completes T12 HbA1c test with study staff
    - Participant completes T12 CONT survey with study staff (CASIC)
    - Participant receives $15 gift card for completion of survey
    - Participant formally exits research study

9.2 Language capacity

Informed consent, survey administration, and diabetes education must be provided to all Spanish-speaking participants by bilingual study staff. Other study contact may be conducted with an interpreter.

9.3 Compensation

In order to realistically compensate participants for the time they spend participating in this research study and encourage full participation, participants will be reimbursed according to the following schedule:

- Intervention Group: $30 gift card on completion of T6 follow-up survey; $15 gift card on completion of T12 follow-up survey
- Wait-List Control Group: $15 gift card on completion of baseline survey; $15 gift card on completion of T6 follow-up survey; $15 gift card on completion of T12 follow-up survey

Compensation will be provided in the form of assorted store gift cards (e.g., Walmart, Target, etc., but **should *not* include major grocery stores**). Study staff will have participants sign the "Participant Compensation Receipt Form" (***Appendix AL***) upon receipt of a gift card.

9.3.1 Transportation Vouchers

If a study participant reports transportation costs as a major barrier to completing T6 and/or T12 follow-up activities, site staff can provide transportation vouchers (e.g., gas card, bus token, public transit pass, etc.) not to exceed $10 in value. Transportation vouchers may be offered to study participants up to two times (at T6 and T12), and **only** for completing study follow-up activities. Transportation vouchers should not be used to assist participants in attending other study or

intervention activities, nor should they be used in place of existing participant compensation (see section 9.3 above).

Site staff should enter any information (date, amount, type, and notes) for participants who do receive transportation vouchers in the study MS Access database.

9.4 Final Study/Early Discontinuation Evaluations

Participants should be actively followed through all study visits till the final visit, unless he or she withdraws informed consent.

It is important to note that if a study participant discontinues any part of the intervention but does NOT actively withdraw informed consent, he/she should still be followed to the end of the study. That is, participants in any component of the intervention (e.g. picking up food boxes, attending educational sessions) should still have HbA1c testing and complete follow-up survey as regularly scheduled.

10 Adverse Events and Safety Reporting

All adverse events should be reported to UCSF and Morgan Smith (FANO) **within 24 hours**. Study staff should complete an "Adverse Event" report (***Appendix AN***) for each incident that occurs, and enter the data into the MS Access database (if appropriate [involves a study participant] and when possible).

An adverse event can include study participants, or include study staff and food pantry clients that participate in any study activity (e.g. blood glucose screening event). An adverse event report should be completed for all events, with the one exception of low blood glucose screening results for pantry clients who do not report a history of diabetes. Food pantry clients with a blood glucose screening result < 70 mg/dL who do not report a history of diabetes do not require treatment by study staff, and the event does not need to be reported as an adverse event.

Adverse events which are reasonable to anticipate include:

1. Low blood glucose (hypoglycemia)
2. High blood glucose (hyperglycemia)
3. Reports of suicidality or homicidality
4. Reports of elder abuse or neglect
5. Reports of poor food quality
6. Study related injury

Each of these adverse events, along with steps on how to address, are discussed below.

10.1 Blood glucose < 70 mg/dL (Hypoglycemia)

- For the purposes of this study, hypoglycemia will only be addressed as an adverse event for clients who have a screening blood glucose result < 70 mg/dL, **and** who report a history of diabetes
    - Some clients with a diabetes history (especially if their diabetes is poorly controlled) may report hypoglycemic symptoms at a higher threshold (e.g., < 100 mg/dL); in these cases it is appropriate to treat the symptomatic client as if hypoglycemic and document as an adverse event
    - While some conditions exist that may cause hypoglycemia in people without diabetes, these condition are extremely rare
    - For clients who do **not** report a history of diabetes and have a screening blood glucose < 70mg/dL, it is not necessary for study staff to treat or report as an adverse event
- In clients reporting a diabetes history, any blood glucose lower than 70 mg/dL is considered low ("hypoglycemia") and requires immediate intervention to bring the glucose level up into a normal range.
- The GE100 Blood Glucose Monitor displays results between 20 and 600 mg/dL (if a test result is under 20 mg/dL, the meter will display "Lo" – in this event repeat test to confirm correct glucose level).
- A client / study participant with a blood glucose < 70 mg/dL should immediately be given an appropriate hypoglycemia snack (15 grams of quickly absorbing carbohydrate). Study staff should stock pre-packaged glucose tabs (e.g., "Dex4 Glucose Tablets") during all blood testing and DSME events to use in these cases (note: 1 Dex4 glucose tab contains approximately 4 grams of CHO; clients experiencing hypoglycemia should thus receive 4 tablets).
- Study staff should recheck the client's blood glucose 15 minutes after the client consumed the snack. If the client's blood glucose level has not increased to over 70 mg/dL, repeat dosing of glucose tablets / hypoglycemic snack and recheck glucose levels every 15 minutes until the glucose returns to a normal level.
- Caution client against eating / drinking too much fast-acting carbohydrate too quickly (e.g., more than 15 grams every 15 minutes) in order to prevent post-treatment hyperglycemia.
- Once the client is experiencing normoglycemia, a longer-acting complex carbohydrate snack (peanut butter and crackers, cheese and crackers, nut and raisin mix, yogurt and fruit, half a whole grain bagel with cream cheese, etc.) should be given to help maintain normal blood glucose levels if the next planned meal or snack is more than 1-2 hours away.
- Effort should also be made to identify the underlying cause of the hypoglycemia in order to help avoid future episodes.
- Refer client as needed to PCP or local community health center for further evaluation and treatment management.
- These events should be reported in the MS Access database for all study participants.

10.2 Blood glucose > 240 mg/dL, or HbA1c > 9% (Hyperglycemia)

- The GE100 Blood Glucose Monitor displays results between 20 and 600 mg/dL (if a test result is over 600 mg/dL, the meter will display "Hi" – in this event, repeat test to confirm glucose level; perform QC check on meter as necessary).
- The A1C+Now system displays test results up to 12.9% (for results greater than 12.9%, the device will display > 13%).
- If a participant (or client not yet enrolled in the study) has a blood glucose result between 240 – 399 md/dL, or a HbA1c result between 9% - 12.9%, study staff should refer the client back to their primary care provider for evaluation. If the client or participant does not have a primary care provider, study staff should make a new patient referral to a partner clinic following study protocols. Partner clinic agreements contain recommended timeframes for contacting referred patients with these results (within 1 week) to schedule a patient appointment to occur within 1 month from receiving the referral.
    - Hyperglycemia in the absence of symptoms <u>does not require action by study staff or reporting as an adverse event</u>; all testing results should be recorded and saved in the MS Access database.
- If a participant (or client not yet enrolled in the study) has a blood sugar greater than 400 mg/dL (or confirmed "Hi" reading on the glucometer), or a HbA1c result > 13%, study staff should refer the client back to their primary care provider and/or facilitate an appointment being made. If the client or participant does not have a primary care provider, study staff should make a new patient referral to a partner clinic following study protocols.
    - Food bank – clinic partnership agreements outline that clinics will attempt to contact referred clients with these results <u>within 24 hours</u>, and will schedule appointments for clients experiencing severe hyperglycemia <u>within 72 hours</u> of receiving a referral from the food bank.
    - All clients with severely elevated blood glucose results should also be encouraged by study staff to initiate contact with their PCP or nearest community clinic.
    - Hyperglycemia in the absence of symptoms of study staff action <u>does not require reporting as an adverse event</u>; all testing results should be recorded and saved in the MS Access database.
- If necessary, clients can also be provided with information about local emergency medical care (local Emergency Rooms and hospitals) if the client prefers or needs immediate medical attention.
- If necessary and/or at the client's request, study staff can also call "911" to initiate the local emergency response system (EMS) to have the client evaluated by health care professionals onsite. <u>Severe hyperglycemia accompanied by any of the following symptoms potentially constitutes a medical emergency and warrants activation of the EMS: nausea and/or vomiting, chest pain, abdominal pain, or altered mental status.</u>
- Only hyperglycemia events where clients report symptoms and study staff respond/act (e.g. activating local EMS) are **<u>required to be reported as an adverse event</u>**.
    - Complete an Adverse Event Report and contact Morgan Smith within 24 hours of event.
    - These events should be reported in the MS Access database for all study participants.

10.3 Reports of severe depression, suicidality, or homicidality

The participant surveys contain multiple items asking about participant activity, behavior, and health (including a standard 8-question section used to monitor the severity of depression). It is possible that during survey administration (or during other project-related activities [e.g., DSME group classes, 1-on-1 encounters, etc.)], participants will reveal symptoms of major depression that could include disclosure of suicidal / homicidal thoughts, plans, and risks. While food bank and project staff may not have expertise in the treatment of mental health emergencies, it is critical that project staff is skilled in identifying potential risks and responding appropriately to protect participants' and others' well-being. This section describes how to handle possible mental health emergencies identified during study activities.

All food bank sites and partner pantries should maintain a list of local mental health resources for staff reference and to be provided to any participant who suggests severe depression and/or depression with suicidal or homicidal thoughts.

Suicidal Ideation Protocol

Suicidal ideation (SI) refers to a person's thoughts about or a preoccupation with suicide. The range of suicidal ideation varies greatly from fleeting thoughts, to extensive thoughts, to detailed planning, role playing (e.g., standing on a chair with a noose), and incomplete attempts. Study staff should be attentive to study participants who may exhibit any variation of SI.

If during a study activity a participant reports suicide ideation, study staff should immediately ask this question to ascertain intent:

- "I am so sorry you feel this way. For your safety, I have to ask a difficult question: do you have a plan to act on these thoughts to harm yourself?"

- If a participant answers "no" (**no intent**)
    - Staff should respond: "I am so sorry you feel this way, but I am glad you do not have plans to harm yourself. If you remember from the consent form, having thoughts of harming yourself, even if you won't act on them, is a reason that I need to contact Dr. Seligman (the doctor in charge of this study), your doctor or your doctor's team. We do this to make sure you are safe. Before we continue with the survey / activity, please give me a minute to speak with a doctor who may be able to help you."
    - Staff should contact participant's primary care provider or provider's clinic to have PCP assess participant over the phone.
    - If participant does not have a PCP (or does not know the name of the provider or of their health care clinic), study staff should contact Dr. Hilary Seligman at 415-443-4171 (pager) or on her cell at 415-336-4460 to report incident and have her assess the participant over the phone.
        - If participant's PCP, other clinic provider, or Dr. Seligman is able to speak with the client and confirms the client has no intent, proceed with survey. Document event in MS Access database.

        - If participant's provider, clinic, or Dr. Seligman is unable to speak with client, staff should contact local community health clinic or local mental health resource to have other trained professional assess participant. If medical/mental health professional is able to speak with the client and confirms the client has no intent, proceed with survey. Document event in MS Access database.
    - If the contacted medical professional identifies intent to harm, follow any physician instructions, stop study activity, do not leave participant alone, and call 911 to activate the local emergency response system (see below).
    - Page Dr. Hilary Seligman at 415-443-4171 or on her cell at 415-336-4460 to report incident.
    - Document event in detail; include report in MS Access database for study participants.

- If a participant answers "yes" (**has intent**)
    - Staff should respond: "I am so sorry you are feeling this way, and I am very concerned you might harm yourself. If you remember from the consent form, if you report you may harm yourself I will need to contact your doctor or other medical professional. We want to make sure you get the help you need to keep you safe. I apologize, but I need to stop this survey/activity now. Please give me a moment to speak with a doctor who can help you."
    - Stop survey administration or study activity immediately.
    - Do NOT leave participant alone; ask participant if another study staff person or food bank staff person can sit with them for a few minutes.
    - Call 911 to report a mental health emergency; inform operator of situation, your location, and the participant's disclosure of SI with intent.
    - Stay with client until emergency medical response arrives to evaluate participant
    - Page Dr. Hilary Seligman at 415-443-4171 or on her cell at 415-336-4460 to report incident.
    - Document event in detail; include report in MS Access database for study participants.

The primary investigator must be made aware of any emergencies involving study participants as soon as possible.

10.4 Reports of Elder Abuse or Neglect

- Employ standard site-specific protocols or page Dr. Hilary Seligman at 415-443-4171, or call on her cell at 415-336-4460.
- If unable to reach Dr. Seligman, study staff should call "911" to report situation and activate the emergency response system.
- Document event in detail; include report in MS Access database for study participants.

The primary investigator must be made aware of any emergencies involving study participants as soon as possible.

10.5 Reports of Poor Food Quality

All food banks participating in the FAITH-DM study are members of the Feeding America network and as such, must meet certain minimal compliance standards with respect to food safety and food distribution. Food banks are audited periodically by the Feeding America National Office and may also undergo periodic auditing by external entities. Food banks are required, in turn, to periodically monitor practices of their agencies.

Feeding America maintains a timely distribution of food recall information to all food sourcing personnel in the network. In addition, Feeding America provides education to all food banks on current guidance with respect to food industry use of dates for use by dates, best by dates and other practices. These practices will be reviewed with the study sites and the quality of food distributed will also be observed during project site visits.

Key information to be reviewed includes:

- Packing or manufacturing date
    - Used by manufacturers for tracking and recalls
    - Not an expiration date
- Sell-by date
    - This is a quality date
    - It tells the store how long to display the product for sale
    - The product is still safe to eat past this date
- Best-by or best if used by date
    - This is a quality date
    - It tells clients the date by which the product should be eaten for best flavor or quality
- Use-by or expiration date
    - This is the last date recommended for the product while at peak quality.
    - Most products (if not temperature controlled for safety - TCS) are still safe to eat past this date
    - Cut product (TCS foods) must be kept 41˚F or below to control potential bacterial growth
    - Any other type of produce can be kept at room temperature or refrigerated; refrigeration provides extended shelf life but may affect the quality of the produce
    - Mold on produce is a spoilage indicator; mold will not give someone a food borne illness but product should be disposed of if mold is observed

In the event that any participant expresses a concern about the quality of food received, the site coordinator should determine if the concern is related to any potential food safety issues and if so, notify the food bank food sourcing management immediately so that appropriate follow-up measures can be taken. If a participant reports that he or she believes that food received through the program may have made them ill, food bank management should be notified immediately, so that they can implement appropriate procedures, and an adverse event form must be completed. Morgan Smith, FANO project manager, must be notified within 24 hours to determine appropriate follow-up with the participant.

10.6 Study Related Injuries

Any study related injury is considered an adverse event and must be reported. Study related injuries may include:

- Sharps / needle stick injury and/or blood exposure
- Fainting and related injuries (e.g., falls)
- Excessive bleeding

In the event of a study related injury, staff should immediately respond to address the incident.

10.6.1 Sharps Injuries and Blood Exposures

(Adapted from CDC Emergency Needlestick Information, http://www.cdc.gov/niosh/topics/bbp/emergnedl.html):

For sharps / needle stick injuries, and/or blood exposure, study staff should immediately:

1. Wash needlesticks and cuts with soap and water
2. Flush splashes to the nose, mouth, or skin with water
3. Irrigate eyes with clean water, saline, or sterile irrigants
4. Report the incident to site supervisor
5. Seek medical treatment
    a. Injured staff and/or client may need to seek medical care with local urgent or emergency care for treatment and evaluation for post-exposure prophylaxis
    b. Contact Clinician Consultation Center (UCSF, http://nccc.ucsf.edu/) at 1-888-448-4911 (9 a.m. – 2 a.m. EST, seven days a week) for clinical guidance on obtaining Post-Exposure Prophylaxis
6. Complete Adverse Event Reporting Form (***Appendix AN***), enter event details into MS Access database (if event includes a study participant), and notify Morgan Smith (FANO) within 24 hours of event.

10.6.2 Fainting and Related Injuries

While unlikely, it is possible that a client or staff could faint during a screening activity. A person experiencing fainting episodes can be triggered by factors or situations such as hypoglycemia, low blood pressure, excessive pain, dehydration, standing for long periods of time, emotional distress and anxiety.

In the event a client or staff faints or is injured during a study activity, study staff should:

1. If possible, assist the client to sit down or lie down on the floor *before* fainting in order to prevent a fall and related injuries.
2. Make sure the client is breathing; sudden cardiac arrest may look similar to fainting

a. If client is not breathing, or not breathing normally, call 911 and initiate CPR (if appropriate and staff is trained to do so)
3. If necessary (e.g., client has no history of fainting, client was injured during fall, and/or client does not recover consciousness after 2-3 minutes), call 911 to activate local emergency medical system
4. Complete Adverse Event Reporting Form (***Appendix AN***), enter event details into MS Access database (if event includes a study participant), and notify Morgan Smith (FANO) within 24 hours of event

10.6.3 Excessive Bleeding

Some clients who participate in a blood screening activity may have a reduced capacity for normal blood clotting (which can be caused by some medications, an underlying health condition, etc.). While excessive bleeding is unlikely to occur as a result of a screening activity, it is important that screening staff are aware of how to identify and respond to a case of excessive bleeding with a client.

1. Apply direct pressure at puncture site (site staff should follow universal precautions, wear gloves, and utilize barrier protections) using available supplies (gauze pads, cotton balls, etc.)
2. Elevate puncture site
3. If bleeding is significant, does not stop, or gets worse, call 911 to activate the emergency response system
4. Complete Adverse Event Reporting Form (***Appendix AN***), enter event details into MS Access database (if event includes a study participant), and notify Morgan Smith (FANO) within 24 hours of event

10.6.4 Infection

If a food pantry client or study participant reports an infection that resulted from their participation in a study related screening event, staff should complete an Adverse Event Reporting Form (***Appendix AN***), enter event details into MS Access database (if event includes a study participant), and notify Morgan Smith (FANO) within 24 hours of report.

11 Study Compliance

Clinical trials are expensive endeavors and every effort should be made to maximize adherence to the protocol and minimize non-compliance. Comprehensive training on the study protocol, early review of the data, and routine communications with the sites help to minimize protocol deviations. However, protocol deviations do occur, especially in trials such as this one conducted n community settings. There is therefore a mechanism in place to track protocol deviations and procedures and to notify appropriate parties about their occurrence.

Protocol deviations include, but are not limited to the following:

- Randomization of an ineligible participant

- Failure to obtain Informed Consent
- Enrollment of a participant into another diabetes study occurring at the same time
- Wrong treatment administered to participant, such as a participant who is randomized to the waitlist control group and instead receives the intervention
- Outcome measurement not performed, such as follow-up HbA1c or follow-up survey

All protocol deviations should be reported to Morgan Smith (FANO) within 48 hours and officially recorded on the Protocol Deviation Log (***Appendix F***). Morgan Smith will discuss these deviations with UCSF within 48 hours so that corrective actions may be taken if necessary. While there are rational and expected reasons for occasional deviations, a site with continuous problems is at risk of losing its funding.

12 Data Collection and Study Forms

All survey data collection will be done within the CASIC system, and all study tracking will take place within Microsoft Access databases. Copies of all study forms will be maintained in the MOP for reference. See ***Appendix D*** for Electronic Forms completed at each study visit.

FAITH-DM is a complex study requiring multiple points of data collection with study participants. Ensuring that all data are collected and properly recorded is critical to study staff being able to accurately analyze results. Research assistants and site staff can use the document “Data Collection Best Practices” (***Appendix AT***) as a guide to consistently maintain quality data collection.

12.1 Source Documentation

A source document is any document on which study data are initially recorded.

Source documents for this study include:

- Screening Log
- CASIC forms
- Healthcare utilization abstraction forms
- Informed consent, HIPAA, and medical records release forms
- Participant compensation receipts
- MS Access database

12.2 Participant Binder

This section describes how participant data are maintained in the study. All essential study documents must be retained at each food bank in a Participant Binder(s) and include the following:

- Signed consent forms
- Paper tracking forms (if any)
- Data correction forms (if any)

12.3 General Instructions for Completing Forms

All data recorded on study forms must be verifiable in the source documents maintained by the food banks. In addition to the Informed Consent, HIPAA, and medical records release forms, additional formats include:

1. CASIC (for survey administration)
2. MS Access database

12.3.1 Best practices for completing paper forms

- ***Header:*** Complete the header information on **EVERY** page, including pages for which no study data are recorded.
- ***Participant ID:*** The participant ID must be recorded on **EVERY** page, including pages for which no study data are recorded. Participants must NOT be identified by name on any study document. Use only the participant ID number.
- ***Abbreviations:*** Use of abbreviations not specifically noted in the instructions for completing the forms can be problematic and should be held to a minimum.
- ***Correcting errors***: If an error has been made on the study forms, place a ***single*** line through the erroneous entry and record the date and your initials. Indicate the correct response.
- ***Skipping items***: Do not skip any items. Some items may carry "Unknown" or "Not Applicable" response choices which should be selected when necessary.
- ***Incomplete data***: Data may not be available to complete the form for various reasons. Circle the item for which information is not available and indicate the reason near the appropriate field:
    - If an evaluation was not done, write ND and provide a reason.
    - If the information is not available, but the evaluation was done, write NAV.
    - ***Note: Only in rare circumstances, as in the case of lost documentation****, should NAV be recorded on the form. Every effort should be made to obtain the information requested.*
    - If an evaluation is not applicable, write NA.
    - ***Incomplete or Illegible forms***: Incomplete forms that do not have adequate explanation (as described above) compromise the integrity of the entire study. Errors, such as incomplete or illegible forms, are problems that require time and energy to resolve. The use of CASIC helps to prevent these problems.

Incomplete or illegible paper forms:

- If an entire page of the form cannot be completed (e.g., no parts have any responses), and it is unlikely that it will be completed, draw a diagonal line through the form and write NOT DONE, NOT AVAILABLE or NOT APPLICABLE, as appropriate
- The header information must be completed even though no data are recorded on the form
- Do not leave forms incomplete or unused without explanation. Include the explanation on the form itself

12.3.2 CASIC Instructions

CASIC data collection software will be used to record all data from participant baseline and follow-up surveys. CASIC is a secure web-based data collection software hosted on servers at UCSF. To access CASIC via the internet, go to https://faithdm.ucsf.edu/CASIC/ and sign in using your secure log-in credentials. When internet access is not reliably available, site laptops will be equipped with CASIC Remote. Instructions on how to use CASIC and CASIC Remote follow.

Note: because CASIC is accessible in both online and offline formats for use in completing participant surveys, we will never use paper versions of the participant surveys. Using CASIC exclusively for survey completion will help to maintain consistent, quality data collection, and reduce potential survey administration problems inherent with the use of paper surveys (e.g., correct implementation of the complex skip patterns used throughout the surveys).

Instructions for using CASIC

1. Go to https://faithdm.ucsf.edu/CASIC/ and log-in
2. Select "FAITH-DM" study
3. From the drop-down menu, select the assessment you wish to administer, the food bank from which the participant was recruited, and the participant ID (from randomization envelop)
4. Begin assessment, being sure to double check accuracy of all information entered
5. Whenever possible, complete survey in single session

Instructions for using CASIC Remote

1. Open CASIC remote from the desktop while internet connection is still available and select "sync" in order to ensure use of the most up-to-date survey (see **section 12.3.2**)
2. In the field, open CASIC remote, log in, and select "Start Assessment"
3. From the drop-down menu, select the assessment you wish to administer, the food bank from which the participant was recruited, and the participant ID
4. Begin assessment, being sure to double check accuracy of all information entered
5. Whenever possible, complete survey in single session
6. When internet connection is reestablished at the end of each day during which data collection took place, click "sync" again to upload all data to the server

For more detailed information regarding CASIC, visit www.westportal.com.

All survey data should be correctly entered into CASIC within **14 days** from survey initiation. Contact UCSF Project Coordinator (Sophie Rosenmoss) with any CASIC-related questions or issues.

12.3.3 CASIC Remote Syncing Process

Before and after data collection at a field site that may not have reliable internet access, it is best to sync the data on CASIC Remote with the host. Doing so will reconcile all patient survey information so that anything that has been collected using either CASIC online or CASIC Remote will be reflected on both platforms. To sync the data, do the following:

1. Make sure you have adequate internet connection
2. Log onto CASIC Remote using Mozilla Firefox at localhost/CASICRemote/Default.aspx
3. Make sure that the URL in the CASIC Host box is https://faithdm.ucsf.edu/CASICHost/Services.asmx
4. Click “Test”
5. Click “Save” or “Continue”
6. Under “Host services” on the left navigation panel, click on “Host URL”
7. Click “Synchronize subject data” in the navigation panel
8. Click “download” to download information from CASIC online and “upload” if you have collected data offline on CASIC Remote in the field and would like to upload to CASIC online

12.3.4 Downloading Updated Instruments in CASIC Remote

Below are the step-by-step instructions for downloading updated instruments in CASIC remote. Note: If you wanted to just updated a single or a few instruments you do not have to do the first part of step 3 (deleting the study). You would want to keep the study and only delete the instruments in question. Contact Sophie Rosenmoss if you have any questions while trying to do this.

1. Download the updated survey to CASIC Remote
    a. Step one: log onto CASIC Remote using Mozilla Firefox at localhost/CASICRemote/Default.aspx
    b. Step two: Under “Host services” on the left navigation panel, click on “Host URL”
        i. Make sure that the URL in the CASIC Host box is https://faithdm.ucsf.edu/CASICHost/Services.asmx
        ii. Click test
        iii. Click save (or continue)
        iv. You must be connected to the internet to do this
    c. Step three: Click “Study setup” under Host Services.
        i. Scroll down to Available instruments, delete list of instruments (attached here) from computer
    d. Step four: On the same page under “Study setup” next to FAITH DM, click “Setup on this computer”
    e. Step five: Synchronize subject data by clicking “Synchronize subject data” in the navigation panel then clicking “download” to download information from CASIC online and “upload” if you have collected data offline on CASIC Remote in the field and would like to upload to CASIC online. You will do this regularly before and after going to the field for data collection offline.

12.3.5 Paper survey instructions

All participant surveys will be completed electronically using either CASIC online or CASIC remote. Paper surveys will not be used with participants in this study.

12.3.6 MS Access database instructions

This study uses Microsoft Access databases to store tracking information. Specifically, the Microsoft Access database will have the following forms and sub-forms:

- Screening form (for all individuals screened): Screening will be completed on paper forms; study staff is responsible for entering data on each individual screened from paper forms into Access databases at the end of each day.
- Baseline data and participant status form (for all individuals enrolled): This form is completed after initial enrollment of a study participant and is the only form in which study staff can edit participant status.
- Contacts Form: This form will contain all contact information for the participant
- PCP Contact Form: This form will contain all the contact information for a participant's PCP
- Study Data Forms
    - HbA1c form: Record all HbA1c values here
    - Food boxes form: Record all data on participant food box pick-up here
    - Education sessions form: Record all data on participant class attendance here
    - Primary care contact form: Record all data on contact study staff has with primary care here
- Study Data – Browse Only: When study staff need to retrieve, but not edit, data, use this form
- Reports: Study staff use this form to run reports on collected data
- Utilities: This option is used to make changes to the database, such as adding a new interviewer
- Close database: This form safely closes the database

Microsoft Access tracking forms can be used offline and uploaded to the FAITH-DM folder using VPN at the end of each day. It is important that all data is entered each day and securely saved and uploaded to the FATIH-DM folder using the instructions outlines in section 13.1.1.

13 Data Management

It is the food banks' responsibility to ensure that all forms are complete, intact, and transmitted to the Coordinating Center, as appropriate:

13.1 Storage and Transmission of Electronic Files

This section addresses use of the MS Access and CASIC programs for storage and transmission of study data. The UCSF Project Manager will monitor uploads weekly and will contact sites as needed for troubleshooting and quality control / process improvement.

13.1.1 Backing up Microsoft Access Databases to UCSF server

All tracking forms are housed on site-specific Microsoft Access (MA) databases. Each site will have one computer that has the MA database. To prevent data loss, sites will employ the following back-up instructions daily and/or weekly. Though the MA database stored locally on the laptop hard drive will be the "original copy", study staff must upload a copy of the MA database to the UCSF servers (weekly, at a minimum). Upload the latest version of the MA database to UCSF's servers using the following process:

Uploading Access information to UCSF server

After you are finished collecting data for the day in Access following these steps:

1. Close the Access database
2. Log in to UCSF Pulse client using your UCSF credentials (the "Pulse" client uses Secure File Transfer Protocol [SFTP] for secure file transfer capabilities between networked hosts)
3. Open your "Public Documents" folder in one window (this is found under Documents → My Documents → Public Documents)
    a. In this folder you will see the access database you created today. To confirm it's the correct one, the date modified field to the right of the title should read with today's date (or whenever you last entered info into it)
4. In a separate window, open the FAITH DM Site Data folder, then open your specific site folder (Houston, Detroit, or Oakland)
    a. You can do this by right clicking on the FAITH DM Site Data folder and selecting "open in new window"
5. Drag the most recent back end file from the Public Docs folder to the FAITH DM Site Data/Site specific folder
6. Right click on the new file in UCSF's Site Data folder and rename with today's date

Alternatively, you can do all of steps 1-3 and instead right click on the most recent Access file in your public documents folder, select "copy" and then open the FAITHDM Site Data/site folder, right click in the folder, and select "paste". Then rename the file with today's date.

13.1.2 CASIC Online

1. Go to https://faithdm.ucsf.edu/CASIC/
2. Enter User ID and password
3. Select FAITH-DM Study
4. Select study location (food bank name)
5. Select assessment
6. Start survey
7. Questions save every time you click "next"

8. Be sure to click “close window” when done

13.1.3 CASIC Remote

1. Before leaving for field site that may not have internet access, open CASIC Remote and click “sync” to ensure you have the most up-to-date survey and participant list (see **section 12.3.2**)
2. Open CASIC Remote from desktop
3. Log in using User ID and password
4. Select FAITH-DM Study
5. Select study location (food bank name)
6. Select assessment
7. Start survey
8. be sure to click “close window” when done
9. When internet connection is reestablished, upload study data by clicking “sync”

13.2 Administrative Forms

Administrative forms provide documentation of study processes and assist with study operations. Administrative forms for this study include:

- Facsimile Transmittal Sheet - serves as a cover page for all faxes, and must include HIPAA confidentiality language (***Appendix AB***)
- Screening Log - a record of all individuals screened for participation in the study. It should be arranged chronologically and be kept up-to-date at all times (***Appendix B***).
- Participant Identification Code List – a record of the participant's name, ID number, randomization arm, and study entry and exit dates. Due to the confidential nature of this information, it should be maintained only on the encrypted computer, kept in the MS Access Database, apart from other forms and data files at the food bank. The information contained in the list must be maintained by the food bank until 3 years after completion of the study and/or return of the study computer to UCSF.
- Protocol Deviation Log – used to document deviations from the protocol as they are identified by participant, or study staff. This log (***Appendix F***) will be kept and maintained centrally by FANO (Morgan Smith).

13.3 Retention of Study Documentation

All study documents should be retained and securely stored for **3 years** following study completion (study completion ends after the end of last data analysis). All study related electronic documents and data sets will be securely stored for **5 years** following study completion, and then deleted.

Best practices for secure document storage:

- Study documents with participant identifying information should be stored separately from documents containing general information or de-identified participant data

    - For example, study consent forms and participant baseline forms contain identifying information and should be stored separately from screening logs
- When possible, use permanent markers to black out participant identifying information (e.g., name, DOB) on forms that also contain a participant ID #
- Keep documents organized in 3-ring binders with appropriate tabs
    - Consent forms and baseline forms can be stored by participant last name
    - Forms with de-identified data should be filed in numerical order by participant ID #
- Binders and documents with participant data should be stored in drawers or cabinets that can be secured with a locking mechanism
    - Only FAITH-DM study staff and approved site staff should have access to these storage areas

Once the documentation retention period has passed, all study documents should be destroyed via:

- Document shredding
- Release of documents to secure document disposal service

13.3.1 HCUA Data Stored at Food Bank Sites

As outlined in **section 7.7**, the research assistants (RA) at each site are responsible for requesting, obtaining, storing, and transmitting all HCUA data to the Urban Institute (UI). Transmission of HCUA data (either via mailings of photocopied surveys and records, or via electronic file transfer using secure flash drives) will ultimately result in the existence of two sets of HCUA data (local copies stored at each food bank, and a master copy located at the Urban Institute).

In order to maintain data security, the research assistants at each food bank will destroy all local HCUA data at the conclusion of data collection (projected to be early October, 2017). Prior to destruction of HCUA data, each RA will confirm with Urban Institute project staff that local data collection is complete, and that UI has received all mailings and packages sent by the site RA that include any HCUA data (e.g., completed HCU provider surveys, de-identified medical records, etc.).

Once UI confirms receipt of all HCUA data from a site, the RA will commence with destruction of local HCUA data copies via:

- Document shredding
- Release of documents to secure document disposal service
- Permanent deletion of all electronic files and electronic folders containing any HCUA data

13.4 Data Analysis Plan

13.4.1 Sample size estimation

We used the sampsi program in Stata to calculate the necessary sample size to detect a 0.4% decrease in HbA1c with 90% power. Using our preliminary data from the pilot phase of this project, we projected that the average A1c would decrease from 9.5% to 9.1% with a correlation between the

2 observations per individual at 0.51. Given these parameters, we determined that 300 individuals were needed in both the intervention and waitlist arms of this RCT. In order to allow for 20% attrition from baseline to follow-up, we increased the final recruitment goal to 720 individuals total (240 per site).

sampsi 9.5 9.1, sd1(1.6) sd2(1.9) method(ancova) pre(1) post(1) r1(.51) power(0.9)

Estimated sample size for two samples with repeated measures
Assumptions:

```
                                    alpha =    0.0500  (two-sided)
                                    power =    0.9000
                                       m1 =       9.5
                                       m2 =       9.1
                                      sd1 =       1.6
                                      sd2 =       1.9
                                    n2/n1 =      1.00
          number of follow-up measurements =         1
           number of baseline measurements =         1
   correlation between baseline & follow-up =     0.510

Method: ANCOVA
relative efficiency =    1.352
    adjustment to sd =    0.860
        adjusted sd1 =    1.376
        adjusted sd2 =    1.634

Estimated required sample sizes:
                  n1 =       300
                  n2 =       300
```

13.4.2 Data sources

The primary sources of data for this analysis will be from the point-of-care HbA1c testing done on site at the food pantries and the participant survey data, both at baseline and follow-up. In our assumptions, rolling enrollment lasted for approximately 6 months, and the length of follow-up between baseline and follow-up was also approximately 6 months (4-9 months overall).

13.4.3 Hypotheses

We are testing several hypotheses in this study.

1. The primary hypotheses which we are powered to examine is a significant improvement in HbA1c over a 6-month timeframe.
    a. For all of these outcomes, we also hypothesize that the effect sizes will be largest among those who completed a minimum amount of exposure to all intervention components. A priori, we defined engagement in the intervention components as: picking up 80% of diabetes-appropriate food boxes, attending the 2 required diabetes education classes, and having at least 1 primary care visit over the 6-month follow-up period.
    b. We also hypothesized that the intervention would have the largest effect on those in the poorest A1c control (>9%) and those with very low food security status at baseline.

2. Secondary hypotheses: The secondary outcomes of interest are improvements in fruit/vegetable intake, diabetes distress, self-reports of severe hypoglycemic events, depressive symptoms, medication adherence, tradeoffs between affording food vs medication/supplies, food security status, and food stability.

3. Healthcare utilization hypotheses/analyses will be covered in a separate analysis plan

13.4.4 Statistical analyses

For all the outcomes specified above, we will determine significant improvements using an ANCOVA specification:

$$Y_{i,t=1} = \beta_0 + \beta_1 T_i + \pi Y_{i,t=0} + \varepsilon_i$$

Where $Y_{i,t=1}$ is the given outcome variable measured post-treatment, $Y_{i,t=0}$ is its baseline value, T_i is an indicator for being assigned to treatment, and ε is the error term. Since randomization is at the individual-level, HuberWhite standard errors will be used. β_1 will provide the intent-to-treat effect.

Loss to follow-up

We intend to collect follow-up data on at least 80% of participants. We will conduct a formal missingness investigation to determine if the attrition rate differed between intervention and waitlist groups. If treatment status is found not to significantly affect attrition at the 5 percent significance level, then all estimation will proceed without any adjustment for attrition. If attrition is found to be related to treatment status, we postulate that attrition will be higher for the control group, and will employ Lee bounds to obtain bounds on our treatment estimates which are robust to this attrition (https://ideas.repec.org/c/boc/bocode/s457477.html). Multiple imputation for missing outcome data will also be explored as sensitivity analyses (http://aje.oxfordjournals.org/content/175/3/210.full).

Per protocol/exposure to treatment

Among those with complete baseline and follow-up A1c ascertainment, we will also examine the influence of the amount of exposure to the program. Specifically, we will determine whether the

participants who met our criteria for being “engaged” in the program (overall and by specific intervention component) had larger effects than those who were less engaged.

In this analysis, because the randomization benefits will be lost, we will adjust for other covariates in our model that we hypothesize to influence A1c and self-management improvements: age, gender, race/ethnicity, educational attainment, language, and site/location.

Subgroup analyses

While we are randomizing within sites, we also plan to conduct subgroup sensitivity analyses by both adjusting for site and examining changes within site to determine differential effectiveness by location. Site-specific differences will be shared with the food banks, but only reported publicly in manuscripts if found to be significantly different.

Other planned subgroup analyses (as specified in our hypotheses) are by baseline glycemic control (>9%) and food security status.

13.5 Health Care Utilization Data Analysis Plan

Overview of analysis

The health care utilization analysis is designed to explore the effects of the intervention on the use of health care services by the study participant, specifically primary care visits, emergency room/department visits and inpatient utilization. The pilot project that preceded the development of this randomized controlled trial did not collect health care utilization data; therefore, this aspect of the analysis will provide new information on whether the intervention affects health care utilization. There is an opportunity to collect both self-reported health care utilization data from study participants before (T0) and at the conclusion of the six-month intervention or waitlist period (T6), as well as six months following completion of the intervention or waitlist period (T12). A survey will also be sent to primary care providers for records of selected services for both the intervention and waitlist groups after the initial six month enrollment period (T6). This survey will request data for the six month period prior to enrollment, as well as the six months the study participant was enrolled in either the intervention or waitlist group. At T12, the same survey will be sent to providers caring for original intervention study participants and will request data for the period between T6 and T12. Providers caring for individuals in the original waitlist group will not be surveyed at T12.

The participant and provider data can provide insight on whether the intervention has an effect on the utilization of selected health care services, and by using geographically adjusted cost averages for the associated services, can provide some general information on potential cost implications for those utilization patterns. Other data that can inform the analysis, such as participant self-reported health status, health care coverage status and reports of missed time at school or work will also be included in the analysis.

13.5.1 Participant and provider data collection process

Self-reported data on the use of selected health care services will be collected from all participants in the survey administered at enrollment (T0), after six months in the study (T6), and again six months after completion of the initial intervention or waitlist period (T12) (see **section 7.6** for a general description). In each survey, the study participant will be asked to report on health care utilization in the prior six months. At enrollment (T0), the participant will also be asked to provide consent for the release of medical record information from their current primary care provider during the enrollment process.

If the participant reports he or she does not currently have a primary care provider, the participant will be given an active referral if part of the treatment group and offered a provider resource sheet if part of the waitlist control group.

After the participant has been in the study for six months, the site RA will send a health care utilization survey to the primary care provider the participant identifies at enrollment. The site RA will also ask if there has been any change in primary care provider during the prior six months and will send additional surveys as appropriate. The provider survey will be accompanied by (see ***Appendix Y***) a brief explanation of the survey and contact information for any questions or assistance needed in completing the request, as well as a copy of the signed HIPAA and medical records release authorization.

The T6 provider survey will query dates of service for primary care visits made in the past 12 months for each participant (the six month period prior to enrollment, and the following six month period during the intervention or waitlist window), as well as the primary associated CPT codes and up to four ICD-9/ICD-10 diagnosis codes. The provider survey is not restricted to services provided for diabetes or diabetes complications since it may be difficult to discern whether a particular condition is associated with or affected by diabetes. The provider survey will also ask for dates of any scheduled but missed appointments. Providers will be asked to list the dates of service, primary procedure codes and diagnosis codes for any emergency department visits or inpatient hospital admissions for which they have records. Although the records of these services may be less complete than those delivered directly by the provider practice/clinic, it is standard practice for hospitals to forward discharge summaries if a provider is identified at the time of admission and we will obtain this information whenever possible.

At T12, provider surveys will be sent only to those providers who have cared for a study participant originally enrolled in the intervention group. The information collected will be identical to that requested at T6, but will focus on utilization during the intervening six-month period. Providers who cared for a study participant originally enrolled in the waitlist group will not receive a survey for that participant.

See **section 7.7** for additional details on the processes for communicating with providers and obtaining completed health care utilization surveys.

13.5.2 Health care utilization indicators and hypotheses

One of the four arms of the intervention is the active referral to a primary care provider if the participant does not have one at the time of enrollment. In addition, the self-management support (SMS) activities in the intervention are designed to reinforce engagement of the participant with the primary care provider as a component of their diabetes management. Thus, our primary indicator will be change in the reported utilization of primary care services, as assessed by self-reported data and provider reports where available.

Our hypothesis is that the intervention participants will have increased engagement with their primary care provider when compared to the control group, and when compared to their level of engagement prior to the intervention. Because this particular model is unique in its use of food pantries as a point of outreach and support and its incorporation of a diabetes-focused food security intervention, there is no prior literature that directly informs our hypothesis development. However, we can draw some insight for hypothesis development from other studies of the impact of self-management support models on health care utilization. For example, Hamid et al. (2014) reported on a cluster-randomized design used to assign 268 diabetes patients to a nurse-community health worker intervention or usual care. Hospitalizations, emergency department, and primary care physician visits were collected retrospectively for one year prior to, and during, the intervention to assess changes in health care utilization. Adjusted incidence rate ratios for primary care physician visits were significantly higher in the community health worker intervention relative to the usual care. The authors found no main intervention effect on emergency department utilization, but visits in the prior year modified the intervention effect on emergency department visits. Increased primary care physician utilization was associated with greater decreases in HbA1c.

In a review of studies implementing at least some features of chronic disease management models (including SMS), Bodenheimer, Wagner and Grumbach (2002) reported mixed evidence on the impact of diabetes interventions on health care utilization. However, the authors were surprised to note that while they expected shorter-term interventions would not affect diabetes health care utilization or costs because of the relatively long horizon for the evolution of disease complications, some studies suggested that even shorter-term interventions reduced utilization in some services, including the length of hospital stays, fewer hospital stays and reduced utilization of emergency department visits. Some studies failed to show a reduction in overall health care costs; at least one did show a reduction in emergency department and specialty visits but not overall costs.

It is not clear whether this intervention can be expected to have a significant impact on reducing the use of more intensive services, especially since neither diversion of patients from more intensive services nor intensive chronic disease management are specific aims of the study, and there is no change in payment incentives related to utilization. However, based on some evidence of reduced utilization associated with SMS and community-oriented models in the literature, our secondary indicators will include changes in inpatient hospital stays, inpatient hospital length and number of emergency department visits. We hypothesize that there may be some trend toward reduction in more intensive services, at least for those with sufficient uptake of the intervention.

In some cases, however, it is possible that increased utilization might be observed and even desirable; for example, if patients learn to identify high-risk health situations more effectively and seek treatment as a result of the intervention. An analysis of primary diagnostic codes associated with utilization will be conducted to assess the extent to which utilization appears to be associated with diabetes-related conditions, especially more acute events such as severe hypoglycemia. We will also examine whether there is an association between changes in health care utilization and improvement in the primary study indicator of improved HbA1c.

13.5.3 Sample size estimation

The health care utilization analysis will utilize the sample generated by the FAITH-DM study. The estimated recruitment goal for the project is 720, with a projected sample size of 600 (300 each in intervention and waitlist arms) after estimated loss to follow-up of 20%. This sample provides the basis for the analysis of the self-reported utilization data and the pool of participants from which provider surveys will be requested. It is our goal to collect provider data from at least 80% of the intervention participants and 70% of the waitlist control participants (it is anticipated that this group will yield fewer primary care provider relationships, since they are not receiving the intervention that supports these). The pilot project upon which this study was based suggested that most individuals who participated in food pantry screening reported that they had a primary care provider at the time of their enrollment in the pilot project. However, prior health records were not requested from those providers in the pilot so it is difficult to know prospectively how many provider contacts will actually yield records, given that individuals struggling with food insecurity may also have been disconnected from health care access in the months prior to their recruitment at the food pantry.

13.5.4 Statistical analyses

For each of the outcomes from the utilization analysis we would assess the impact of the intervention using the following specification:

$$Y_i = \beta_0 + \beta_{1,i}T + \beta_{2,i}Post + \beta_{3,i}T * Post + \epsilon_i$$

Where Y_i is the given outcome variable, T_i is an indicator for being assigned to treatment, *Post* is an indicator that the observation is from the post intervention time period, and ϵ_i is the error term. The impact of the intervention is measured by β_3 which measures the intent to treat effect – or the change in the outcome of interest for the treatment group compared to the change in the outcome of interest for the wait-list group. Since randomization is at the individual-level, HuberWhite standard errors will be used.

Loss to follow-up

We intend to follow the same procedures for loss to follow-up as specified in the analysis of the primary study outcome (HbA1c). We will conduct a formal missingness investigation to determine if the attrition rate differed between intervention and waitlist groups. If treatment status is found not to significantly affect attrition at the 5 percent significance level, then all estimation will proceed without

any adjustment for attrition. If attrition is found to be related to treatment status, we postulate that attrition will be higher for the control group, and will employ Lee bounds to obtain bounds on our treatment estimates which are robust to this attrition. Multiple imputation for missing outcome data will also be explored as sensitivity analyses.

Subgroup analyses
While the study is randomizing within sites, we also plan to conduct subgroup sensitivity analyses by both adjusting for site and examining changes within site to determine differential effectiveness by location. Site-specific differences will be shared with the food pantries, but only reported publicly in manuscripts if found to be significantly different.

Other planned subgroup analyses (as specified in our hypotheses) are by baseline glycemic control (>9%) and food security status.

14 Quality Control Procedures

Data integrity and study credibility depend on factors such as:

- Ensuring adherence to the protocol
- Obtaining complete follow-up information on all participants enrolled
- Using quality control measures to establish and maintain high standards for data quality

Quality control procedures for point-of-care testing is described in **section 7**.

Data entry directly into CASIC or MS Access allows for immediate range checks. Data questions will be posed by the study statistician (Courtney Lyles) to sites as needed. Data quality will be reviewed by the study statistician at least every six months.

Site visits will be conducted annually (or as needed). Protocol deviations will be reviewed within 48 hours to determine if corrective actions need to be taken. This procedure is not intended to be punitive, but to assist with avoiding similar problems across sites in the future.

Ongoing quality control and iterative improvement helps to ensure the highest quality study possible.

14.1 Standard Operating Procedures

One aspect of site quality control is a set of standard operating procedures (SOPs). SOPs describe generic procedures that are specific to the site, and should be drafted and maintained by study staff at each site. The SOPs should be located in a central location and made easily available to staff for reference.

For FAITH-DM, SOPs should include:

1. Storage of study materials (outlines where participant binders, quality control logs, screening forms, blood testing materials, etc.) are stored
2. Secure storage of study documents with participant data (signed consent forms, paper enrollment forms, signed HIPAA forms, etc.)
3. Copies of all handouts with site-specific information
    a. Diabetes education handouts used during screenings (pre-diabetes range; diabetes, controlled; diabetes, uncontrolled)
    b. Primary care provider referral forms
    c. Mental health referral handouts
    d. Reminder materials (diabetes class postcards)
    e. Retention materials (birthday / holiday cards)

14.2 Site Monitoring

FANO and UCSF will conduct site monitoring visits during the course of the study. These will be arranged in advance with each food bank.

FANO and/or UCSF project staff will conduct initial site visits at all three food bank sites between October 1, 2015, and February 28, 2016. Site visits will be planned with input and availability of project staff at each food bank. Additional goals of site visits are: ensure FAITH-DM activities are being conducted as designed; provide feedback and technical assistance to food bank FAITH-DM project staff; problem-solve any unanticipated issues that arise during implementation of FAITH-DM protocols at the food bank sites; and provide an opportunity for food bank staff to provide feedback regarding implementation of study procedures.

Once the site visit is complete, a site monitoring report is drafted to provide feedback regarding any problems or issues that may have been uncovered during the visit. The report will state the problems uncovered during the visit and describe recommendations to correct them. A timeline will be agreed upon and included in the report to ensure that follow-up of the issues is completed and implemented into the study's procedures.

Any additional site visits will be scheduled as/if needed during the remainder of the FAITH-DM study period. FANO and UCSF project staff will communicate closely with food bank staff in the event additional site visits are required and need to be scheduled. In the pilot study these site visits occurred approximately annually.

The purposes of monitoring visits are to:

- Ensure the rights and safety of participants
- Confirm that the study is conducted in accordance with Good Clinical Practice guidelines
- Ensure maintenance of required documents
- Verify adherence to the protocol
- Monitor the quality of data collected

- Ensure accurate reporting and documentation of all adverse events and unanticipated problems

During monitoring visits, data recorded are reviewed and verified against source documents to ensure:

- Informed consent has been obtained and documented in accordance with IRB regulations
- The information recorded on forms is complete and accurate, where applicable
- There are no omissions in the reports of specific data elements or protocol deviations
- Missing study components

Food bank staff must ensure that FANO/UCSF has access to all study documents, including informed consent forms, intervention accountability records, and source documents. **This is a requirement of the IRB.**

14.3 Acceptable Roles for Volunteers

Food banks may choose to use volunteers to participate in aspects of study implementation, provided that they have the appropriate training and credentials for the role and are able to implement the study protocol as outlined in this document and per direction of the project team. Acceptable roles for volunteers may include:

- Packing of food boxes
- Signing in participants during food distributions
- Distribution of food boxes
- Blood sugar and HbA1c screening: RN, RD, CHW, or other volunteers who are properly trained and credentialed as per local and state guidelines and who are willing to commit to ongoing volunteer participation to assure quality control
- Survey administration: please make sure volunteers have practiced survey administration prior to their first administration
- Diabetes education: RD, RN, CDE, CHW volunteers with expertise in diabetes education who are trained and able to implement the diabetes education component of the study as directed may participate in the education through:
    - Leading group class sessions 1 and/or 2
    - Participating as an expert guest speaker for the Open Forum/Support Group
    - Providing one-on-one education

<u>Any volunteer who interacts with a study participant in any way must complete their CITI training and forward the certificate to Morgan Smith for filing with the Western Institutional Review Board.</u>

15 Reports

Once a study begins, routine reports compiled by the Coordinating Center are an important quality control tool.

15.1 Reporting Schedule

- Food bank informal monthly reports will describe target and actual enrollment by site and in aggregate, individuals screened, and participant disposition (enrolled, active, completed, discontinued, and lost to follow-up); sites will also report all staff and volunteers that have completed CITI training and are eligible to work directly with study participants and study data
    - Morgan Smith (FANO) will be responsible for assembling these reports and communicating to UCSF.
    - During initial enrollment period (September – December, 2015), these reports will be bi-monthly
- Participant Overview Report (compilation of data from all sites and includes: numbers screened, enrolled, randomized group totals, participants completed, and participants lost-to-follow up); monthly report during enrollment period compiled by UCSF
- Food bank site progress and budget reporting: annually by each site and submitted to FANO (Morgan Smith and/or FANO Grants Team)
    - Year 1 report covers study period July 1, 2015 – April 30, 2016: due May 26, 2016
    - Year 2 / FINAL report covers study period May 1, 2016 – October 31, 2017: due October 5, 2017; final report will request information on project activities, and both year 2 and extension funding awards
- HCUA Reporting (Urban Institute)
    - Quarterly report to Morgan Smith (FANO) with updates
- FANO will be responsible for all official reporting to project funder (LJAF)

16 Data and Safety Monitoring Board

At this time we have no plans to convene a Data Safety and Monitoring Board due to the low-risk nature of the research we are conducting.

However, in order to track data quality, enrollment numbers, and other study events, UCSF study staff (study statistician, principle investigator, and project coordinator) will conduct an internal review of study data every 6 months, and report general results to coordinating center team members. In order to maintain research best practices and study rigor, this review will **not** include any analyses, audits, or interpretations of raw study data. The primary purpose of these reviews are for quality control.

Internal reviews should be conducted on or around the following dates:

- March 1, 2016
- September 1, 2016
- March 1, 2017
- September 1, 2017

17 Study Completion and Closeout Procedures

Study closeout activities are performed to confirm that the food banks' study obligations have been met and post-study obligations are understood. Closeout activities include:

- Verification that study procedures have been completed and data have been collected.
- Final uploads of all food bank site MS ACCESS Database data due by 9/30/17.
- Final uploads of all food bank site CASIC survey data due by 9/30/2017.
- Final submission by food bank sites of HCU-surveys shipped to Urban Institute by 9/30/17.
- Comparison of the food banks' study files against the Coordinating Center's records for completeness.
- Assurance that all data queries have been completed.
- Assurance that correspondence and study files are accessible for external audits.
- Reminder to food banks of their ongoing responsibility to maintain study records for 3 years and to report any relevant study information to the Coordinating Center.
- Participant notification of the study completion.

17.1 Participant Notification

The Coordinating Center will develop a sample letter to notify participants that the study is completed, ask whether they would like to be informed of the results, and thank them for their participation. Food banks may modify this letter to personalize it and add their own branding.

17.2 Site Procedures Post-Study

The Feeding America National Office will likely want to highlight the trial results both internally and externally. This may include messages of appreciation. Staff from participating food banks may be asked to assist with the dissemination of trial results and best practices, for example at national workshops. Feedback will be provided to participating clinics.

17.3 Ancillary funding

If additional money is secured, it will be put towards 12-month follow-up HbA1c screening and survey administration. Procedures for these activities will be discussed in detail with each food bank and described in detail in the MOP prior to initiation of any activities.

17.3.1 Extension plan

In late 2015, the Urban Institute was awarded a grant from the Robert Wood Johnson Foundation (RWJF). Under the grant, Urban will serve as a transdisciplinary research hub in support of RWJF's *Policies for Action: Policy and Law Research to Build a Culture of Health*. Urban has dedicated a part of this award is towards ancillary, or "extension", funding for FAITH-DM.

As initially outlined in **section 17.3** (Ancillary Funding), this extension funding will be dedicated towards additional HbA1c testing, survey administration, and HCU activities for participants at the 12-month (T12) mark. An overview of these activities is provided here:

T12 Activity	Intervention Group	Control Group
HbA1C Testing	Yes – new extension activity	Yes – original protocol
Participant T12 Post-Survey	Yes – new extension activity	Yes – revised from original protocol
HCUS Provider Survey	Yes – new extension activity	No

Primary rationale for extension activities:

- The T12 follow-up activities with the intervention group will provide important data on how well participants **maintain** any benefits that they may have experienced at the immediate end (T6) of the intervention. Identifying health promotion interventions that positively impact outcomes for the long term has important implications for public health programming and policy development.
- The extension plan will also allow us to compare, to a degree, the efficacy of the primary study intervention to the "modified" intervention that the control group receives. This comparison may provide important information on how well specific intervention components work (e.g., the formal vs. modified DSME program).

17.3.2 IRB Approval

Because these extension activities include significant changes to the existing study protocol, the Coordinating Center re-submitted the revised protocol to the study IRB for approval. The revised protocol, along with associated participant materials, were approved by the Western IRB on **3/18/16**.

17.3.3 Revised Project Budgets

The study extension plan includes additional funding for the Coordinating Center and the food bank sites to adequately cover the costs associated with the new activities. The Feeding America grants team will issue revised grant awards to the food bank sites in summer 2016. These award letters will detail the increased grant amounts dedicated to food bank staffing, medical and testing supplies, outreach materials, participant and provider incentives, and other extension-related items.

17.3.4 Description of New and Revised Study Activities

This section describes in detail the study activities that are new, or that are revisions to the original study protocol, related to the implementation of this extension plan. **Note: the entire MOP has also been updated and reflects these revisions.**

- Participant Recruitment and Enrollment
    - Site staff will use a revised recruitment flyer (***Appendix AJ***) and communicate the 12-month timeframe and activities when informing food pantry clients, prospective study participants, and new participants about the study

    - Staff will use an IRB-approved form ("FAITH-DM Updates for Study Participants", (***Appendix AW***) to update all participants at T6 of T12 study activities
- Intervention Group Activities
    - Under the original study protocol, intervention group activities ended at T6. With the extension plan, site staff will work to engage with all intervention group participants to conduct a final visit at T12.
    - Participant outreach: at or near the T11 mark, site staff will attempt to contact participants (phone and by mailing T12 engagement materials) to provide information about T12 testing and surveys, and to attempt to schedule a study visit
    - Site staff will conduct a final HbA1c test with participants at T12 (testing window: months 11-13) at a project site following normal study protocols
    - Site staff will complete a final post-survey (INT-12) with each participant as part of this final visit. This survey is identical to the T6 post-survey, but does not include the final section with items on satisfaction. Intervention group participants who complete the final T12 survey will receive a final incentive ($15 gift card) according to normal study protocols.
    - Site staff will complete an active referral per existing study protocols for any participant identified at T12 as not having a source of primary medical care
    - Site staff will use the ACCESS database and CASIC system to record all data per normal study protocols.
- Control Group Activities
    - Per the original study protocol, control group participants are scheduled to receive a T12 HbA1c test; the extension plan keeps this process unchanged
    - The T12 "satisfaction" survey will be replaced with the T12 CONT Post Survey (identical to the T6 Post Survey administered to intervention group participants) on CASIC for all control group participants at T12, and administered per normal study protocols
    - Site staff will complete an active referral per existing study protocols for any participant identified at T12 as not having a source of primary medical care
    - The extension grant includes new funding for control group participants to receive a $15 gift card upon completion of their T12 surveys; site staff will distribute gift cards per normal study protocols
- HCUA Activities
    - The extension plan includes a final round of HCU surveys (HCUS) for the intervention group only at T12
    - Site staff will use revised HCU provider letters to send to PCPs for participants assigned to the intervention group
    - Staff will follow original protocols for provider communication to obtain HCUS surveys at the T6 time frame for all study participants
    - At T12, site staff will send intervention group providers additional communication and a second survey (HCUS) that requests care utilization data for the T6 – T12 timeframe
    - Site staff will follow normal HCUA protocols for sending provider communication materials and surveys, conducting provider follow-up to encourage HCUS survey

completion, and survey collection, packaging, and mailing to Urban Institute project staff (see section 7.7.4 HCUA Activities at Twelve Months [T12] for details)
- Extension funding is included to submit payments ($20 per HCUS survey completed) to providers, following established study protocols for payments

17.3.5 List of Revised Forms and Study Materials

The following study documents were revised or developed to reflect study changes connected to the extension plan:

- Sample Recruitment Flyer
- Participant Flow – Overview
- FAITH-DM Updates for Study Participants [*new*]
- Intervention Group T12 Post Survey
- Control Group T12 Post Survey
- Participant Compensation Receipt Form
- HCUA Provider Letters (1-6)
- HCUA Provider Letter (HCU Letter 7 – T12 Current Pt INT) [*new*]
- HCUA Provider Letter (HCU Letter 8 – T12 Newly Referred Pt INT) [*new*]
- HCUS Provider Survey (T6 & T12)
- T6 & T12 Engagement Materials for Intervention & Control Groups [*new*]

17.3.6 Reporting

Site staff will follow original study protocols for reporting all study related information, data, events, and materials to the Coordinating Center.

Site staff will follow any new grant-related reporting requirements (narrative and budget reporting) per instructions detailed in grant award letters. Sites will submit a final project report by **October 5, 2017** as part of the final project report (via the FA Member Grants reporting portal).

17.3.7 Study Closeout

Study completion and closeout procedures will remain in place as originally outlined in study MOP.

17.4 Confidentiality Procedures

It is the responsibility of UCSF to outline and enforce participant and study data confidentiality policies. Study staff has responsibilities regarding data safeguards. Data must not be released to any unauthorized individuals, unless such a release is approved by the Coordinating Center and is not in violation of applicable Federal and state laws.

This section of the MOP will discuss the safeguards which have been put in place by the Steering Committee to ensure participant confidentiality and data security.

The following is a list of study participant confidentiality safeguards:

- ***Fax transmissions*** – all faxes sent to health care partners should include a HIPAA compliant cover page (***Appendix AB***). Participant data should only be sent from / to HIPAA-compliant fax machines.
- ***Data flow procedures*** – data identifying participants should not be transmitted from study sites to the Coordinating Center. **Use the participant ID only on all study forms**.
- ***Electronic files*** – data identifying participants that are stored electronically should be maintained in an encrypted form or in a separate file. Only allow study data to reside on computers and equipment purchased by UCSF specifically for the FAITH-DM trial. These computers have been pre-loaded with virus protection and encryption software.
- ***Forms*** - forms or pages containing personal identifying information, including name and date of birth, should be separated from other pages of the data forms. All computer systems and paper back-up forms have been designed to separate all study information from personal identifying information.
- ***Access*** - participant records should not be accessible to **any** persons outside the study without the express written consent of the participant. No staff member or volunteer without CITI certification should be able to access any study documentation.
- ***Storage*** – all study forms and related documents should be stored in a secure location. The Coordinating Center and the food banks should use the following computer security best practices to ensure that the data remain confidential:
    - **Passwords**: Passwords provide limitations on general access to computer systems and to the functions that individuals can use. Passwords should be changed on a regular basis.
    - **User Training**: Study staff with access to clinical computer systems will be trained in their use and in related security measures. Training will include explanations of how to access the system and a discussion of the need for, and importance of, system security. This will be done at the Study Training meeting.
    - **System Testing:** Prior to the use of a new computer system, and subsequent to any modifications, the system should be tested to verify that it performs as expected. Testing should verify that the password-activated access system performs as intended.
    - **System Backups:** Two copies of all data are kept. The primary copy is on the hard drive of the computer. The backup is electronically transmitted to the UCSF secure server daily.

17.5 Publications and data release

Investigators have a responsibility to the public to make study results available as soon as possible. Data should not be released inappropriately or without the approval of UCSF.

UCSF has responsibility for data analysis, manuscript development, and manuscript submission. A publication plan and author list will be created at the conclusion of the study. Main study results will be disseminated as soon as possible in both abstract form and peer reviewed manuscript form. Dr. Seligman will take primary responsibility for this process and will be listed as either first or senior author.

As required by law, UCSF will report basic results to ClinicalTrials.gov within 12 months of trial completion. The funder has also requested that we report basic results to them prior to publication. We will adhere, within reason, and as defined by our contract, to all funder requests.

17.6 MOP Maintenance

The MOP is maintained and updated throughout a study. The MOP will be available to study staff in loose-leaf and electronic form. Each page of the MOP is numbered, dated, and contains a version number to facilitate any changes and/or additions. The MOP may serve as a history of the project, documenting the time and nature of any changes in procedures and policies.

The MOP will be continuously reviewed by the Coordinating Center to ensure that the operating procedures described are accurate. If any procedures have been changed or modified, the MOP should be updated and the appropriately modified pages distributed, with instructions, for replacement in the MOP. A MOP template for changes is included in ***Appendix G***. It is the responsibility of the Coordinating Center to maintain the MOP and document all MOP changes, and communicate MOP changes to the food banks.

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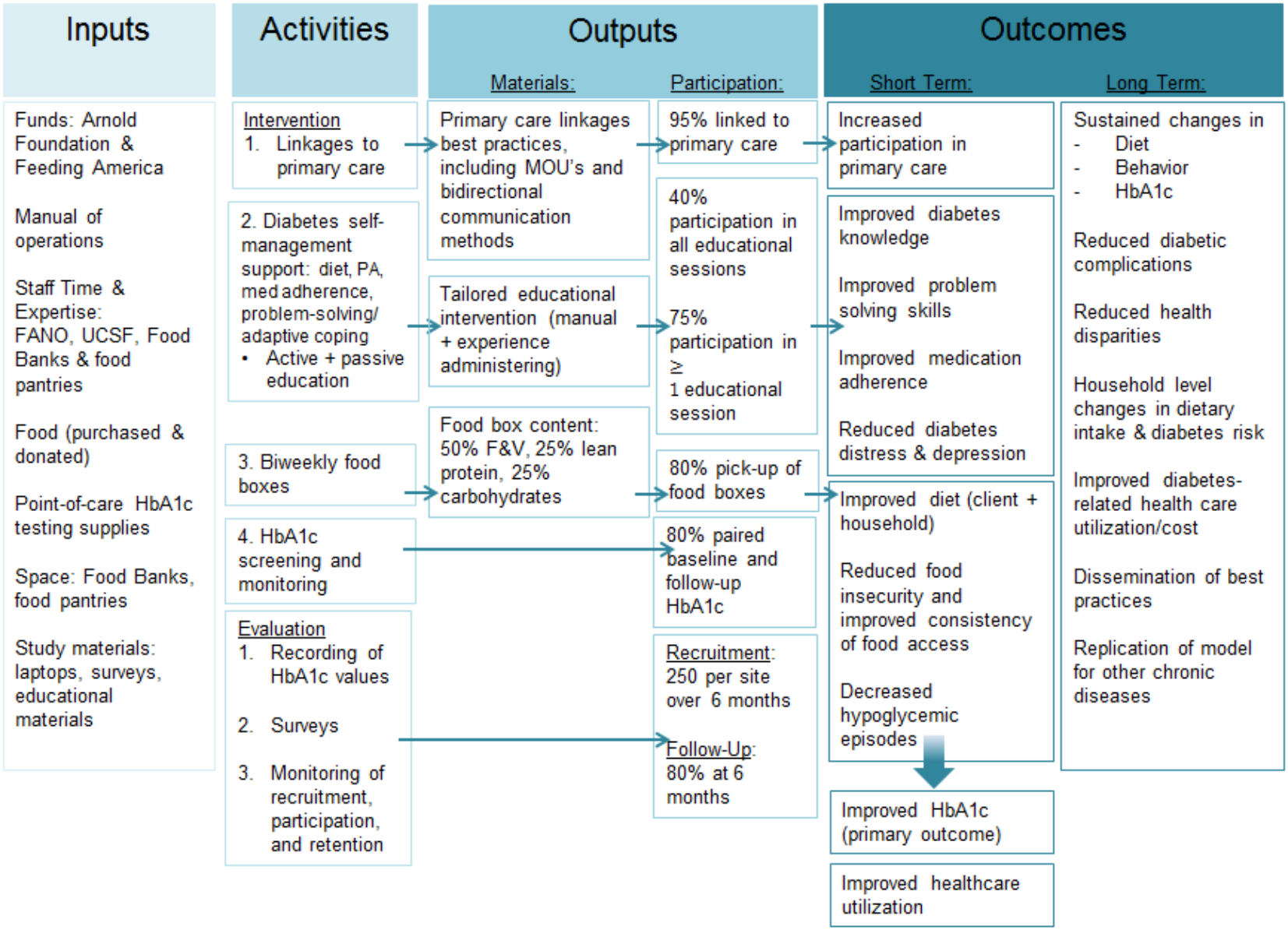
Appendix A – Logic Model



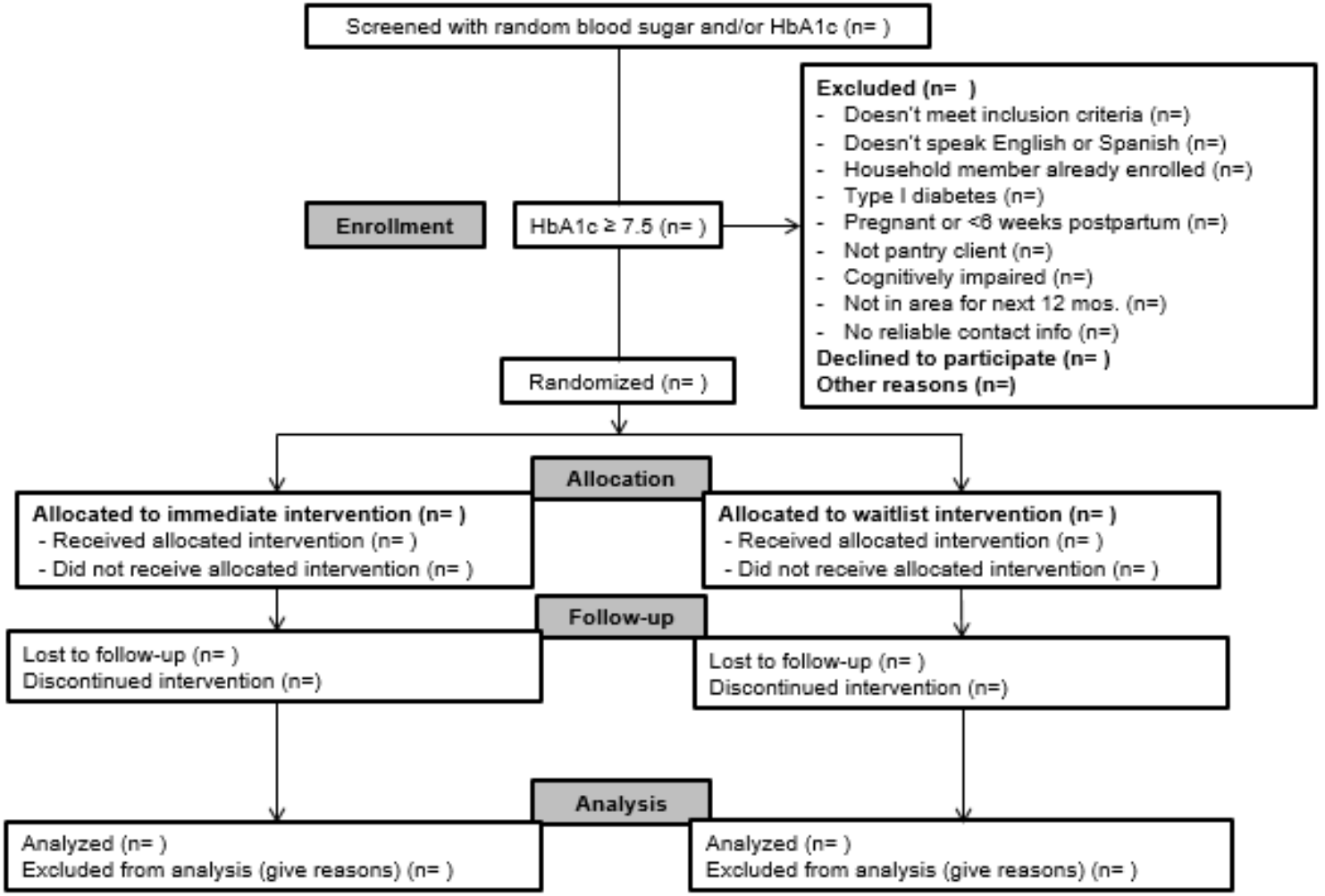
Appendix B – Screening Log

Blood Sugar	Fasting[1]?	HbA1c[2]	Repeat	Age[3]	Gender	Race/ Ethnicity	ONLY if HbA1c 7.5 or higher
	☐ Fasting ☐ Non-fasting		☐ YES	☐ 18-40 ☐ 41-60 ☐ 61+	☐ Female ☐ Male	☐ White ☐ Black ☐ Latino ☐ Other	☐ **ENROLLED** **NOT ENROLLED DUE TO:** □ Doesn't speak Eng or Sp □ HH member enrolled □ Type I diabetes □ Pregnant/<6 wks postpartum □ Not pantry client □ Cognit. impaired □ Not in area for next 12 mos. □ Declined:________________________ □ No reliable contact info
	☐ Fasting ☐ Non-fasting		☐ YES	☐ 18-40 ☐ 41-60 ☐ 61+	☐ Female ☐ Male	☐ White ☐ Black ☐ Latino ☐ Other	☐ **ENROLLED** **NOT ENROLLED DUE TO:** □ Doesn't speak Eng or Sp □ HH member enrolled □ Type I diabetes □ Pregnant/<6 wks postpartum □ Not pantry client □ Cognit. impaired □ Not in area for next 12 mos. □ Declined:________________________ □ No reliable contact info
	☐ Fasting ☐ Non-fasting		☐ YES	☐ 18-40 ☐ 41-60 ☐ 61+	☐ Female ☐ Male	☐ White ☐ Black ☐ Latino ☐ Other	☐ **ENROLLED** **NOT ENROLLED DUE TO:** □ Doesn't speak Eng or Sp □ HH member enrolled □ Type I diabetes □ Pregnant/<6 wks postpartum □ Not pantry client □ Cognit. impaired □ Not in area for next 12 mos. □ Declined:________________________ □ No reliable contact info
	☐ Fasting ☐ Non-fasting		☐ YES	☐ 18-40 ☐ 41-60 ☐ 61+	☐ Female ☐ Male	☐ White ☐ Black ☐ Latino ☐ Other	☐ **ENROLLED** **NOT ENROLLED DUE TO:** □ Doesn't speak Eng or Sp □ HH member enrolled □ Type I diabetes □ Pregnant/<6 wks postpartum □ Not pantry client □ Cognit. impaired □ Not in area for next 12 mos. □ Declined:________________________ □ No reliable contact info

1. Fasting is more than 8 hours from last intake.
2. Perform HbA1c if: history of diabetes or gestational diabetes, fasting blood sugar 140 or higher, or non-fasting blood sugar 160 or higher.
3. Do not check blood sugar or HbA1c on any person younger than 18 years of age.

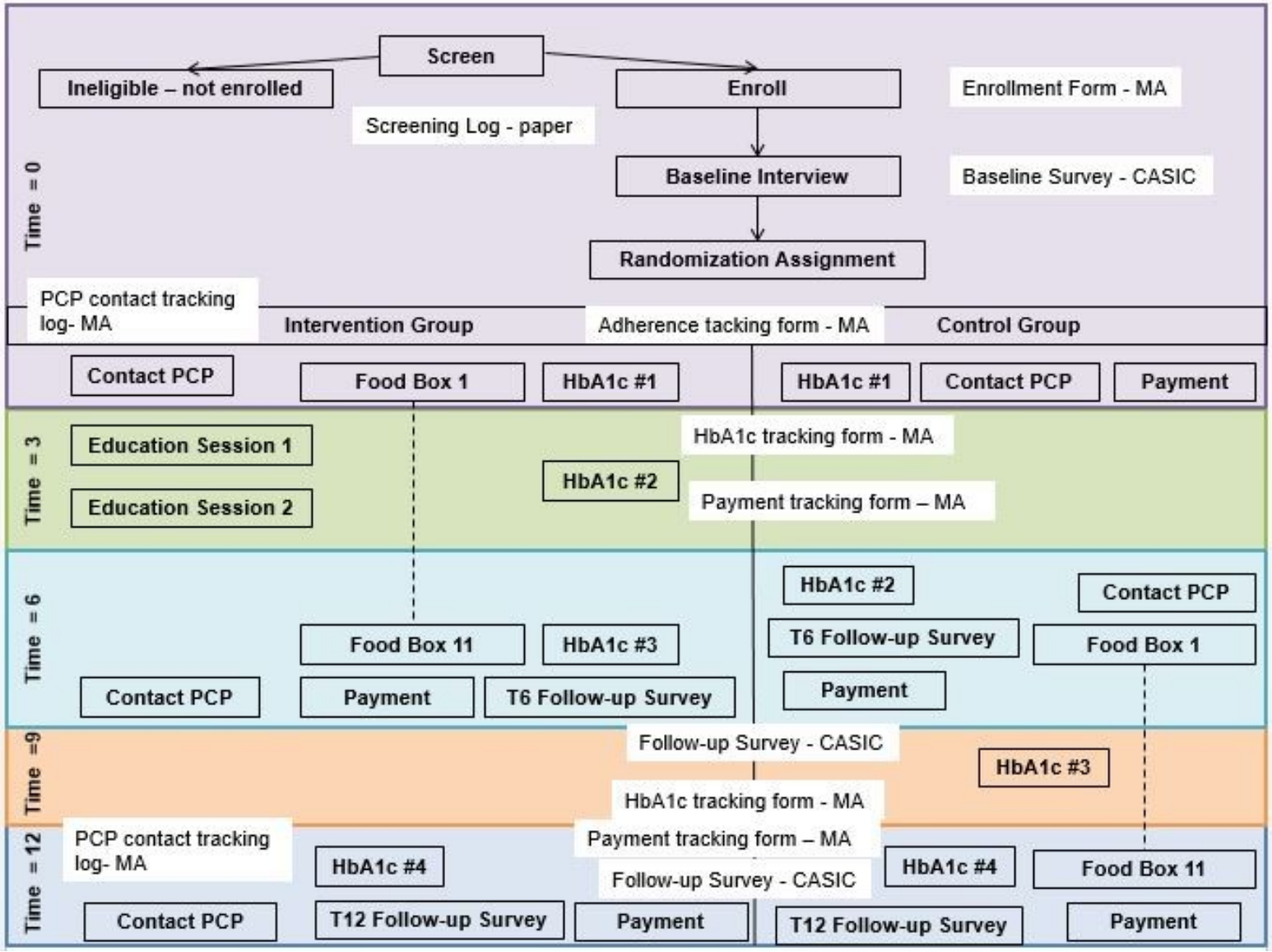
Appendix C – FAITH-DM Flow Chart

The Screening Log and the MS Access database should allow us, at study end, to track every potential participant screened for the study. This chart will be used to describe participant flow through the study.



Appendix D – Electronic Forms Completed at Each Study Visit

MA = MS Access Database. The MS Access database contains many forms (outlined here).



INTERVENTION GROUP	
TIMELINE	**ACTIVITY / STUDY VISIT**
T0: Day 1 (Month 1, Week 1)	• Food bank client participates in diabetes screening (blood glucose and/or HbA1c testing) event at food pantry; study staff verifies that client meets eligibility requirements for study inclusion • Client agrees to participate in study and completes written consent form with study staff (informed consent, HIPAA authorization, and medical records release form) • Participant completes baseline survey with study staff • Participant randomly assigned to study intervention group by study staff • Participant receives 1st bi-monthly food box and passive education materials and receives information from food bank staff on group diabetes education classes • RA sends participant's PCP the baseline provider communication packet
Month 1, Week 2	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff • Participant attends Session 1 of group diabetes education class around this time
Month 2, Week 1	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff • Participant attends Session 2 of group diabetes education class around this time
Month 2, Week 2	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
Month 3, Week 1	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff • Participant attends monthly group drop-in diabetes education class around this time
T3: Month 3, Week 2	• Participant completes 3-month HbA1c test with study staff • Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
Month 4, Week 1	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff • Participant attends monthly group drop-in diabetes education class around this time
Month 4, Week 2	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
Month 5, Week 1	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff • Participant attends monthly group drop-in diabetes education class around this time
Month 5, Week 2	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
T6: Month 6, Week 1	• Participant completes 6-month HbA1c test with study staff • Participant completes final survey with study staff • Participant receives $30 gift card for completion of survey • Participant receives final bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff • Participant attends monthly group drop-in diabetes education class • RA sends participant's PCP the T6 provider communication packet and HCUS
T12: Month 12	• Participant completes 12-month HbA1c test with study staff

	• Participant completes T12 INT survey with study staff (CASIC) • Participant receives $15 gift card for completion of survey • RA sends participant's PCP the T12 provider communication packet and HCUS • Participant formally exits research study

WAIT LIST CONTROL GROUP	
TIMELINE	**ACTIVITY / STUDY VISIT**
T0: Day 1 (Month 1, Week 1)	• Food bank client participates in diabetes screening (blood glucose and HbA1c testing) event at food pantry; study staff verifies that client meets eligibility requirements for study inclusion • Client agrees to participate in study and completes written consent form with study staff (informed consent, HIPAA authorization, and medical records release form) • Participant completes baseline survey with study staff • Participant randomly assigned to study control group by study staff • Participant receives $15 gift card for survey completion • RA sends participant's PCP the baseline provider communication packet (control)
Month 1, Week 1 – Month 6 , Week 2	• Participant attends regular food pantry distributions and receives normal services per food pantry guidelines (does NOT receive diabetes food packages or education)
T6: Month 7, Week 1	• Participant completes HbA1c test with study staff • Participant completes final survey with study staff • Participant receives $15 gift card for survey completion • Participant receives 1st bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff from food bank staff • RA sends participant's PCP the T6 provider communication packet and HCUS
Month 7, Week 2	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
Month 8, Week 1	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
Month 8, Week 2	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
Month 9, Week 1	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
T9: Month 9, Week 2	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff • Participant completes HbA1c test with study staff
Month 10, Week 1	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
Month 10, Week 2	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff

Month 11, Week 1	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
Month 11, Week 2	• Participant receives bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff
T12: Month 12	• Participant receives final bi-monthly food box, passive education materials, and 1-on-1 education from food bank staff • Participant completes T12 HbA1c test with study staff • Participant completes T12 CONT survey with study staff (CASIC) • Participant receives $15 gift card for completion of survey • Participant formally exits research study

Appendix F – Protocol Deviation Log

Site _____

Protocol deviations must be reported to Morgan Smith (FANO) within 48 hours of discovery. Morgan Smith is responsible for keeping the Protocol Deviation Log.

Protocol Deviation Code:	Participant Initials	Participant ID#	Date Deviation Occurred: mm/dd/yyyy	Date Protocol Deviation Documented: mm/dd/yyyy	Contact Person (if applicable)	Notes

PROTOCOL DEVIATION CODES

Consent Form:
1. Missing or not obtained
2. Not signed and dated by participant
3. Does not contain all required signatures
4. Outdated; current IRB-approved version not used

Randomization:
5. Ineligible participant enrolled and/or randomized
6. Participant is randomized prior to determining whether eligible for study.
7. Participant randomized prior to completing baseline survey

IRB:
8. Not reporting a serious complication within 24 hours;
9. Approvals not kept up to date
10. Enrollment and/or treatment occurs prior to IRB approval or during period when on "on hold."
11. Reportable serious adverse events not reported to IRB

Participant
12. Receives wrong intervention (immediate vs waitlist)
13. Visits occur outside expected follow-up window
14. Entered into another diabetes study

Study Data and/or Forms
15. Missing HbA1c
16. Missing surveys
17. Forms or data not sent from clinical site to coordinating center

Appendix G – MOP Modification Log

MOP Modification Log

Protocol Name: Feeding America Intervention Trial for Health – Diabetes Mellitus

MOP MODIFICATION LOG					
VERSION #	**SECTION #**	**PAGE #**	**DATE MODIFIED**	**A / D / R ****	**BRIEF MODIFICATION SUMMARY**

** **A** = Addition, **D** = Deletion, **R** = Revision

This log is the responsibility of the Coordinating Center.

Appendix H – CONSORT 2010 Checklist

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	

Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	

Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix I – Passive Diabetes Self-Management Education Materials

AADE7 Self-Care Behaviors

1. Healthy Eating
2. Being Active
3. Monitoring
4. Taking Medication
5. Problem Solving
6. Reducing Risks
7. Healthy Coping

Study participants will receive 11 sets of passive education materials over a six-month period. Each set will be included with one of the bi-monthly food box distributions. This schedule was designed so that all participants, regardless of what week during the year they enroll and enter the study, will receive nearly identical sets of education materials over the course of their participation.

Time Frame	Subject Area	Resources	Recipes	Notes
Enrollment	Introduction to FAITH-DM; Basic Diabetes Information	FAITH-DM Welcome Letter and Resources; ACP Guide (***intervention arm only***); LAD – What's My A1C?	** Project staff at food bank sites will develop diabetes-appropriate recipes based on current food inventory, participant preferences, etc.	Participant also receives weekly materials with 1st box at time of enrollment; participants in control group receive ACP guide and first set of weekly materials with first food package pick-up after 6-month waiting period
January – week 1	Healthy Eating 1	LZ – Diabetes MyPlate, Portion Distortion		
January – week 2	Being Active 1	IDC – Activity Pyramid LAD – My Weekly Exercise Plan		
February – week 1	Healthy Coping 1	IDC – Life Balance Pyramid; LAD – Diabetes and Depression		
February – week 2	Problem Solving	LAD – Saving Money on Medicines, Diabetes Supplies, Sick Days with Diabetes		
March – week 1	Reducing Risks 1	LAD – Tips for Good Foot Care, Diabetes and Your Eyes; State-		

Time Frame	Subject Area	Resources	Recipes	Notes
		specific smoking cessation info		
March – week 2	Monitoring	LAD – Blood Sugar Meters, Blood Sugar Diary, Low Blood Sugar, High Blood Sugar		
April – week 1	Taking Medication	LAD – Your Diabetes Pills, Diabetes Pills - Actions, Medicines You Inject - Actions		
April – week 2	Healthy Eating 2	LZ – MyPlate on a Budget, Sugar Shockers		
May – week 1	Being Active 2	LAD – Let's Get Moving, Walking Works		
May – week 2	Reducing Risks 2	LAD – High Blood Pressure and Diabetes, Cholesterol and Diabetes, Diabetes Care Schedule		
June – week 1	Healthy Eating 3	LAD – The Nutrition Facts Label; Healthy Cooking Tips		
June – week 2	Healthy Coping 2	LAD – Diabetes and Stress; My Goal This Month		
July – week 1	Healthy Eating 1	LZ – Diabetes MyPlate, Portion Distortion		
July – week 2	Being Active 1	IDC – Activity Pyramid LAD – My Weekly Exercise Plan		
August – week 1	Healthy Coping 1	IDC – Life Balance Pyramid; LAD – Diabetes and Depression		
August – week 2	Problem Solving	LAD – Saving Money on Medicines, Diabetes Supplies, Sick Days with Diabetes		
September – week 1	Reducing Risks 1	LAD – Tips for Good Foot Care, Diabetes		(Begin participant enrollment, 2015)

Time Frame	Subject Area	Resources	Recipes	Notes
		and Your Eyes; State-specific smoking cessation info		
September – week 2	Monitoring	LAD – Blood Sugar Meters, Blood Sugar Diary, Low Blood Sugar, High Blood Sugar,		
October – week 1	Taking Medication	LAD – Your Diabetes Pills, Diabetes Pills - Actions, Medicines You Inject – Actions		
October – week 2	Healthy Eating 2	LZ – MyPlate on a Budget, Sugar Shockers		
November – week 1	Being Active 2	LAD – Let's Get Moving, Walking Works		
November – week 2	Reducing Risks 2	LAD – High Blood Pressure and Diabetes, Cholesterol and Diabetes		
December – week 1	Healthy Eating 3	LAD – The Nutrition Facts Label; Healthy Cooking Tips		
December – week 2	Healthy Coping 2	LAD – Diabetes and Stress; My Goal This Month		

LZ = Learning Zone Express

- Diabetes MyPlate
- Portion Distortion
- MyPlate on a Budget
- Sugar Shockers
- USDA MyPlate (screening resource only for clients with A1C result < 5.7%)

LAD = Learning About Diabetes

- What's My A1C
- My Weekly Exercise Plan
- Diabetes and Depression
- Saving Money on Medicines
- Diabetes Supplies
- Sick Days with Diabetes
- Tips for Good Foot Care
- Diabetes and Your Eyes
- Blood Sugar Meters
- Blood Sugar Diary
- Low Blood Sugar
- High Blood Sugar
- Your Diabetes Pills
- Diabetes Pills – Actions
- Medicines You Inject – Actions
- Let's Get Moving
- Walking Works
- High Blood Pressure and Diabetes
- Cholesterol and Diabetes
- Diabetes Care Schedule
- The Nutrition Facts Label
- Healthy Cooking Tips
- Diabetes and Stress
- My Goal This Month

ACP = American College of Physicians

- Diabetes Guides

IDC = International Diabetes Center

- The Activity Pyramid
- The Life Balance Pyramid

State Smoking Cessation Resources

- CA: http://www.nobutts.org/
- MI: http://www.michigan.gov/healthymichigan/0,4675,7-216-33084_33091_33302---,00.html
- TX: http://www.yesquit.org

Appendix J – Screening Results Form [English]

Thank you for having your blood sugar and/or hemoglobin A1c (A1C) checked here today. Your A1C tells you what your average blood sugar was for the last three months. If your A1C is high, you may have diabetes. For people who already have diabetes, a common goal is to have an A1C close to 7%.

Your blood sugar is: _____ mg/dL (normal is 70 – 160)

Your A1C is: _____ %

[ ] This is normal (A1C 5.6% or less).

[ ] This is a little high (A1C 5.7% - 6.4%). You may have pre-diabetes. We suggest you see your doctor to find out for sure whether you have pre-diabetes.

[ ] This is high (A1C 6.5% or higher). You may have diabetes. We suggest you see your doctor to find out for sure whether you have diabetes.

Your A1C test result is <u>not</u> a diagnosis of pre-diabetes or diabetes. Only a doctor can tell you whether you have pre-diabetes or diabetes, or if your diabetes is well-controlled. Please see the back of this form for information about community health care centers and additional food resources.

(Site Specific Information)

Food Resources

- **Food Bank:**
- **SNAP:**
- Special Nutrition Program for Women, Infants, and Children (**WIC**):

Community Health Centers & Programs

- Clinic 1
- Clinic 2
- Clinic 3
- Clinic 4
- Local DPP
- Local DSME Program

Appendix K – Screening Results Form [Spanish]

Gracias por haberse verificado los niveles de azúcar en la sangre y de hemoglobina A1c (A1C) hoy. Su A1C le dice su promedio del nivel de azúcar durante los últimos tres meses. Si su A1C es alto, es posible que usted tenga diabetes. Para las personas que ya tienen diabetes, un objetivo común es tener un A1C cerca de 7%.

El nivel de azúcar en su sangre es: _____ mg/dL (normal es 70 – 160)

Su A1C es: _____ %

[ ] Esto es normal (A1C 5.6% o menos).

[ ] Esto es un poco alto (A1C 5.7% - 6.4%). Es posible que usted tenga pre-diabetes. Le sugerimos que visite su doctor para averiguar si usted tiene pre-diabetes.

[ ] Esto es alto (A1C 6.5% o más alto). Usted puede tener diabetes. Le sugerimos que visite su doctor para averiguar si usted tiene diabetes.

Su A1C resultado de la prueba no es un diagnóstico de pre-diabetes o diabetes. Solo un doctor le puede decir si tiene pre-diabetes o diabetes, o si su diabetes está bien controlada. Por favor consulte la parte atrás de esta forma para información sobre centros comunitarios de salud y más recursos para comida.

(Site Specific Information)

Recursos de Comida

- **Banco de alimentos o despensa: Food Bank:**
- **SNAP (estampillas para comida)**:
- Programa de Nutrición Suplementar para Mujeres, Bebes, y Niños (**WIC**):

Centros y Programas de Salud en la Comunidad

- Clinic 1
- Clinic 2
- Clinic 3
- Clinic 4
- Local DPP
- Local DSME Program

Appendix L – GE100 Blood Glucose Monitor User Manual

(Refer to User Manual.)

Appendix M – GE100 Getting Started Guide

(Refer to Guide.)

Appendix N – A1CNow+ Professional Procedure Guide

(Refer to Procedure Guide.)

Appendix O – DRAFT Food Bank – Clinic MOU

(Food Bank Logo)

MEMORANDUM OF UNDERSTANDING

THE XXX FOOD BANK
Street Address
City, State, Zip Code
Phone, Fax

and

COMMUNITY HEALTH CENTER
Street Address
City, State, Zip Code
Phone, Fax

EFFECTIVE DATES: January 1, 2016 to December 31, 2017

Part I: Introduction

This Memorandum of Understanding between the **XXX Food Bank**, hereinafter referred to as the FOOD BANK, and the **XXX Community Health Center**, hereinafter referred to as The Organization, outlines policies and procedures related to the **Feeding America Intervention Trial For Health - Diabetes Mellitus (FAITH-DM)**, an IRB-approved randomized controlled trial with an intervention that includes the distribution of healthy food boxes, fresh produce, and diabetes education to low-income, food insecure individuals ages 18 or older, and maintains a referral system with community health care organizations for clients diagnosed with or at risk for type 2 diabetes.

Part II: Term and Termination

This agreement shall be effective for the period from **January 1, 2016** to **December 31, 2017**, and may be extended thereafter upon mutual consent of the parties in writing. Either party may terminate this agreement by giving at least thirty (30) days written notice. This written notice will include closeout responsibilities, procedures, and timelines.

The Food Bank and the Organization and its designated representative(s) agree to the guidelines and procedures set forth here:

Part III: Description of Work: The Organization

Patient Referrals

1. If the Organization accepts direct referrals, the FOOD BANK will refer clients directly to the Organization for a new patient appointment, or (if the client has already established care with the Organization) for a follow-up appointment using the following process:
    a. For food bank clients needing primary care who are referred from FOOD BANK to The Organization, The Organization agrees to attempt to contact clients within 2 weeks of receiving the referral from FOOD BANK in order to schedule a new patient appointment for the referred clients to be seen at The Organization.
        i. The Organization agrees to attempt to schedule new patient appointments for referred clients to take place within 3 months from date of referral.
        ii. For clients referred from the FOOD BANK with blood glucose results between 240 mg/dL – 399 mg/dL, or HbA1c results 9.0% - 12.9%, The Organization agrees to attempt contacting the clients within 1 week of referral to schedule a new appointment that will take place within 1 month from the date of referral.
        iii. For clients referred from the FOOD BANK with a blood glucose result > 400 mg/dL, or with an HbA1c result > 13%, The Organization agrees to attempt contacting the client within 24-48 hours of referral to schedule a new appointment that will take place within 1 week from the date of referral.
    b. The Organization will identify a staff person(s) that can be contacted by FOOD BANK staff so that study staff can verify The Organization attempted to contact and schedule appointments with clients referred for care from the FOOD BANK.
2. If the Organization does NOT accept direct referrals from any agency, then the FOOD BANK will provide clients needing care with written information, verbal instructions, and encouragement for the client to make a new appointment with their existing PCP or a new patient appointment at the Organization by using the Organization's existing patient appointment scheduling process.
3. The Organization can implement a process to identify any existing clinic patients who may be food-insecure or at risk for food-insecurity, and who may benefit from resources organized and/or managed by the FOOD BANK.
    a. See attached document: *FAITH-DM FI Clinical Training Brief* for detailed information on how to screen patients for food insecurity and refer patients into the local hunger safety net.
4. The Organization will refer clinic patients to the FOOD BANK via existing food bank protocols for referrals.
5. NOTE: The Organization can **NOT** refer clinic patients directly into the FAITH-DM trial.
    a. For Organization patients with diagnosed type 2 diabetes referred from the clinic to the FOOD BANK, FAITH-DM staff will use existing study protocols to recruit and enroll clients into the FAITH-DM trial.
6. When requested (but no more than quarterly), The Organization will provide FOOD BANK with data on referral processes and on FOOD BANK-referred clients that establish care with The Organization.

Health Care Utilization Analysis

7. The FAITH-DM study includes a Health Care Utilization (HCU) Analysis to examine health care utilization patterns for both treatment and control group participants. Study participants will be asked to provide HIPAA Authorization and a Medical Records Release for their primary care providers (PCP) to release information from their medical records to FAITH-DM study staff.

8. The Organization will receive surveys to complete for their patients who are participating in the FAITH-DM study:
    a. HCUS: survey requesting patient visit information for a continuous twelve-month period (six months of visit information prior to the participant's enrollment, and six months of visit information during the patient's participation in the study)
    b. HCUS: follow-up survey requesting patient visit information for a six-month period after the patient's participation in the intervention (*if study is extended*)
9. The HCU surveys will have similar information requests that include: CPT and diagnostic codes for primary care visits, hospital admissions and discharges, Emergency Room admissions and discharges, missed primary care appointments, and other medical record information.
10. The Organization agrees to complete all Health Care Utilization surveys for FAITH-DM study participants per project guidelines.
    a. Surveys are designed so that Medical Records and/or administrative staff can complete all surveys (no PCP time is required to complete surveys)
    b. For each study participant who is also a patient at the Organization, the FOOD BANK will send a survey packet to the Organization that includes: informational letter, provider survey, and instructions on how to complete the survey
    c. The Organization agrees to complete and return completed surveys to the FOOD BANK within 1 month of receiving the original request
        i. Specific instructions on how to return each survey (fax information, email information, etc.) will be included with each survey request sent by the FOOD BANK
11. The Organization will track all surveys completed and returned to the FAITH-DM staff, and submit a quarterly invoice to the FOOD BANK for payment related to medical record data extraction requests.
    a. The Organization will receive **$20 per completed survey** / medical record extraction request

Project Administration

12. The Organization agrees to be listed in future publications as a participating partner site in the FAITH-DM study.

Part IV: Description of Work: FOOD BANK

Patient Referrals

1. If the FOOD BANK accepts direct referrals from organizations:
    a. Upon receiving a patient referral from The Organization, the FOOD BANK will be responsible for contacting the patient per existing food bank protocols to assess eligibility for participation in any food bank or partner agency food program.
    b. The FOOD BANK will make at least three (3) attempts to contact the referred patient. If the FOOD BANK is unable to contact the patient, or if the patient declines to participate in any food distribution / pantry program, then the referral will be closed and the FOOD BANK will notify The Organization that the referral was closed.
2. FOOD BANK FAITH-DM staff will screen food bank clients for type 2 diabetes risk and control at existing food distribution sites using Point-of-Care blood glucose and HbA1c testing.
3. If the Organization accepts direct referrals, the FOOD BANK will refer clients to The Organization who are assessed as being at risk (HbA1c result ≥ 5.7%) and who state they are without a primary medical provider. By identifying and referring these clients, the FOOD BANK aims to facilitate a

process for clients to establish medical care and receive follow-up evaluation regarding diabetes risk and/or health status.

   a. For food bank clients with an HbA1c result ≥ 9.0%, The FOOD BANK will refer clients to The Organization if they state they are without a primary medical provider (and live within The Organization's service area), or if they state that they already receive care at The Organization.
   b. The FOOD BANK will complete a "Screening and Referral Form" indicating the dates of screenings, HbA1c and other screening results, and additional client information for food pantry clients not enrolled in the FAITH-DM trial (see attached document: *FAITH-DM Screening and Referral Form*)
   c. The FOOD BANK shall obtain client consent to share Protected Health Information (PHI) with The Organization.
   d. The FOOD BANK will fax completed referral forms to The Organization.

4. If the Organization does NOT accept direct referrals from any agency, then the FOOD BANK will provide clients needing care with written information, verbal instructions, and encouragement for the client to make a new appointment with their existing PCP or a new patient appointment at the Organization by using the Organization's existing patient appointment scheduling process.
5. The FOOD BANK will implement an Emergency Action Plan if during a screening event, food distribution, or education activity, a client is identified as needing medical attention. In the event of a client emergency, FOOD BANK staff will implement study procedures, and/or contact 911 to activate the local emergency response system.
6. In order to evaluate project effectiveness, the FOOD BANK will be tracking client data for the duration of the FAITH-DM study. The FOOD BANK will comply with the Health Insurance Portability and Accountability Act (HIPAA) and existing laws and regulations regarding client privacy and Protected Health Information (PHI). The FOOD BANK will maintain appropriate safeguards to secure PHI.

Health Care Utilization Analysis

7. FAITH-DM staff will obtain participant consent, HIPAA authorization, and a Medical Records release to receive patient medical record information from The Organization.
8. FAITH-DM staff will send (via fax, mail, or hand delivery) The Organization patient-specific packets that include: background information on the project's Health Care Utilization (HCU) Analysis, copy of patient's HIPAA authorization and Medical Records release forms, and provider survey to be completed by The Organization's staff.
9. The FOOD BANK agrees to pay The Organization $20 for each medical record request fulfilled (completed survey).
   a. The FOOD BANK will submit payments to The Organization quarterly.

Project Administration

10. The FOOD BANK agrees to share any data and study results with The Organization, as long as the data and results are shared in formats and at times that adhere to FAITH-DM study guidelines.
11. This memorandum supersedes all previous agreements, including scopes of works and timeframes included therein, between FOOD BANK and The Organization regarding participation in the FAITH-DM study.

Part V: Signatures

_____

Name, Title Date
Community Health Center

_____

Name, Executive Director Date
XXXXX Food Bank

Documents:
FAITH-DM Food Insecurity Training Brief
FAITH-DM Screening and Referral Form

Appendix P – Food Insecurity Training Brief (for Clinic Partners)

Clinical Training: Food Insecurity Screening

Background

The USDA defines food insecurity (FI) as a household-level economic and social condition of limited or uncertain access to adequate food. "Adequate" refers to the quantity or quality of food for all household members to maintain an active lifestyle at all times. In contrast, hunger is an individual-level physiological condition (a physical discomfort from lack of food) that may result from food insecurity.[1] The USDA recognizes two levels of food insecurity, which they refer to as "low" and "very low" food security. Households reporting more severe difficulty accessing food—such as missing meals, losing weight, or going an entire day without eating—are considered very low food secure.

Feeding America reports[2]:

- In 2013, 14.3% of U.S. households (17.5 million households) were food insecure
- In 2013, 49.1 million Americans lived in food insecure households (33.3 million adults and 15.8 million children)
- In 2013, 5.6% of households (6.9 million households) experienced very low food security
- In 2013, households with children reported food insecurity at a significantly higher rate than those without children, 19.5% compared to 11.9%
- In 2013, households that had higher rates of food insecurity than the national average included households with children (19.5%), especially households with children headed by single women (34.4%) or single men (23.1%), Black non-Hispanic households (26.1%) and Hispanic households (23.7%)
- In 2013, 5.4 million seniors (over age 60), or 9.0% of all seniors were food insecure

(LOCAL DATA) According to the (NAME) Food Bank, 1 out of 6 (NAME) County residents are food insecure. This translates to more than (NUMBER) residents in need of food assistance each month.

Impact of Food Insecurity – Why Screen?

Food insecurity is a major public health problem. Family members in food insecure households are more likely to report poorer health and depressive symptoms, and have higher risks for chronic diseases like obesity, hypertension, and diabetes. Food insecure patients managing chronic diseases like diabetes are also more likely to have worse control (e.g., elevated HbA1c levels) potentially leading to poorer health outcomes.[3] FI also negatively impacts children's health and development status and increases risk for iron-deficiency anemia, acute infection, chronic illness, hospitalization, and developmental and mental health problems.[4,5] Identification of FI and referral to appropriate nutrition and support services can help to prevent illness, support patients in chronic disease management, and promote wellness.

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[1] USDA Economic Research Service. 2013. Definitions of Food Security. Accessed at: http://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us/definitions-of-food-security.aspx#.Uz8lwPldXTo

[2] Feeding America. 2014. Hunger and Poverty Statistics. Accessed at: http://feedingamerica.org/hunger-in-america/hunger-facts/hunger-and-poverty-statistics.aspx

[3] Seligman et al. 2012. Food insecurity and glycemic control among low-income patients with type 2 diabetes. *Diabetes Care*,35,233-238.

[4] Seligman et al. 2010. Food insecurity is associated with chronic disease among low-income NHANES participants. *J Nutr*,140,304-310.

[5] Hager et al. 2010. Development and validity of a 2-item screen to identify families at risk for food insecurity. *Pediatrics*, 126, e26-e32.

Clinical Setting

Screening for FI is appropriate and warranted in the clinical setting, especially in environments where a significant percentage of the patient population has been identified as low-income. FI screening can be fast and incorporated as a standardized protocol into existing patient intake procedures. Because food insecurity is often cyclical in nature with alternating periods of food access and food scarcity, screening should be included as a standard part of care during each patient visit. Medical assistants, nursing assistants, nurses, and other clinical staff are all well-positioned to implement FI screening.

Two-Item Food Insecurity Screener

This 2-item FI screen is based on Questions 1 & 2 of the U.S. Household Food Security Survey and is sensitive (97%), specific (83%), and valid among low-income families with children.[6] The FI screen quickly identifies households at risk for FI, enabling providers to target services that address the health and developmental consequences of FI.

I'm going to read you two statements that people have made about their food situation. For each statement, please tell me whether the statement was **often true**, **sometimes true**, or **never true** for your household in the last 12 months.

1. "We worried whether our food would run out before we got money to buy more." Was that often true, sometimes true, or never true for your household in the last 12 months?

2. "The food that we bought just didn't last and we didn't have money to get more." Was that often, sometimes, or never true for your household in the last 12 months?

A response of "often true" or "sometimes true" to either question = positive screen for FI.

Implementation

- Utilize and train clinical staff (MA, CNA, RN) to conduct FI screening
- Screen every patient at every visit
- Include positive screen note for review and discussion by patient's PCP, social worker, or other health care provider as part of visit
- Consider clinical assessment of health-related consequences of FI during patient visit
- Provide nutrition resources (for example, referrals to food banks and their partner food pantries or meal programs, the Supplemental Nutrition Assistance Program (SNAP, formerly known as food stamps), the Special Supplemental Nutrition Program for Women, Infant and (WIC) and senior feeding programs Assess for referrals and clinical action (dietitian, social worker, psych, vitamin supplementation)
- Use existing documentation processes and Electronic Health Records systems to track referrals and individual and aggregate clinic data

Resources

Food Bank Referral Line: **###-###-####** & website:
SNAP: (number, website, etc.)
WIC: (number, website, etc.)
USDA Food Insecurity: http://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-us.aspx#.U0gZGPldXTo

[6] Hager et al. 2010. Development and validity of a 2-item screen to identify families at risk for food insecurity. *Pediatrics*, 126, e26-e32.

Appendix Q – GE100 Quality Control Log

GE100 Quality Control Log

Site:

Project Lead:

STAFF INITIALS	DATE	TEST NAME	TEST LOT NUMBER / EXPIRATION DATE	NORMAL LEVEL CONTROL	COMMENTS
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	
		GE100 (Blood Glucose)		Range: Result:	

Form adapted from: http://wwwn.cdc.gov/clia/Resources/WaivedTests/pdf/14_248840-A_Stang_RST_Booklet_508.pdf **NOTES:

Appendix R – A1C+Now Quality Control Log

Site:
Project Lead:

FAITH DM

Staff Initials	Date	Test Name	Test Lot Number / Test Expiration Date	Level 1 Control	Level 2 Control	Comments
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	
		A1C+Now (HbA1c)		Lot #: Range: Result:	Lot #: Range: Result:	

Appendix S – Medical Waste Tracking Log

Medical Waste Tracking Log
OFF-SITE TREATMENT

Facility Name:

Facility Address:

Program Contact:

START DATE	CONTAINER	DATE FULL	DATE SHIPPED	MEDICAL WASTE CO.	DATE TREATED	STAFF INITIALS
(Example) 09/12/15	1-gallon sharps	10/21/15	10/25/15	SHARPS Compliance, Inc.	11/09/15	JD

NOTES:

Appendix T – The Informed Consent Process

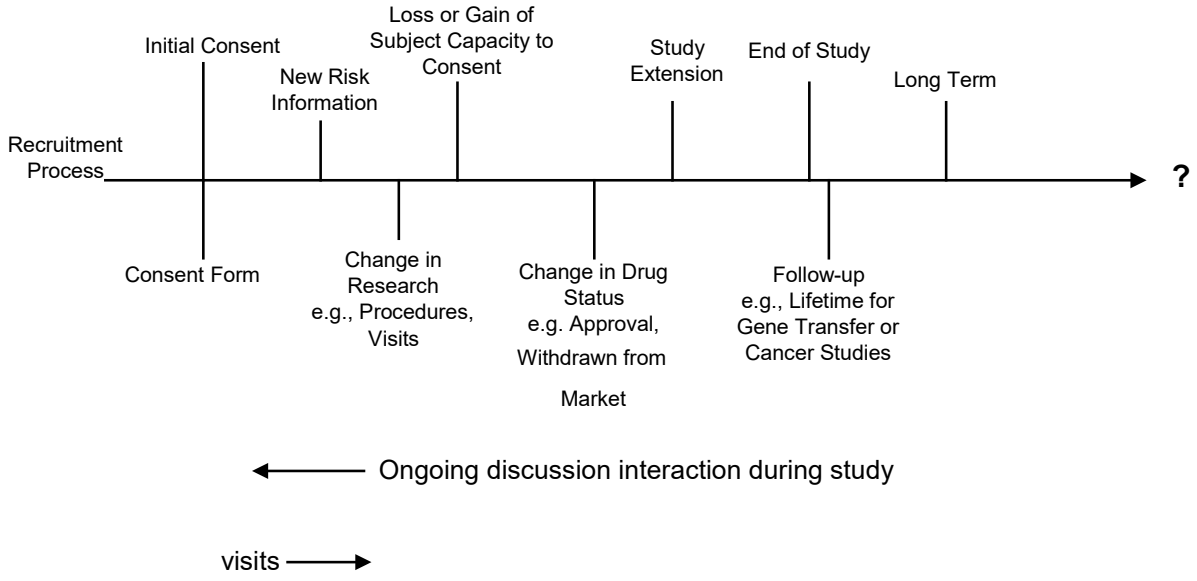
(Adapted from Western Institutional Review Board, "Guide for Researchers 3/9/2015")

The informed consent process is central to the ethical conduct of research. It is an ongoing conversation between the human research subject and the researchers that begins before consent is given and continues until the end of the subject's involvement in the research (see consent process diagram, below). There are various tools for the investigator to use to optimize this conversation, but the most important feature of informed consent is the investigator commitment to the process.

A. Goals of the informed consent process:

- Give the subject **information** about the research
- Make sure the subject has **time** to consider all options
- Answer all of the subject's **questions** before the decision is made
- Make sure that all information is **understood** by the subject
- Obtain the subject's voluntary informed **consent** to participate
- **Continue to inform** the subject throughout the research study
- **Continue to re-affirm subject consent** to participate throughout the research study

B. Consent Process Diagram



C. Tools an investigator might use to assist the informed consent process

- Consent Form -- also called Informed Consent Form (ICF), Informed Consent Document (ICD) or Patient Consent Form (PCF)*

- Pamphlets or other reading materials*
- Internet information*
- Instruction sheets*
- Audio-visual presentations*
- Charts or diagrams*
- Discussions
- Consultation with others

** These items require IRB review before use.*

D. Investigator responsibilities in regard to informed consent

- Obtain consent before initiating study-specific procedures.
- Provide a **quiet, comfortable, and private setting** for the informed consent process whenever possible.
- **Explain** the consent process to the subject.
- Make sure the subject has **time to consider** all options; allow subject to take the form home before signing (whenever possible).
- Consider the **subject's reading abilities**. Check to make sure the protocol does not exclude subjects unable to read. If enrollment of limited or nonreaders is allowed, involve an impartial witness in the informed consent process. WIRB has posted a standard generic form you can use to document the involvement of an impartial witness if your approved consent form lacks the necessary signature block for that; see the Download Forms page of www.wirb.com for the document titled "Impartial Witness form for Limited and Non-Readers."
- **Answer all questions.**
- To the extent possible, make sure the subject **understands enough information** about the research study to give informed consent.
- To the extent possible, make sure the subject can consent **free from coercion or other undue influence**.
- Since the informed consent process continues throughout the subject's participation in the study, c**onsent should be informally verified on a continuing basis.**
- **Significant new information** must be given to the subject, and continuing consent documented in some way; for example, new risk information presented to the subjected in an addendum to be signed by subjects who agree to continue to participate.

E. Issues to consider during the consent process

- Was the subject alert and, in your opinion, able to read and understand the language in the consent form?
- If the subject was unable to read the consent form, and limited or non-readers were allowed to participate, did you have an impartial witness present for the

entire process? (An impartial witness is someone with adequate reading ability who is independent of the trial, who cannot be unfairly influenced by people involved in the trial, who attends the informed consent process while the consent form is being read to the subject, who reads the informed consent form and any other written information supplied to the subject, and who is
willing to attest to this by signing the consent form.)

- If the subject is not fluent in English, was an approved translation of the consent form provided in the primary language of the subject? Was there also a bilingual translator present to assist with the informed consent process? Note: a translator alone is not considered adequate.
- Was the subject under any pressure (for example, family pressure, lack of medical insurance) to participate in the research? Was this discussed?
- Did the subject take time to carefully read the consent form, or read it along with you?
- Were the risks as set forth in the consent form carefully explained to the subject?
- Are there any other risks or concerns not stated in the consent form and were these explained to the subject?
- Was the subject asked if he or she had any questions about the study?
    - Did the subject have any questions or concerns?
    - Were the subject's questions answered?
    - Was the subject satisfied with the answer(s) they were provided?
- Did the person conducting the consent discussion check for subject understanding by asking some basic questions about the research? Did the responses reflect adequate understanding?
- Did the subject express a clear decision to proceed with the study?
- Was the consent form signed by the person who conducted the informed consent discussion?
- Was the consent form signed by a witness (if required)?
- Was the consent form signed by the Principal Investigator (if required)?
- If a Legally Authorized Representative is allowed to sign for the subject, were additional concerns about the subject's understanding and assent considered and addressed?

F. Consent by Legally Authorized Representatives

The laws regulating who can consent for *adults* who lack the capacity to consent for themselves are defined at the state level and vary from state to state. Persons who can consent for adults who lack the capacity to personally provide informed consent are known as Legally Authorized Representatives (LARs). See 45 CFR 46.102(c) and 21 CFR 50.3(l). Such trials, unless an exception is justified, should be conducted in individuals having a disease or condition for which the investigational product is intended.

WIRB's initial review submission forms solicit information about plans for use of LARs from investigators who plan to enroll adults who lack the capacity to consent for themselves. Sites should be able to explain how they determine which individuals meet the criteria for being a Legally Authorized Representative (LAR) under their state/provincial and local law. WIRB can provide a copy of the relevant statutes for your state upon request; however, advice from your legal counsel is strongly recommended. Sites should also be able to explain the process they use for verifying that an individual is qualified to serve as an LAR.

Appendix U – Participant Baseline Survey

(See attached survey.)

Appendix V1 – Participant T6 Follow-Up Survey, Intervention Group

(See attached survey.)

Appendix V2 – Participant T6 Follow-Up Survey, Control Group

(See attached survey.)

Appendix W1 – Participant T12 Follow-up Survey, Intervention Group

(See attached survey.)

Appendix W2 – Participant T12 Follow-up Survey, Control Group

(See attached survey.)

Appendix X – HIPAA Authorization Form

(See attached form.)

Appendix Y – Health Care Utilization Provider Letters (1-8)

(See attached documents.)

Appendix Z – Health Care Utilization Survey (HCUS)

(See attached survey.)

Appendix AB – HIPAA Fax Cover Sheet

HEALTH INFORMATION
FAX COVER SHEET

Date: _____

From: _____

Fax #: _____ Phone#: _____

Cover Sheet plus _____ pages

Comments:

TO: _____

Fax #: _____

IMPORTANT: This facsimile transmission contains confidential information, some or all of which may be protected health information as defined by the federal Health Insurance Portability & Accountability Act (HIPAA) Privacy Rule. This transmission is intended for the exclusive use of the individual or entity to whom it is addressed and may contain information that is proprietary, privileged, confidential and/or exempt from disclosure under applicable law. If you are not the intended recipient (or an employee or agent responsible for delivering this facsimile transmission to the intended recipient), you are hereby notified that any disclosure, dissemination, distribution or copying of this information is strictly prohibited and may be subject to legal restriction or sanction.

If you have received this transmission in error, please notify the sender by telephone (number listed above) to arrange the return or destruction of the information and all copies.

Appendix AC – FAITH-DM DSME Program Curriculum

(See attached materials.)

Appendix AD – Education Class Reminder Postcard

FAITH DM | Feeding America Intervention Trial For Health
Diabetes Mellitus

The diabetes classes offered by **Alameda County Community Food Bank** are a good way for you to learn more about controlling your diabetes. You are signed up for the

NAME OF CLASS // TIME & LOCATION

We encourage you to bring a friend or family member.

We look forward to seeing you there! If you have any questions, call

CONTACT FOOD BANK INFO

ALAMEDA COUNTY COMMUNITY FOOD BANK
PO BOX 2599
OAKLAND, CA 94614

ALAMEDA COUNTY COMMUNITY FOOD BANK
MEMBER OF FEEDING AMERICA

Appendix AE – FAITH-DM Informed Consent Form

(See attached form.)

Appendix AI – FAITH-DM Screening and Referral Form

FAITH DM | Feeding America Intervention Trial For Health Diabetes Mellitus

Screening and Referral Form

Date: _____ Client Name: _____
Date of Birth: _____ Client Phone: _____

A. Health Screening

Blood Glucose: _____ mg/dL ☐ Fasting ☐ Random

HbA1c: _____ % (Finger-stick sample A1CNow+ System)

Client-Reported Health History:
☐ Pre-DM ☐ GDM ☐ T1DM ☐ T2DM
☐ No known history of diabetes

Has healthcare source or PCP? ☐ Yes ☐ No

Clinic / Practice Name: _____

PCP Name: _____

Food Bank
Referring Staff Name: _____

Referring Staff Phone: _____

NOTES:

B. Referral

☐ Referral from Food Bank to clinic / provider:

_____

☐ Other (e.g., Emergency Room referral):

_____

Preferred Language

☐ English ☐ Spanish ☐ Other:

Client Consent to Release Information:
I give my consent to the (NAME) Food Bank to share information about my screening results and the other information on this form with my doctor or a health care center.

Doy mi consentimiento para el (NAME) Food Bank para compartir información sobre los resultados de mis pruebas y el otro información en esta forma con mi médico o un centro de salud.

_____
Client Signature / Firma

_____
Date / Fecha

Food Bank
FAITH-DM Manager:
Street, City, State, Zip
T: ###-###-####; Fax: ###-###-####
Email:

Appendix AJ – Sample Recruitment Flyer

Food Bank Logo

RESEARCH STUDY

The **[Food Bank]** has partnered with Feeding America, the University of California San Francisco, and the Urban Institute to conduct a 2-year research study looking at how food bank programs may be able to help adults living with type 2 diabetes. We are now recruiting people to participate in the study.

Who is eligible?

Adults (18 years old and up)
Have type 2 diabetes
Food pantry client
Speak English or Spanish
Will stay in the study area for at least the next year

What will you be asked to do?

Complete 3 surveys over the next 12 months (each survey takes about 30 minutes)
Do blood sugar and A1c tests 4 times over 12 months (using a drop of blood from your finger)
Pick up 2 free healthy food boxes a month for 6 months
You may be asked to attend 2 group diabetes classes (2 hours each)

Compensation

You will receive $45 in gift cards for participating in this study.

If you have any questions or are interested in participating, please contact:
Food Bank FAITH-DM staff at (###) ###-####

FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####
FAITH-DM Research Study Phone: (###) ###-####

Appendix AK – Education Handouts for Screening

Education Handouts for Screening

Notes:

- Every food bank client who participates in blood glucose and/or A1C screening will receive a "Screening Results Form" that includes testing results, local health care information, and local food resource information
- For clients who enroll in study, see *FAITH-DM Passive Education Materials Schedule* for education materials that participants receive

SCREENING CATEGORY	RESOURCE	NOTES
Food bank clients with no diabetes history and normal blood glucose results	No additional educational resources	
Clients with elevated BG results (≥140 mg/dL fasting or ≥160 mg/dL random), but with an A1C result that is < 5.7%	USDA MyPlate Handout (Learning Zone Express) https://www.learningzonexpress.com/p-1386-usda-myplate-handouts.aspx	English, Spanish 2-sided tear pad (8.5 x 11) $11.95 per 50 sheets ($0.24/ea.)
Clients with an A1C result in pre-diabetes range (5.7% - 6.4%)	"All About Your Risk for Pre-diabetes, Type 2 Diabetes, and Heart Disease" (ADA resource) -AND- Diabetes MyPlate Handouts (Learning Zone Express) https://www.learningzonexpress.com/p-1708-diabetes-myplate-handouts.aspx	English, Spanish 2-sided 8.5 x 11; requires FB sites to print English, Spanish 2-sided tear pad (8.5 x 11) $11.95 per 50 sheets ($0.24/ea.)
Clients with an A1C result of 6.5% - 7.4% (diabetes, controlled)	"Taking Care of Type 2 Diabetes" (ADA resource) -AND- Diabetes MyPlate Handouts (Learning Zone Express) https://www.learningzonexpress.com/p-1708-diabetes-myplate-handouts.aspx	English, Spanish 2-sided 8.5 x 11; requires FB sites to print English, Spanish 2-sided tear pad (8.5 x 11) $11.95 per 50 sheets ($0.24/ea.)
Clients with an A1C result ≥ 7.5% (but who do not enroll in study for whatever reason)	ACP Living With Diabetes Guides	English, Spanish 60-page printed booklet $64 per box of 40 ($1.60/ea.)

Appendix AL – Participant Compensation Receipt Form

FAITH DM | Feeding America Intervention Trial For Health Diabetes Mellitus

Participant Compensation Receipt Form

Date / Fecha: _____

Participant Name / Nombre de Participante: _____

Activity / Actividad: survey / encuesta

I CERTIFY THAT I HAVE RECEIVED A GIFT CARD FROM THE XXXX FOOD BANK IN THE AMOUNT OF $ _____FOR MY PARTICIPATION IN THE FAITH-DM PROJECT. THE GIFT CARD HAS BEEN GIVEN TO ME IN PERSON DURING OR AFTER THE RESEARCH ACTIVITIES IN WHICH I PARTICIPATED.

CERTIFICO QUE HE RECIBIDO UNA TARJETA DE REGALO DE LA XXXX BANCO DE ALIMENTOS POR LA CANTIDAD DE $ _____ POR MI PARTICIPACIÓN EN EL PROYECTO FAITH-DM. LA TARJETA REGALO HA DADO A MÍ EN PERSONA DURANTE O DESPUÉS DE LAS ACTIVIDADES DE INVESTIGACIÓN EN LA QUE PARTICIPÉ.

SIGNATURE OF PARTICIPANT /
FIRMA DE PARTICIPANTE _____

ALTERNATE CERTIFICATION

TO BE USED WHEN OBTAINING PARTICIPANT SIGNATURE IS NOT POSSIBLE: I CERTIFY THAT THE ABOVE NAMED STUDY PARTICIPANT COMPLETED THE STUDY ACTIVITY AND IS DUE PAYMENT OF $ _____. A GIFT CARD WILL BE ISSUED AND MAILED TO THE PARTICIPANT'S HOME ADDRESS OR GIVEN IN PERSON TO THE PARTICIPANT.

Signature of FAITH-DM study staff person _____

Date gift card mailed: _____

INSTRUCTIONS

Study participants should be asked to sign this form for each study survey they complete. Per FAITH-DM study protocols, Control Group participants will receive a $15 gift card after completing the baseline survey, and a second $15 gift card after completing the T6 follow-up survey. Intervention Group participants will receive $30 in gift cards after completing the T6 follow-up survey. Participants in both groups will receive a final $15 gift card upon completion of the T12 follow-up survey.

Appendix AM – Participant Baseline Enrollment Form

Participant Baseline Enrollment Form

Item	Data	Notes
Interviewer's initials		
Participant ID		
Date Enrolled		
Enrollment site / pantry name		
Baseline HbA1c result (%)		
Household size	☐ 1 – 2 ☐ 3 – 4 ☐ 5+	
Age Category	☐ 18 – 40 ☐ 41 – 60 ☐ 61+	
Date of Birth		
Preferred Language	☐ English ☐ Spanish	
Consent signed	☐ Yes	
Participant given copy of consent	☐ Yes	
HIPPA release signed	☐ Yes	
Medical Records release signed	☐ Yes	
Baseline survey complete	☐ Yes	Timing:
Randomization assignment given	☐ Intervention ☐ Waitlist control	
Gift card given and receipt signed	☐ (Waitlist control only)	
Referral given	☐ Active (Int.) ☐ Passive (Control)	
Participant name (First, Middle, Last)		
Mailing Address		OK to send mail? ☐
Cellphone	☐ Yes:	OK to text? ☐ OK to leave VM? ☐ ☐ Any ☐ Non-confid.
Email	☐ Yes:	OK to send email? ☐ ☐ Any ☐ Non-confid.
Name of friend / spouse we can contact:		Relation:
Phone number of friend or spouse:		OK to call & lv. msg? ☐ ☐ Any ☐ Non-confid.
Is there another person we can contact:		Relation:
Phone number of 2nd contact:		OK to call & lv. msg? ☐ ☐ Any ☐ Non-confid.
Primary care provider name		Or No PCP ☐
PCP Clinic name		
Clinic address		
Clinic phone		

Appendix AN – Adverse Event Reporting Form

ADVERSE EVENT REPORTING FORM

Date: _____

Site: ☐ ACCFB ☐ GCFB ☐ HFB

Pantry Site / Location:

Person completing form:

List of people involved in incident:

If incident involves a pantry client, does the client report a history of diabetes? ☐ Yes ☐ No
If incident involves a pantry client, is the client a participant in the study? ☐ Yes ☐ No

If "Yes", Participant ID#: _____

Adverse Event:

- ☐ Low blood glucose (hypoglycemia: report and treat clients reporting a diabetes history)
- ☐ High blood glucose (hyperglycemia: report only when action is required for symptomatic clients)
- ☐ Reports of suicidality or homicidality
- ☐ Reports of elder abuse or neglect
- ☐ Reports of poor food quality
- ☐ Study related injury
- ☐ Other:

Description of Incident:

Action Taken:

Follow-up Action Required:

Date Reported to Study Coordinating Center (Morgan Smith, FANO): _____

Date Entered in MS Access (if event involved study participant): _____

Appendix AO – Medical Records Release Form

FAITH DM

AUTHORIZATION TO RELEASE/REQUEST MEDICAL INFORMATION

Name of Patient: _____

Maiden/Other Name: _____

Date of Birth: _____ Phone Number: _____

Patient Address:_____

City, State, Zip: _____

I authorize the following person/organization to release the health information described on this form:_____

Address: _____

City, State, Zip: _____

Phone_____ Fax _____

Who can receive and use this information?:

<Insert Food Bank Name, Address, Fax #, Phone # and Contact Person> and the FAITH-DM study

Specific type of information to be disclosed:

___Office Visit dates and summary

___History & Physical

___Inpatient hospitalization summary

___Emergency Room Discharge Summary

___Diabetes Care summary

___Insurance/Payor Information

___Other _____

Dates of requested information: From _____ To _____

The purpose and need for disclosure: *This individual is enrolled in a diabetes research study with <insert name of food bank>, Feeding America, University of California San Francisco, and Urban Institute. Medical information will be used as part of the study's health care utilization analysis.*

Your initials are required to release the following information:

_____Mental Health Records (excluding psychotherapy)

_____Genetic Information (including Genetic Test Results)

_____Drug, Alcohol, or Substance Abuse Records

_____ HIV/AIDS Test Results/Treatment

Right to Revoke: I understand that I have a right to revoke this authorization at any time. I understand that if I revoke this authorization, I must do so in writing and present my written revocation to the person/organization listed as authorized to release my records. They may have already released the information based on your original authorization. The releasing organization cannot release any additional information after receiving your revocation. Neither the releasing organization nor *<insert name of food bank>* will condition treatment or payment based on this authorization or revocation of authorization unless otherwise allowed by law.

Effective Time Period: Your protected health information will be disclosed as specified in this authorization. This authorization will expire after 36 months from the date of signature, or until we have completed the disclosure(s) you have requested, whichever is shorter. Research institutions that receive federal funds, such as the research institutions associated with the FAITH DM project (The Urban Institute and The University of California San Francisco) are prohibited from re-disclosing your information to others without your permission. If you have given permission for release of information to others not covered by federal or state privacy laws, the information could be subject to re-disclosure by the recipient and may then no longer be protected.

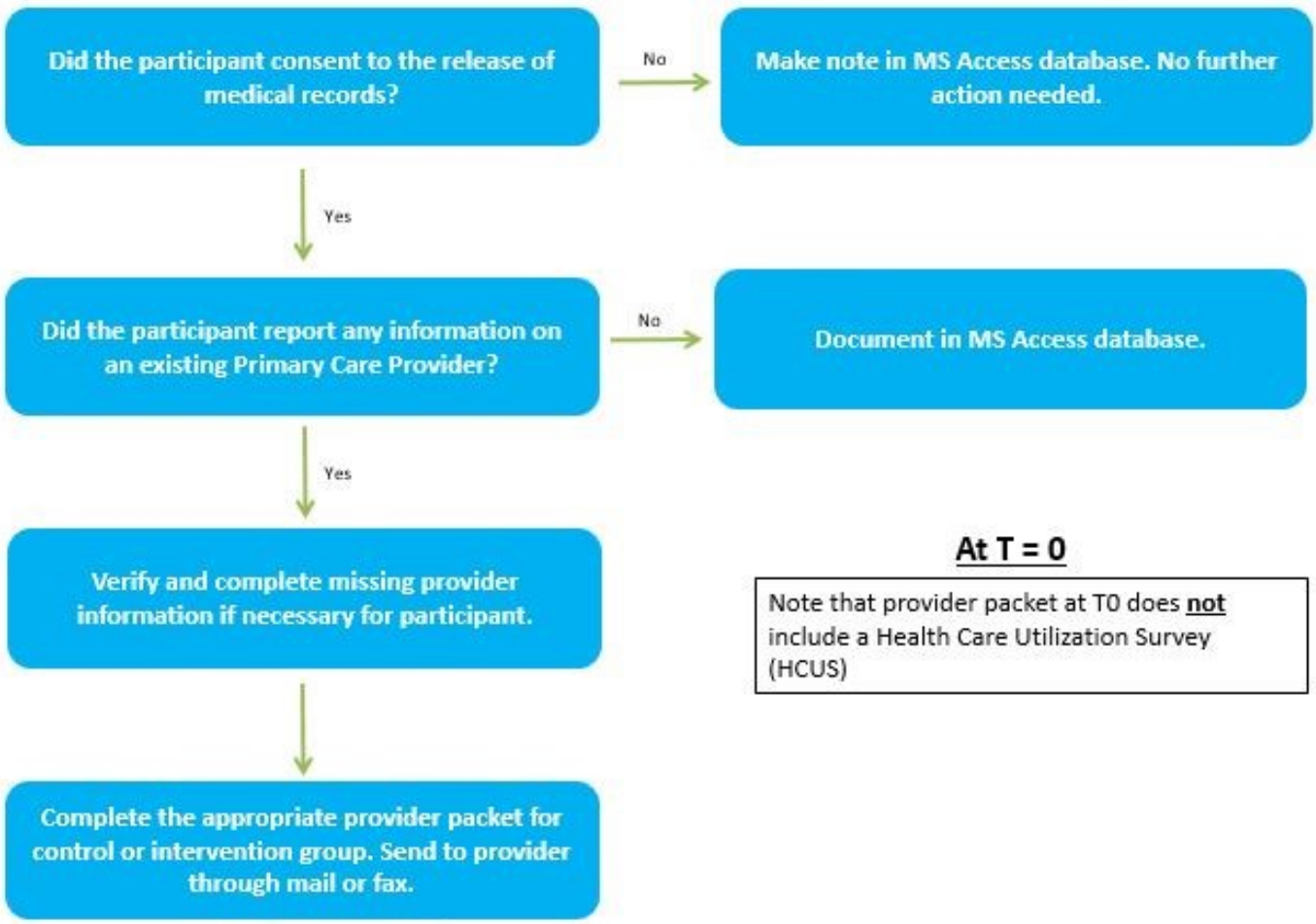
_____

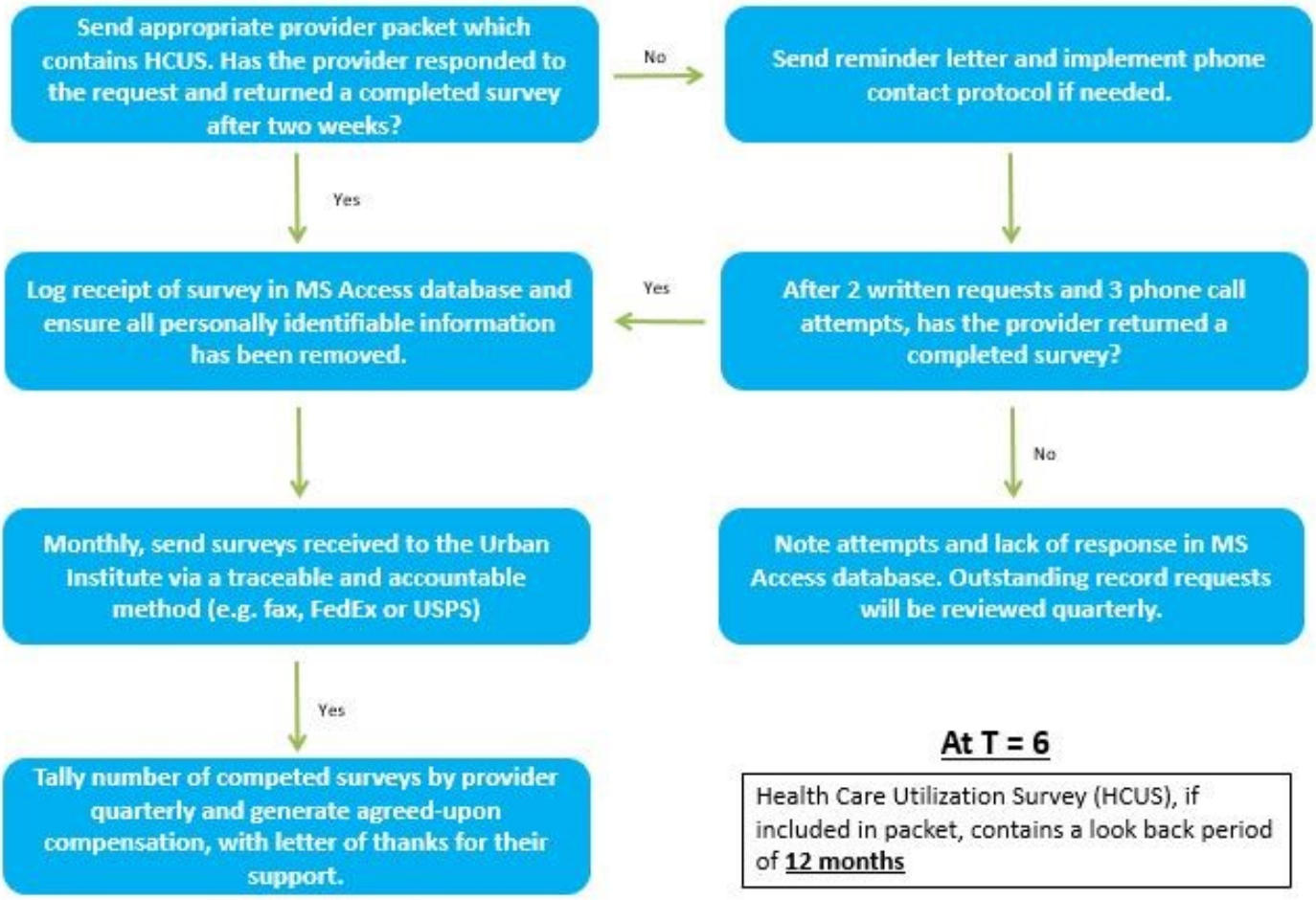
Name of Patient/Personal Representative (please print)

_____

Signature of Patient/Personal Representative Date

Appendix AP – HCUA Flowcharts





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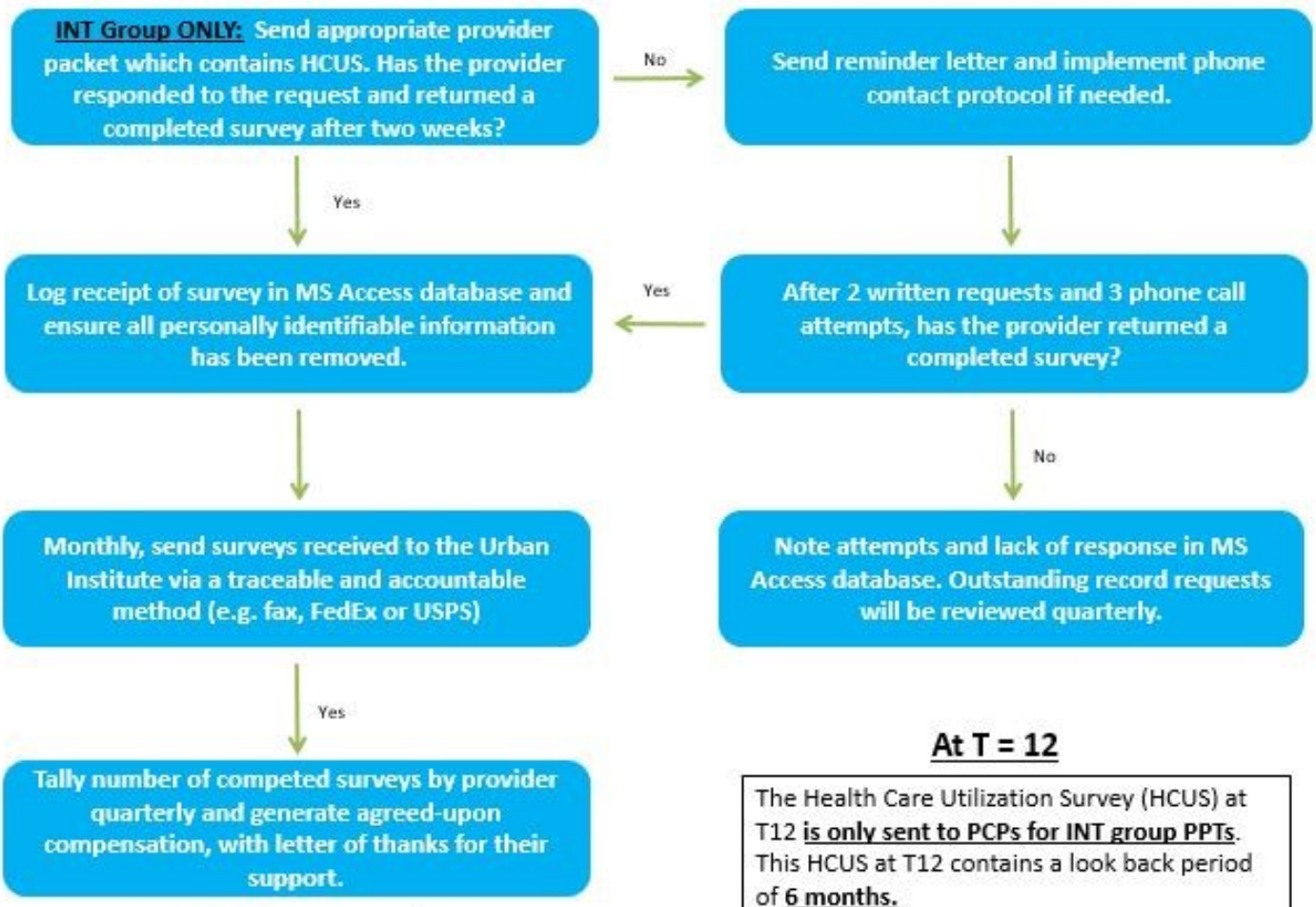

At T = 12

The Health Care Utilization Survey (HCUS) at T12 **is only sent to PCPs for INT group PPTs**. This HCUS at T12 contains a look back period of **6 months.**

FAITH DM | Feeding America Intervention Trial For Health Diabetes Mellitus

Appendix AQ – Study Flow Handout

FAITH DM | Feeding America Intervention Trial For Health Diabetes Mellitus

How a Participant Moves through the FAITH-DM Study

Food Pantry Client Screened
- Does client have *uncontrolled* type 2 diabetes (HbA1c ≥ 7.5%)?
- Does client meet study entry criteria?
- Does client want to participate in the study?

If "Yes" to all, client:
- Completes consents to participate
- Completes baseline survey
- Randomly assigned to either:
  - Intervention Group ***or*** Waitlist Control Group

Intervention Group
- Participant begins receiving diabetes food packages immediately
  - 2 times a month for six months
- Participant receives diabetes education
  - Handouts with each food package
  - Monthly group classes
  - Check-ins with staff at the pantry
- Participant referred to a doctor (if needed)
- Participant receives monitoring of HbA1c

Intervention Group
- After six months, participant completes blood test (HbA1c) and second survey
- At 12 months, participant completes final HbA1c test and last survey
- Participant exits study

FAIT DI is a year, randomized controlled trial to investigate how food bank interventions can support clients with type 2 diabetes. Feeding America has partnered with three member food banks, the University of California San Francisco, and the Urban Institut to run the tria

Waitlist Control Group
- Participant receives **normal** pantry services for six months

Waitlist Control Group
- After six months, participant completes blood test (HbA1c) and second survey
- Waitlist period over; participant begins program (modified intervention)

Waitlist Control Group
- Participant begins receiving diabetes food packages
  - 2 times a month for six months
- Participant receives diabetes education
  - Handouts with each food package
- Participant referred to a doctor (if needed)
- Participant receives monitoring of HbA1c

Waitlist Control Group
- At 12 months from enrollment participant completes final HbA1c test and last survey
- Participant exits study

Appendix AR – Screening Supplies

FAITH DM | Feeding America Intervention Trial For Health Diabetes Mellitus

Screening Supplies

Document Box	**Quantity (2 screeners)**
1. Screening Log	20
2. Screening Results (E/S)	100 each
3. Screening and Referral Form (for non-participants)	20
4. Education handouts	
a. Matrix (for study staff)	2
b. MyPlate (E/S)	25 each
c. ADA Risk handout *and* DM MyPlate (E/S)	10 each
d. ADA T2DM handout *and* DM MyPlate (E/S)	10 each
e. ACP Guides (E/S)	10 each
5. Participant Enrollment Form (paper)	20 each
6. Study Informed Consent Forms (E/S)	20 each
7. Medical Record Release Form	20
8. Randomization envelopes	20
9. Participant Compensation Receipt Form	20
10. MISC Forms	
a. Recruitment Flyers (E/S)	5 each
b. Protocol Deviation Form	5
c. Adverse Event Reporting Form	5
d. Passive Education Schedule	2
e. GE100 QC Log	1
f. A1C+Now QC Log	1
g. Medical Waste Tracking Log	1
h. Copy of CLIA certificate of waiver	
i. Copy of medical waste certificate (if applicable)	

Testing Supplies Boxes	Quantity (2 screeners)	Vendor
A1C+Now Kits	4 boxes (20 tests/box)	WM
GE100 Meters	4 meters	GE
Testing strips	4 boxes (50/box)	GE
Sharps containers	3 each (1 gallon)	SC
Hand Sanitizer	3 each	AM
Nitrile Gloves	3 boxes	AM
Alcohol prep pads	2 boxes	AM
Cotton balls	3 qt. zip lock bag (50 each)	AM
Lancets, 28G	1 box (200)	AM
Lancets, 21G	1 box (200)	AM
Band-Aids	1 box (50)	AM
Sani-wipes	1 each	AM
Dental Bibs	100 each	Amazon
Dex4 Glucose Tabs	10 each (10 count tubes)	Amazon
Boxes (e.g., wine)	2	misc. (for trash)
Trash bags	4	misc.

Vendor Key & Ordering Information

1. **WM**: Whitmire Medical, http://www.whitmiremedical.com/, Michael R. Falck, michael@whitmiremedical.com, 206.898.7444,
2. **GE**: GE Diabetes (Bionime Corporation), www.gediabetes.com, Katie Enright, Sales Representative, 919.451.0865, katie.enright@bionime.com
3. **SC**: Sharps Compliance, Inc., http://www.sharpsinc.com/, http://www.sharpsinc.com/store/medical-waste-recovery
    a. Three 1-gallon sharps recovery system: http://www.sharpsinc.com/store/three-1-gallon-sharps-recovery-system-94
4. **AM**: Allegro Medical, http://www.allegromedical.com/

Appendix AS – Cognitive Impairment Assessment Tool

FAITH DM | Feeding America Intervention Trial For Health Diabetes Mellitus

Cognitive Impairment: Decision-Making Capacity Assessment Tool

Instructions: This form may be used to assess the decision-making capacity of potential participants who may have or may be experiencing cognitive impairments.

Who should assess capacity? In general, the consent assessor should be a member of the research team or consultant familiar with dementias and/or cognitive impairment, and qualified to assess and monitor capacity to consent on an ongoing basis.

Potential Participant Name: _____

ASSESSMENT QUESTIONS:

1. Does the individual understand he/she would be participating in research and that research is voluntary?
   ☐ Yes ☐ No
2. Does the individual understand what will happen to him/her if he/she decides to participate?
   ☐ Yes ☐ No
3. Does the individual know how long he/she will be in the research study?
   ☐ Yes ☐ No
4. Can the individual explain one or two risks associated with the research study?
   ☐ Yes ☐ No
5. Can the individual explain what he/she should do to stop being in this research study?
   ☐ Yes ☐ No
6. Does the individual know who to contact if he/she experiences problems or has questions about the study?
   ☐ Yes ☐ No
7. Can the individual explain what alternatives there are if he/she chooses not to participate?
   ☐ Yes ☐ No

STUDY STAFF EVALUATION:

8. Does the individual express a choice about whether or not to participate?
   ☐ Yes ☐ No* *(Not eligible for study)*
9. Does the individual have the decision-making capacity to give informed consent for this study?
   ☐ Yes ☐ No* *(Not eligible for study)*

_____

Printed Name of Study Staff Signature of Study Staff Date

* NOTE: Potential participants who are found to have diminished capacity **must** be excluded from the study; document "ineligible due to cognitive impairment" in MS Access database and file this form in study binder.

Appendix AT – Data Collection Best Practices

Data Collection Best Practices

Compiled by Shavonnea Brown, MA, in November 2015
FAITH-DM Research Assistant at the Gleaners Community Food Bank (Detroit, MI)

1. Keep all forms organized
    a. Each form that has to be entered into Access should have its own folder
    b. Once each form has been completed put it into its respective folder—this reduces the risk of losing information
    c. As data is entered from each form keep a checklist of what has been entered
2. Familiarity with forms
    a. Give a brief demonstration to staff and volunteers about the purpose of each form
    b. Ensure that all staff and volunteers are familiar with each form and know where to find extra forms when needed
3. Collecting data
    a. When using the screening log form write the result(s) down immediately
        i. Be sure that the demographic information is filled in for each result that is recorded
        ii. Be sure that enrollment status is also filled in for eligible participants
        iii. If an eligible participant decides not to enroll, indicate why he or she declined
    b. Make sure there are enough copies of each form
    c. Each volunteer or staff person participating in the screening should have his or her own screening log
    d. Collect screening logs and any other forms from each screener at the end of the day
    e. Before beginning the enrollment process have all forms that you will need assembled (i.e. consent forms, medical records release form, enrollment form, compensation form and randomization envelope)
        i. Before completing the survey have the participant sign the consent form and complete the medical records release form
        ii. After completing the survey have the participant complete the enrollment form—be sure to go through each section of the form with the participant to ensure that it is completed accurately
            1. On the enrollment form make sure to complete the checklist portion (the portion that indicates that all forms and the survey have been completed)
    f. Collect all forms used at box distributions and education sessions (i.e. box distribution pickup lists and education session class sign in)
    g. Before a participant leaves make sure that all necessary enrollment forms have been completed
4. Entering data
    a. If possible block off at least an hour each day where you can enter data
    b. If possible limit the number of people that enter data—for example the RA and one or two volunteers enter all study data
    c. Group forms together so that each form can be entered into its respective window at one time—for example put all the screening logs together so that while the screening log window is open all of this data can be entered
    d. TRIPLE check the data once it has been entered. Go back at least two times to make sure that all data has been accurately entered.
    e. Store all papers forms in a locked drawer in case you have to go back to check the accuracy of the data once it has been entered

Appendix AU – Participant Follow-Up Testing Results Form

Participant Follow-up Testing Results

Date: _____

Participant ID #: _____

Blood glucose result: _____ mg/dL

HbA1c result: _____ %

Notes:

Staff note: shred this form after entering data into ACCESS

Participant Follow-up Testing Results

Date: _____

Participant ID #: _____

Blood glucose result: _____ mg/dL

HbA1c result: _____ %

Notes:

Staff note: shred this form after entering data into ACCESS

Participant Follow-up Testing Results

Date: _____

Participant ID #: _____

Blood glucose result: _____ mg/dL

HbA1c result: _____ %

Notes:

Staff note: shred this form after entering data into ACCESS

Appendix AV – Barriers to Participation in FAITH-DM Activities Form

Barriers to Participation in FAITH-DM Activities

Instructions: Complete this form to document information participants provide about challenges / barriers to taking part in study activities. Return completed forms to the Research Assistant.

Date:

Participant ID#: _____

FAITH-DM Service Discussed by Participant: (Check any and all that apply)

____ A1C / Blood Glucose Screening and Monitoring

____ Food Packages

____ Diabetes Education

____ Primary Care Provider Referral or Appointments / Visits

____ Other (please specify):

Type of Concern(s) or Barrier(s) that Participant Identified:

____ Transportation (e.g., availability, cost)

____ Time Conflicts (e.g., can't make the times when food distribution, education classes or clinic appointments are available)

____ Food Package Concerns (e.g., doesn't like foods provided, volume is more than household can use)

____ Costs of Primary Care Visits (e.g., can't afford copay, or paying out of pocket if no insurance)

____ Hospitalization / illness / homebound:

____ Other (please specify):

Additional Notes (use this space to provide details you think are helpful to understand the participant's concerns):

For Use by Research Assistant:
Date entered into ACCESS: _____
Date reported* to site manager and/or FA Project Manager (Morgan Smith): _____
**Report if issue(s) may require revision to study elements and/or processes.*

NOTE: *This form may contain protected health information – staff must keep this data secure. Once data is entered into Access database, securely store and/or destroy form according to study protocols.*

Appendix AW – FAITH-DM Updates for Study Participants

FAITH-DM Updates for Study Participants

What is the purpose of this form?
This form is for participants enrolled in the research study: Feeding America Intervention Trial for Health – Diabetes Mellitus (FAITH-DM). The form includes important updates on study activities for participants.

What are the updates?

- Participants assigned to the intervention group will now be asked to complete a fourth HbA1c test that will take place 12-months from the day the participant enrolled into the study
- All participants will be asked to complete a third survey that will take place 12-months from the day they originally enrolled (survey will take about 30 minutes to complete)
- All participants will receive a $15 gift card upon completion of the 12-month follow-up survey
- For participants in the intervention group who originally agreed to share their medical information, we will ask your doctor / clinic to complete a second survey about the care you received during the 6-month period after you completed the intervention

What do I need to do now?
No action is required now. Study staff will contact you at your 12-month mark to schedule a time to complete the HbA1c test and survey. Participants will exit the study after completing the 12-month HbA1c test and survey. There will be no additional study activities after these 12-month items, but participants can continue receiving normal (non-study) food bank and pantry services for which they qualify.

What if I don't want to participate?
As with all study activities, you are <u>not</u> required to complete any additional HbA1c testing or surveys. If you choose to decline these items at month 12, inform the study staff that you do not want to take part. At this point your participation in the research study will end. You can continue receiving normal (non-study) food bank and pantry services for which you qualify.

Who do I call if I have questions?
If you have any questions, concerns or complaints about this research study or these changes, you may call the study site. If you think you have an injury or illness from the study activities, contact the Principal Investigator, Hilary Seligman, MD, MAS at (415) 206-4448.

Study Contact Name: **Morgan Smith, RN, PHN, CNS, CDE**
Project Director, Feeding America
Daytime telephone number(s): 312-629-7247

You should contact the food bank study staff first if you have questions, complaints or concerns about the study. If they cannot be of assistance, you may contact Morgan Smith or Dr. Hilary Seligman.

Please contact Western IRB if:

- You want to talk to someone other than the PI or study staff
- You have a hard time reaching the PI or study staff
- You have questions about your rights as a research subject or concerns or complaints about the research.

  Western Institutional Review Board® (WIRB®)
  1019 39th Avenue SE Suite 120
  Puyallup, Washington 98374-2115
  Telephone: 1-800-562-4789 or 360-252-2500
  E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Please visit the Western IRB website, www.wirb.com for more information about research studies and the role of a research subject.

Appendix AX – HCU Survey Cover Sheet

Health Care Utilization Survey - Cover Sheet

FAITH-DM Research Site: Please complete this cover sheet and attach it to the completed provider survey before submitting it to Urban. Thanks!

Participant ID: _____

Period of Requested Data: _____ to _____
(Copy this from the date range you gave the provider when you sent out the survey. For T6 surveys, the range should be 12 months; for T12 surveys, it will be 6 months).

Date Survey Received at Your Site: _____

Notes about Survey or Attached Patient Records (optional):

_____

_____

_____

_____

_____

_____

_____

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Appendix AY – Data Security and Overview of Study Data Procedures

FAITH DM | Feeding America Intervention Trial For Health Diabetes Mellitus

Data Security: Overview of How Study Data are Obtained, Transmitted, Received, and Stored

Introduction

FAITH-DM is a large, complex, multi-site research trial that involves numerous staff and multiple points of contact with study participants for data collection. There are instructions delineated throughout the study MOP on how staff at the research sites and coordinating center must collect, transmit, receive, and store study data (especially data containing participant PII and PHI). This overview reflects MOP content and provides a comprehensive, centralized overview on all study data processes.

Staff Access to Study Data

All staff engaged in the collection, storage, transmission, or analysis of study data are required to complete and maintain CITI certification. At each institution, the following staff have access to study data as indicated below.

- Research Sites (Food Banks)
  - *Research Assistants*: access to all site-specific data and forms; responsible for adhering to MOP protocols for data collection, storage, security, transfer / upload, etc.; maintain laptops; maintain physical document storage and security; maintain logon information and passwords for study laptops, CASIC, ACCESS and UCSF VPN client
  - *Project Managers*: back-up for Research Assistants; access to all site-specific data; responsible for hard copy final document destruction (to take place three years after study completion)
  - *Other Study Staff* (screeners, educators, HCUA assistants, etc.): access only to the minimum amount of data / forms / study documentation necessary to complete function (e.g., an educator may only need access to participants' names, contact information [phone, email], and study group assignment); staff overseen by RA and/or Project Manager
- Feeding America
  - *Project Manager*: Morgan Smith; access to all de-identified study data; access to any site-specific reports that may include client or participant PII/PHI data as required per study protocols for reporting purposes (e.g., adverse events, barriers, etc.)
  - *Director, CHN*: Michelle Berger Marshall; access to all de-identified study data
- University of California, San Francisco – Center for Vulnerable Populations
  - *Principle Investigator (PI)*: Dr. Hilary Seligman; access to all study data electronically stored on UCSF servers; access to all site-specific data, forms, and study documentation (hard copy and electronic versions)
  - *Project Manager*: access to all study data electronically stored on UCSF servers; access to and responsibility for maintenance of ACCESS and CASIC databases (in collaboration with other UCSF staff); as part of quality control and data management, ensures each research site uploads all study data (ACCESS and CASIC remote surveys) at least weekly

- *Study Statistician*: access to all study data electronically stored on UCSF servers
- *Technology and Support / Admin Staff*: access only to the minimum amount of data electronically stored on UCSF servers necessary to complete functions (server maintenance, database maintenance, etc.); activities and access overseen by UCSF PI and/or UCSF Project Manager

- Urban Institute
  - *HCUA Lead*: Elaine Waxman; access to all de-identified study data transmitted by UCSF; access to all de-identified HCUA provider survey data submitted by research sites
  - *HCUA Project Staff*: access to all de-identified study data transmitted by UCSF; access to all de-identified HCUA provider survey data submitted by research sites (must ensure survey data does not include any PII and, in the event of finding PII, is responsible for blacking-out and/or removing PII from survey data); activities and access overseen by Urban Institute HCUA Lead

Notes

- Research Assistants at each Research Site maintain two laptops that were provided, configured, and encrypted by UCSF
  - Both laptops are:
    - Encrypted and password protected (at the levels of the laptop, CASIC remote, ACCESS database, and UCSF VPN)
    - Loaded with CASIC remote survey software
  - Only 1 laptop per site is loaded with the site-specific study ACCESS database
  - RAs follow best practices when using, transporting, charging, and storing laptops to maintain device security (including storing laptops in locked cabinets, using laptop cables at sites, maintaining password protocols set by UCSF, etc.)
  - All study laptops will be returned to UCSF upon study end and completion of FAITH-DM data collection and uploading processes
- Table Key
  - PII = Personal Identifying Information
  - PHI = Protected Health Information
  - PPT = participant

Data	*Storage*	*Transmission*	*Notes*
Research Sites (Food Banks)			
Client screening logs	Data electronically entered into study ACCESS database; hard copies destroyed (shredded) once data entry complete	Site-specific ACCESS database securely uploaded to UCSF servers daily (whenever new data are entered), or as soon as possible thereafter (weekly, at a minimum) via a secure UCSF VPM client process	Forms contain PHI and, potentially PII; site-specific ACCESS data are stored locally on study laptop (1 per site); all study ACCESS data are, once uploaded, securely stored on UCSF servers
Participant Consent and HIPAA Authorization forms	Hard copies stored in the site *Study Consent Binder*	Copies faxed to PCPs along with HCUS via a HIPAA-compliant fax	Binders securely stored at each site in lockable cabinet / drawer **separate** from other study binders; do **not** include PPT #s; stored for 3 years after study completion and then destroyed (shredded on site or released to secure document disposal service)
Medical Records Release form	Hard copies stored in the site *Study Consent Binder*	Copies faxed to PCPs along with HCUS via a HIPAA-compliant fax	Binders securely stored at each site in lockable cabinet / drawer **separate** from other study binders; do **not** include PPT #s; stored for 3 years after study completion and then destroyed (shredded on site or released to secure document disposal service)
Baseline Enrollment Data form	Data electronically entered into study ACCESS database; hard copies destroyed (shredded) once data entry complete	Site-specific ACCESS database securely uploaded to UCSF servers daily (whenever new data are entered), or as soon as possible thereafter (weekly, at a minimum) via a secure UCSF VPM client process	

Data	*Storage*	*Transmission*	*Notes*
Screening and monitoring results	Data electronically entered into study ACCESS database; hard copies destroyed (shredded) once data entry complete	Site-specific ACCESS database securely uploaded to UCSF servers daily (whenever new data are entered), or as soon as possible thereafter (weekly, at a minimum) via a secure UCSF VPM client process	
Participant Surveys (T0, T6, T12)	All PPT surveys completed using CASIC; surveys completed using remote CASIC stored on study laptops and automatically deleted with each upload	PPT surveys completed on CASIC remote securely uploaded to UCSF servers daily (whenever new data are entered), or as soon as possible thereafter (weekly, at a minimum) via a secure UCSF VPM client process	PPT surveys entered via CASIC live are automatically saved on secure UCSF servers; no local copy is saved on study laptops at sites
Compensation Form	Hard copies stored in *Study Participant Binders*; form completion checkbox entered in ACCESS database	Site-specific ACCESS database securely uploaded to UCSF servers daily (whenever new data are entered), or as soon as possible thereafter (weekly, at a minimum) via a secure UCSF VPM client process	Binders securely stored at each site in lockable cabinet / drawer **separate** from Consent Binders; any PII needs to be removed or blacked out (use PPT #s only); stored for 3 years after study completion and then destroyed (shredded on site or released to secure document disposal service)
Completed HCUS Surveys (T6, T12)	Hard copies stored in *Study HCUA Binders*; dates and details of HCUA letters and other provider communication entered into and stored in study ACCESS database	Site-specific ACCESS database securely uploaded to UCSF servers daily (whenever new data are entered), or as soon as possible thereafter (weekly, at a minimum) via a secure UCSF VPM client process; per MOP protocols RAs are to compile copies of HCUSs each month, confirm surveys are de-identified (or black out PII if necessary), and mail in batches to	Binders securely stored at each site in lockable cabinet / drawer **separate** from Consent Binders; stored for 3 years after study completion and then destroyed (shredded on site or released to secure document disposal service); any PII needs to be removed or blacked out (use PPT #s only); provider face sheet (with PPT name and DOB) should be shredded by RA if PCP returned it along with survey;

Data	*Storage*	*Transmission*	*Notes*
		Urban Institute via traceable shipping method	no need to store hard copies of any PCP letters sent
MISC Forms with Participant Information (Adverse Event, Barriers, etc.)	Hard copies stored in *Study Participant Binder*	Completed forms sent by site RAs to FA Project Manager and/or UCSF PI per MOP reporting guidelines	Binders securely stored at each site in lockable cabinet / drawer **separate** from Consent Binders; any PII needs to be removed or blacked out (use PPT #s only); stored for 3 years after study completion and then destroyed (shredded on site or released to secure document disposal service)
UCSF-CVP			
ACCESS Database Data	Data received from sites weekly via secure UCSF VPN upload process; all data stored securely on UCSF servers	Data de-identified prior to secure transmission to UI and/or FA	Electronic data will remain securely stored for a period of 5 years from the end of study activities (data analysis and reporting), and then permanently deleted from UCSF servers and computers
CASIC Database Data	Data uploaded from CASIC remote when sites access an internet connection, and (with CASIC live) in real time as PPT surveys are completed at sites; all data stored securely on UCSF servers	Data de-identified prior to secure transmission to UI and/or FA	Electronic data will remain securely stored for a period of 5 years from the end of study activities (data analysis and reporting), and then permanently deleted from UCSF servers and computers
Site-specific reports and communication (that may contain PPT info, PHI, and/or PII)	Electronic forms and submissions from sites stored securely on UCSF servers; hard copies securely stored in study binder and lockable drawer/cabinet by PI and/or Project Manager	N/A	Hard copies of study data to be securely stored for a period of three years from the end of study activities, and then destroyed (shredded on site or released to secure document disposal service)
Urban Institute			

Data	*Storage*	*Transmission*	*Notes*
De-identified ACCESS database data	Study data will be stored on secure UI servers and equipment, with access restricted to personnel involved in the study HCUA analysis	Data set will be transmitted to UI by UCSF at the end of data collection (projected to be September, 2017); transmission will occur either through secure electronic transfer or in-person (e.g., by using encrypted flash drives, laptops, and/or other secure devices)	Hard copies of study data to be securely stored for a period of three years from the end of study activities, and then destroyed (shredded on site or released to secure document disposal service); electronic data will remain securely stored for a period of 5 years from the end of study activities (data analysis and reporting), and then permanently deleted from UI servers and computers
De-identified CASIC database data	Study data will be stored on secure UI servers and equipment, with access restricted to personnel involved in the study HCUA analysis	Data set will be transmitted to UI by UCSF at the end of data collection (projected to be September, 2017); transmission will occur either through secure electronic transfer or in-person (e.g., by using encrypted flash drives, laptops, and/or other secure devices)	Hard copies of study data to be securely stored for a period of three years from the end of study activities, and then destroyed (shredded on site or released to secure document disposal service); electronic data will remain securely stored for a period of 5 years from the end of study activities (data analysis and reporting), and then permanently deleted from UI servers and computers
De-identified HCUA provider surveys	HCUS surveys received from research sites will be reviewed for any PII (PII will be removed or blacked out); once survey data are inputted into electronic UI database, hard copy surveys will be securely stored by UI HCUA Lead; electronic data sets will be stored securely on UI servers	N/A	Hard copies of study data to be securely stored for a period of three years from the end of study activities, and then destroyed; any electronic data sets made from HCUA survey data will remain securely stored for a period of 5 years from the end of study activities (data analysis and reporting), and then permanently

Data	*Storage*	*Transmission*	*Notes*
			deleted from UI servers and computers
Feeding America			
De-identified study data (ACCESS, CASIC, and HCUA Survey data)	Any electronic files received from UCSF and UI will be stored on secure FA servers	N/A	Study data may be used for quality assurance and internal reporting purposes (departmental activities, grant reports, donor reporting, etc.); any electronic study data sets will remain securely stored for a period of 5 years from the end of study activities (data analysis and reporting), and then permanently deleted from FA servers and computers
Site-specific reports and communication (that may contain PPT info, PHI, and/or PII)	Reports and communication to be accessed on a PW-protected laptop maintained by FA Project Manager and then saved and backed-up on secure FA servers	N/A	Hard copies of study data to be securely stored for a period of three years from the end of study activities, and then destroyed; electronic study data will remain securely stored for a period of 5 years from the end of study activities (data analysis and reporting), and then permanently deleted from FA servers and computers

Appendix AZ – HCUA Script for reminding provider site to fill out survey

FAITH-DM Health Care Utilization Analysis: Script for reminding provider site to fill out survey

Introduction

Hello, my name is [your name]. I'm working with [name of food bank] on a research study in which one of your patients is enrolled. Could I speak with the person who handles medical records for your practice?

Information about study and survey

[Repeat introduction above if different person] The study is called the Feeding America Intervention Trial for Health – Diabetes Mellitus (or FAITH-DM for short) and we are looking to gain an understanding of the trends in healthcare utilization and the potential impact on health care costs associated with diabetes care management provided in food pantry settings. As such, we are requesting healthcare information for a patient in your care that is enrolled in our study. About [# of weeks since survey was sent] weeks ago we sent you a survey for [name of patient]. Your patient has given permission to share their information with our study, and included with the survey was a HIPAA Authorization and consent to release medical records form signed by your patient. The survey asked for information on office visits, emergency department and urgent care visits, and inpatient hospital admissions for a [12 month or 6 month] period. Additionally, the survey inquired about missed appointments, the patient's source of payment, and what type of clinic you have. Have you received this survey?

If yes

In order to make this process as easy as possible for you, we have provided your clinic the option to either fax us a completed survey (with the first page removed) or a copy of your patient's actual medical record. We prefer that you complete the survey. However, if you choose to provide a copy of your patient's medical record, we want to emphasize that you to black out any personal identifiable information (name, date of birth, SSN, etc.) before sending it to us. [*See Q&A if there is pushback on this*] When do you anticipate you will be able to send us back the survey or copy of your patient's medical records? [*If they have questions/hesitation about completing the request, see troubleshooting section*]

If no

In that case, we will be resending you an information packet that contains the survey and a letter explaining our study in greater detail. How can we best address this package to ensure that it arrives to you?

In order to make this process as easy as possible for you, we have provided your clinic the option to either fax us a completed survey (with the first page removed) or just a copy of your patient's actual medical record. We prefer that you complete the survey. If you choose to fax us a copy of your patient's medical record, we want to emphasize that you black out any personal identifiable information (name, date of birth, SSN, etc.) before sending it to us. [*If they have questions/hesitation about completing the request, see Q&A section*]

Closing, assuming no questions/issues

Thank you for your time in completing this survey for us! Do you have any questions about the survey or study more generally?

Please do not hesitate to contact us with any questions you may have. Our contact information is [phone number and email]. The fax number to send us the survey is [fax number]. [Food Bank RA] is the Research Assistant managing this project at the food bank.

Common Questions and Answers

Our clinic does not have time to complete this request

We understand that it takes time for you (or your medical records staff) to fulfill this request. To compensate for this time, we will provide a $20 payment to your clinic for each survey completed or record copied. Obtaining this healthcare information will be critical in determining how to better help patients with uncontrolled diabetes.

We would need to charge a higher price in order to fulfill your request.

Unfortunately, $20 is what our research budget allows for these survey requests. Would it be at all possible to still send us records? [*If no*] How much do you envision each record will cost? I will need to check with my study director and get back to you. [*If they say no, report the cost they quote to the study director; he or she will make a determination on whether the food bank will make an exception*].

Could you tell me more about the study?

[Food bank name], in collaboration with Feeding America, the University of California San Francisco, and the Urban Institute, is conducting a randomized controlled trial study of a diabetes intervention focused on food pantry clients. The FAITH-DM study is designed to assess the effectiveness of a multi-component intervention for improving diabetes management among a population of food pantry clients in three cities, including [your city], using a treatment and waitlist control group design. The project also includes an analysis of health care utilization, both self-reported by participants and through selected medical record data reported by clinics like yours.

The FAITH-DM intervention components include:

- Screening and monitoring (blood glucose and HbA1c) 4 times over a 12-month period; at baseline, 3 months, 6 months and 12 months
- Twice-monthly diabetes-appropriate food boxes (including fresh produce) for 6 months
- Referral to a primary care provider, if participant does not currently have one
- Diabetes self-management support and education (handouts, classes, and 1-on-1 support).

For adults with type 2 diabetes, diabetes self-management education (DSME) is critical to achieving long-term control of blood sugar levels (glycemic control) and preventing diabetes-associated complications. This education is often difficult to access for highly vulnerable and marginalized adults in the United States. Furthermore, we know that nutritious, diabetes-appropriate foods are often out of reach for food insecure households. The purpose of this study is to determine the extent to which food banks and food pantries can help reach this population with effective diabetes education, food, and access to primary health care, with the ultimate goal of improving diabetes outcomes.

Consent/Confidentiality/IRB concerns

We have obtained informed consent from all participants enrolled in our study. In addition, all participants have signed a HIPAA Authorization and consent to release medical records forms. As we have instructed you to black out any personally identifying information, all data obtained in this study will remain confidential, and no personally attributed information will be released. Our study has been approved by the Western Institutional Review Board, the UCSF IRB, and

the Urban Institute IRB. [*To the volunteer: An Institutional Review Board (IRB) is a committee established to review and approve research involving human subjects, ensuring that all research is conducted in accordance with federal, institutional, and ethical guidelines. Because our study is being conducted by 3 organizations, we had 3 separate IRB's review and approve FAITH-DM*].

What if I can't black out all of the identifying information?

The Institutional Review Board that approved this study has required us to minimize the identifiable information exposed when data is being transferred. We would greatly appreciate it if you were able to black out identifying information. However if this is not feasible, we understand and appreciate your help in sending the record in a secure fashion, either by fax or mail.

Appendix BA – Guide on Use of Encrypted USB Devices for HCUA Data

FAITH-DM Health Care Utilization Analysis: Guide for use of IronKey Encrypted USB Devices

In order to save resources and further secure the health care utilization data being sent and received between FAITH-DM research sites and the Urban Institute, research assistants at the food banks have the option to scan health care utilization surveys and documents and upload them onto secure USB drives for the purposes of shipping these to Urban. These devices, IronKey D250 Basic Secure Drives, are password protected and hardware encrypted. Each food bank will receive two devices so that one is always available when the other is in transit to/from Urban.

Food Bank Research Assistants

When the site receives the USB devices the first time, the site research assistant (RA) should email the Urban Institute research assistant to acquire the password to unlock the device. The password is specific to each site; both USB devices at the site have the same password, but each site has a different password. Once the RA receives the password, the RA can plug the device into the computer from which records and surveys will be uploaded. If the Unlocker does not open immediately, open Windows Explorer; the IronKey Unlocker should now be listed as one of the drives on the computer. Open that drive, and run IronKey. Type the password provided by the Urban Institute. Once the device is unlocked, click the folder icon to open the Secure Files Drive. Add all of the documents to be sent to the Urban Institute to this folder, and lock the device. It is now safe to remove and mail back to the Urban Institute.

Important safety procedures include:

- If you need to step away from your computer while using the device, lock the device.
- DO NOT change a device password. Passwords should be kept separate from the devices and the study computers and stored in a secure place.
- If the password does not work, do not re-attempt more than a few times and contact the Urban Institute for assistance if needed. If an incorrect password is entered 10 times, the device will become permanently unusable.
- When mailing a USB device to the Urban Institute research assistant, use the existing trackable shipping method outlined in the MOP, and check to ensure the device arrives at its intended destination by the expected delivery date. If a package is delayed significantly and/or lost, notify and request assistance from the shipping provider and alert the Urban Institute research assistant handling the HCUA data. Any instances of lost packages that cannot be recovered must be reported to the Urban Institute IRB.
- Files uploaded electronically to a computer at the site must be kept under a password-protected file. Only study-provided computers should be used for scanning sensitive participant information.

Urban Institute

When Urban receives a USB device from a site, the Urban research assistant will send an email to the site to confirm receipt of the device. The Urban research assistant will then access the device by running the IronKey Unlocker, using the password corresponding to the device assigned to the appropriate site. (Passwords are maintained in a separate file on the Urban secure drive.) Once the device is unlocked, the files will be transferred directly into the FAITH-DM folder on the secure drive, and deleted from the USB device. The device will be locked in order to safely remove it. It can then be returned to the food bank for further use. The Urban RA will notify the site when a package is in transit.

Important safety procedures include:

- If you need to step away from your computer while using the device, lock the device.
- When mailing the USB devices, check to be sure all data has been removed before shipping to the site. Use a trackable shipping method, and check to ensure the device arrives at its intended destination within the expected timeframe.