



TEXTMED+FANS
Screening/Enrollment
Protocol

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TEXTMED FANS SCREENING/ENROLLMENT PROTOCOL

1.0 PURPOSE

Purpose of this document is to establish a systematic approach in screening and enrolling participants into this study. Research Assistants are responsible for following procedures and instructions in this document

2.0 PROCEDURES

2.1 INTRODUCTION

Proper overview of study and its requirements will be delivered to participants. The study is not the participant's primary care provider and medical advice should not be given to participants. Research Assistants are expected to provide accurate study information to participant at all times.

If at any given point a patient becomes altered, violent, and/or combative do not put yourself in harm's way. During situations in which Research Assistant's feel uncomfortable or harassed by participant, do not continue engagement and notify Primary Investigator. If a patient expresses suicidal thoughts notify Primary Investigator, doctor caring for patient in the emergency department and assigned Nurse immediately.

At no point should study procedures interfere in patient care or treatment during the patient's Emergency Room visit.

Dress code is, business casual. No shorts, open toe shoes, flip-flops or sandals are allowed. Blue badge should be worn and clearly visible at all times. Research Assistants are required to wear their assigned clean gray lab coats during their shifts.

2.2 KEY WORDS

AMS: Altered Mental Status

APPT: Appointment

AxO: Alert and Oriented

DEM: Department of Emergency Medicine

DM: Diabetes Mellitus

DTO: Danger to Others

DTS: Danger to Self

ED: Emergency Department

EMR: Electronic Medical Record

GD: Gravely Disable

IC: Informed Consent

MON: Month

MOP: Manual of Operations

MSG: Messages

PI: Primary Investigator

Pt: Patient/Participant

RA: Research Assistant

SOP: Standard of Operations

2.3 SCREENING PROCESS

2.3.1 SCREENING

- Step1: (ORCHID/FirstNet)
 - Log into Orchid/First Net Account (SEE APPENDIX 3.1)
- Step2: (Identify Potential Subject of Interest)
 - Open a pt's chart (SEE APPENDIX 3.2)
 - Participants need to meet the following Inclusion/Exclusion Criteria:

INCLUSION CRITERIA:	EXCLUSION CRITERIA
- Has a cell phone	- <18 Years of Age
- Be able to Send/Receives Text Messages	- Language Barrier: Does not Speak English or Spanish
- Has DM and A1C Level \geq 8.5	- Not AxO: Such as 5150, ETOH, Withdraw, Overdose, AMS, Psych, Metro Pts, DTS, DTO, GD
- Identifying a Supporter who is >18 or older, who also a working cell phone	- Critically Ill: Such as Cardiac Arrest, Intubated, Rule Out TB
	- Jail Patients
	- Does Not have a stable form of Contact: Such as Homeless, Shelter, Transitional Housing

- Step 3: (Completing Tracking Log)
 - All potential Participants need to be documented in the TextMed Screening Log Sheet
 - All items need to be properly completed
 - At the end of your shift file the TextMed Screening Log Sheet in the drawer file "Completed Items"

2.3.2 APPROACHING PT

Once potential participants are identified and recorded in Screening Sheet begin approaching pts.

- Knock before entering a room and verify Pt's information
- Hands must wash before and after exiting a pt's room; alcohol hand gel is appropriate if hands are not visibly soiled
- If Pt's are asleep it's okay to wake them up
- Introduce yourself and purpose of visit

ENGLISH SCRIPT:

Hello my name is _____ I'm working with the Research Department here in the Emergency Room

Can I have your name and date of birth?

We're doing a study about mobile phones with patients that have diabetes. The study is called TexMedFans and we're hoping to learning if an educational program can be delivered by text message along with having a support person involved in the program. A support person can a close friend, family, spouse, etc.

Do think we can ask you some questions to see if you qualify?

SPANISH SCRIPT:

Hola mi nombre es _____ estoy trabajando con el Departamento de Investigación aquí en la sala de emergencias

¿Me puede dar su nombre y fecha de nacimiento?

Estamos haciendo un estudio sobre teléfonos móviles con pacientes que tienen diabetes. El estudio se llama TexMedFans y esperamos aprender si un programa educativo se puede llevar a cabo por mensaje de texto, adicionalmente incluyendo una persona de apoyo involucrada en el programa.

Una persona de apoyo puede ser un amigo cercano, familiar, o pareja, etc.

¿Cree que puédanos hacerle algunas preguntas?

- Procedure to ask the following questions ONLY if Pt agrees:

ENGLISH	SPANISH
- Do you have DM?	- ¿Tiene DM?
- Do you know how to read/write?	- ¿Sabe cómo leer/escribir?
- Do you have a working cell phone?	- ¿Tiene un teléfono celular en funcionamiento?
- Do you know how to read/reply to text messages?	- ¿Sabe cómo leer/responder mensajes de texto?
- Do you have a support person you can count on?	- ¿Tiene una persona de apoyo con la que puede contar?
- Is this support person >18 years or older and has a cell phone?	- ¿Es esta persona de apoyo mayor es mayor de 18 años y tiene un teléfono celular?

Note: if the Pt does NOT meet the following inclusion criteria upon asking the questions mentioned above or declines participation, document reason in Screening Log

- Ask Pt to see if they will allow the study team to check their A1C level

A1C TEST SCRIPT

ENGLISH:

To see if you qualify to participate we need to check your A1C level first. Our study requires the A1C level to be 8.5 or higher. This test will require a finger stick, is this okay with you?

SPANISH SCRIPT:

Para determinar si califica para participar, primero debemos verificar su nivel de A1C. Nuestro estudio requiere que el nivel de A1C sea 8.5 o más. Esta prueba requiere una gotita de sangre de su dedo, ¿le parece bien?

IF PT RESPONDS YES TO A1C TEST

Proceed to take blood sample, and inform them that you will be back in about 10min with the A1C results (SEE APPENDIX 3.3)

NOTE: Only two finger stick attempts are allowed. If error codes come up document error on the Manuel of Operations Section 7.5 "HbA1C Issues Encountered Log"

IF PT RESPONDS NO TO A1C TEST

DO NOT collect blood sample. Thank Pt for their time and document decline reason in the Screening Sheet.

- Provided A1C results to pt

NOT ELIGIBLE SCRIPT:**ENGLISH**

Your A1C level was ___. Unfortunately it does not meet our study requirements of an A1C reading of 8.5 or higher to participate. Thank you for your time.

SPANISH

Su nivel de A1C fue ___. Desafortunadamente, no cumple con el requisito de nuestro estudio de un nivel de A1C de 8.5 o más para poder participar. Gracias por su tiempo.

ELIGIBLE SCRIPT:**ENGLISH**

Your A1C level was ___. This means that you are eligible to participate in our study. As we mentioned, this is a Text Message education program. Participants will receive 3 text msg a day for 6 months. Text messages will be about healthy habits, medication reminders, DM trivial questions and more.

Pt's will need to identify a support person whom is willing to participant with them as well. Supporter's will either receive the text messages as well OR a pamphlet containing messages.

SPANISH

Su nivel de A1C fue ___. Esto significa que usted es elegible para participar en nuestro estudio. Como mencionamos, este es un programa educativo de mensajes de texto. Participantes recibirán 3 mensajes de texto por día durante 6 meses. Los mensajes de texto serán sobre hábitos saludables, recordatorios de medicamentos, preguntas tibia de diabetes y más.

Pacientes tendrán que identificar a una persona de apoyo que esté dispuesta a participar con ellos también. La persona de apoyo, tal vez recibirá los mensajes de texto O un folleto con los mensajes.”

- Inquire with participant about their interest in participating in study

IF PT STATES NO TO STUDY PARTICIPATION

Thank Pt for their time and document decline reason in the Screening Sheet. If the concern is something that the patient can be reassured about, please explain the study and compensation, and ask again if they want to participate.

IF PT STATES YES TO STUDY PARTICIPATION

Make sure to clearly delineate what the study entails. (SEE TABLE 2.3.2)

- ✓ Inform Consent will need to be completed during initial enrollment
- ✓ Contact Information will need to be collected which includes:
 - Cell Phone Number
 - Alternative Numbers/Emergency Contact Number
 - Mailing Address
 - Email Address
- ✓ 3Text Messages a day sent for 6 Months
- ✓ Physical Measurements will be collected
 - A1C level
 - Weight
 - Height
 - Abdominal Circumference
- ✓ Completion of Surveys/Questionnaires over the phone, email, or mail

- 3 Months
Compensation amount of \$5 Target Gift Card given at 6Months
- 9 Months
Compensation amount of \$5 Target Gift Card given at 12Months
- ✓ In Person Visits
 - 6 Months
Surveys and Physical Measurements
Compensation amount of \$50 Target Gift Cards
 - 12 Months
Surveys and Physical Measurements
Compensation amount of \$100 Target Gift Cards
- IF randomized to intervention group, exit interview for \$100

Table 2.3.2

	Enrollment	3 Month	6 Month	9 Month	12Month
Consent	X				
Contact Information	X	X ¹	X ¹	X ¹	X ¹
Physical Measurements	X		X		X
Text Messages	X	X	X		
Surveys	X	X	X	X	X
In Person Visit	X		X		X
Exit Interview					X ²
Compensation ³	\$20	\$5	\$50	\$5	\$100

¹Verification of Contact Information

²For TextMed Fan intervention group only

³Only if Time mark is Completed

2.4 PATIENT ENROLLMENT PROCESS

2.4.1 INFORM CONSENT

Informed consent is more than a form, it is a process. Information must be presented to participants so that they can voluntarily decide whether or not to participate in research (1).

The informed consent form must be signed before any study procedures begins (1). For this study IC must be sign before surveys, compensation, physical measurements (NOT including A1C Level), and contact Information is collected. The RA's will verbally explain the purpose and procedures involved in the study. (1). RA's will answer questions and provide information to allow the subject to make an informed decision with ample time to consider participation. (1).

Once Informed Consent is presented and reviewed, follow the guidelines stated below:

- Participant must understand the documents being presented
- Updated IC needs to be used
- Complete IC needs to be single sided
- Participant needs to print name, sign, and date/time for themselves as required in the IC pages.
 - Bill of Rights (Page 1 of 6) Requires:
Participant's Date, Time and Signature
 - General IC (Page 6 of 6) Requires:
Participant's Printed Name, Signature, Date and Time.
RA's Printed Name, Printed Name, Signature, Date and Time.
 - HIPPA (Page 5 of 5) Requires:
Participant's Printed Name and Signature
- Do not sign anything in advance
- Do not indicate where to sign with an "X" since it makes it look like it's part of a signature
- All times for both Participant and RA need to be consistent and preferably documented in military time
- Errors are to be crossed out, Initial and Dated.
 - If RA makes error, Initial and date.
 - If pt. makes error, have them cross out, initial and date.
 - DO NOT re-write or scribble mistaken done attempting to correct
- A note in the back of IC needs to be explicitly elaborate reason why pt was not able to print, date/time for themselves.
 - Section is ONLY completed under the following circumstances:

Patient was unable to Print Name, Date on Time on their own BUT fully understands the study and what it entails

For Example: An Alert and Oriented pt. has an IV line in place where they cannot move their hand

NOTE: These circumstances are rare. Patient should be entering information on their own
- Original signed IC, check list, and receipt all will need to be handed over to lead RA. Subjects will be receiving a signed copy of consent.

2.4.2 RED CAPS CREATION

Correct and precise data entry is of **HIGH IMPORTANCE** in this step. MRNs, Date of Birth, Names, Address NEED to be entered correctly into the system. Refer to appendix 3.4 to create participant profile in Red Caps

When entering Patients First and Last Name use EXACTLY what is seen in Orchid. For subject with two Last Names, Enter both of them as they appear on Orchid. If subject goes by a nickname document alias name in quotes.

Example:

Pt goes by the name Meño. Orchid indicates Juan Manuel, Guzmán López

RedCaps should indicate the following:

First Name: Juan Manuel “Meño”

Last Name: Guzman Lopez

RedCaps passwords or log in information should not be shared under no circumstances. Failure to do so results in falsification of RA entering information into the system. RA will need to log off and clear browser to avoid incorrect data discrepancies.

Example: Survey indicates RA-1 completed section and multiple mistakes were done when entering data. However, RA-1 was not on shift. RA-3 was on shift during survey and data was completed.

2.4.3 CONTACT INFORMATION

Correct contact information is of high importance for the long term success of this study. Any incorrect information entered affects the study’s follow up time point visits.

Please note that three potential Supporters are identified during Patient enrollment.

2.4.3.1 PHONE NUMBER/ADDRESS

Under no circumstances enter bogus information

Example: 555-555-5555 or 323-123-4567

Completely write out the city full name and zip code. No abbreviations should be used.

Clearly indicate if residence is an apartment or a house.

Verify with subject that the information was correctly entered in RedCaps

Example: Incorrect: 1200 N. State St. LA, CA

Correct: 1200 N. State Street Los Angeles CA 90033

2.4.3.2 EMAIL

Email address is an essential component to this study. It is used to create a MyAgile Account and as a method of follow up. If subject does not have an establish email address one will need to be created for them (SEE APPENDIX 3.5). If an email was created for Subject and or Supporter clearly indicate a comment in RedCaps by clicking the comment button

DO NOT enter fabricated Emails

Example: doesnotknowwhottouseone@noemial.com
na@k.com
camen.sanchezUSCdiabetes@gmail.com

Email

Editing existing Study ID

Event Name: Enrollment (Arm 1: Patient English)

Study ID (To rename this below.) immediately

Study ID

What is your email?
* must provide value

Form Status

Complete? Complete

Save Record
 Save and Continue
 Save and go to Next Form
 -- Cancel --

2.4.4 MY AGILE HEALTH PROFILE

As a reminder text messages will only be delivered for 6 months to participants. AgileHealth profiles are created for ALL patients who are enrolled in the program.

Visit the following link admin.agilehealth.com to create an AgileHealth patient profile:

- Enter your username and password to login.
- Enter the program code 'USCDBRCT' and click on Enroll Now. Make sure to turn off Pop-Up Blockers or you will not be able to proceed.
- Fill out the first section labeled 'About Me'. Enter the patient's information and corresponding Study ID assigned in RedCap. Be diligent and make sure all information is correct and click on 'Continue'.
- Next, complete the section labeled 'My Account'. Use the same e-mail provided in RedCap. If patient does not have an e-mail, use the e-mail created when completing the RedCap survey and click on 'Continue'.
- Fill out the 'My Health' section. Since you are enrolling the patient, click on patient. You will need the patient to provide the first name of their potential supporter during this step and log it in the appropriate space. Click on 'Continue'.
- Finally, complete the 'Preferences' section. Select the language the patient prefers to receive their messages in and select the start date for the program.
 - The healthy start date is the first Monday that is three weeks after patient enrollment.
- Click on User Agreements and complete enrollment.
- **IMPORTANT:** Patient must respond 'Yes' to an automated text message sent to their phone after enrolling them in the AgileHealth. If they do not respond 'Yes', then enrollment is not complete.
 - If they do not receive a message then they may have a block by their carrier. Follow the instructions on the Block Lift PDF to lift the block.

2.4.5 SURVEYS

Enrollment, 3 Months, 6 Months, 9 Months, and 12 Months surveys need to be completed in order. This also includes surveys for supporters. There is no reason why surveys should be completed out of order.

DO NOT rush patient/supporter when completing survey. Questions can be sensitive to participants and such they do have the right to not answer specific survey questions. If participants decline to answer specific questions a note must be entered in the comment section of that specific question.

RA needs to thoroughly ask all questions as seen in the survey regardless of previous answers. In other words, DO NOT make assumptions based on previous responses. Be courteous, respectful and professional with patient/supporter.

2.4.6 PHYSICAL MEASUREMENTS

The physical measurements collected in this study include the patient's weight, height, abdominal girth, and blood pressure. Each measurement must be taken carefully and accurately by following the step by step instructions below. Any deviations from the steps below must be noted in RedCaps in detail.

2.4.6.1 MEASURING BODY WEIGHT:

Weight measurement will be recorded in lbs. To ensure you take reliable measurements using the ETEKSCALE body weight scale in the FOD you must:

- Place the scale on a flat even surface
- Ask the patient to stand up and remove any personal belongings (keys, wallets, etc)
- Note: DO NOT ask patients to stand if they are a fall risk (unable to stand due to physical limitations, foot injury, disability, etc.) or have severe discomfort when standing. Enter 999 if pt is unable to be weighed and make a comment in RedCaps
- If patient is unable to stand then ask the patient how much they weigh and record a verbal reporting of weight in RedCaps. Verbal reporting must be noted in RedCaps under the comment section.
Note: If patient is unable to stand and does not know their weight then leave this section empty. Leave detailed explanation in comments section.
- Ask patient to look straight ahead and stay still on the scale. Wait for the digital screen to settle before recording the measurement.
- Weight will be recorded in lbs. All measurements must be recorded to the nearest 10th. Do not round off to the nearest whole number as seen below.



2.4.6.2 MEASURING HEIGHT

Once a patient's weight is recorded keep the patient standing to measure their height. Height Measurement will be collected in centimeters. If they are unable to stand, then take a verbal record of height and note the height as a verbal recording in RedCap. Enter 999 you are unable to collect height and make a comment in RedCaps

When taking measurements of height, you must:

- Ask the patient to remove their shoes prior to taking the measurement
- Ask the client to stand with their hands to their side and look directly forward
- Place the measuring device under the patient's heel, and pull the measuring tape well above the patient's head
- Use a flat index card, ruler, or piece of paper to measure the height on the measuring tape to the nearest tenth of a centimeter. Report height in centimeters in RedCap.

2.4.6.3 MEASURING ABDOMINAL CIRCUMFERENCE

The last measurement to be taken while the patient is standing is the abdominal circumference. If subject is unable to stand, DO NOT attempt to stand pt. Recording of abdominal circumference while pt is sitting on gurney is NOT permitted. A note delineated by measurement was unable to be taken needs to be entered as a comment section in RedCaps. Enter 999 you are unable to collect abdominal circumference and make a comment in RedCaps

When taking measurements of height, you must:

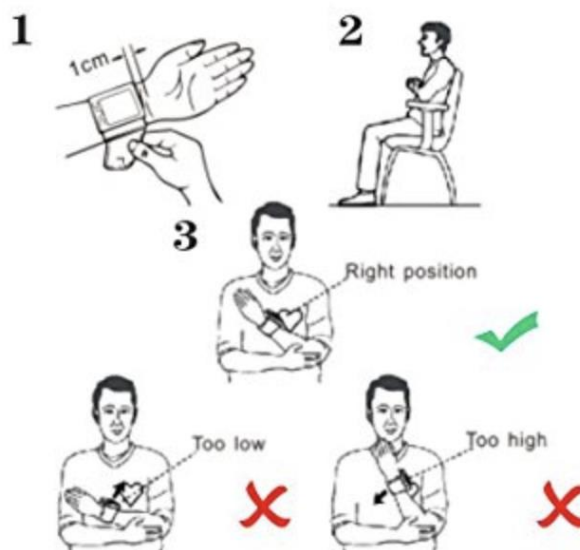
- If a patient is wearing a sweater or clothes, politely ask them to put a hospital gown on. (Give the patient privacy when they do this)
- Place tape measure at the natural waist (usually just above the belly button, the narrowest level of the abdomen)
- Make sure you do not tighten the tape too much, it should be snug, but not compressing the skin.
- Have the patient relax and exhale with hands down to their side.
- Take measurement to the nearest tenth of a cm and record in RedCap

2.4.6.4 MEASURING BLOOD PRESSURE

Blood pressure readings need to be collected using assigned study device to ensure consistency and accurately throughout research study. Do not use blood pressure recorded in patient's chart or monitor. If blood pressure reading is not able to be collected with study device, leave sections empty in recaps and enter a comment indicated why reading was not collected. Enter 999 you are unable to collect blood pressure reading and make a comment in RedCaps

Blood pressure measurement will be recorded three times using the wrist cuff.

- Have the patient seated for five minutes before you take a blood pressure reading.
- Instruct the patient to place both feet flat on the floor
- Use the right wrist, unless it is unavailable. (i.e. I.V.'s, broken wrist, pain, etc.).
- Have patient place their wrist at level of his heart when taking each measurement.
- Record measurements in RedCap.



2.4.7 COMPENSATION

All gift cards are tracked and accounted for. In the beginning of your shift five \$20 Target gift cards will be provided to RAs on shift. Any unsure gift cards need to be returned to the locked cart at the end of the shift.

Complete receipt legibly. It must be completed properly as seen in the Manual of Operations Section 1.

2.4.8 SIX MONTH APPOINTMENTS

Six month appointment will be generated. Six month appointment is expected to be approximately 6 months from health start date. RA's note the appointment time, in the study's overview package

2.5 SUPPORTER ENROMENT

A Supporter can be a close friend or family member that can offer emotional support and learns about diabetes alongside with the patient. Take in mind that NOT all Supporters will be receiving text messages.

This study is a randomized trial. Half of the supporter will receive a text messages alongside with the Participant, this arm is called Intervention TextMedFans. The other half will be provided a pamphlet with the messages for them to follow along with the Participant, this arm is called Control. The Control arm supporters will NOT be receiving text messages. The control arm supporters receiving the same information, but in a pamphlet.

Supporter enrollment into the study can be conducted over the phone or in person. An identified supporter can be accompanying the patient during the ED visit. As such, you can ask patient if supporter is currently on site, in the waiting room, etc. This will speed up the enrollment process.

Whether the Supporter is verbally consented in person or over the phone the overview and study requirements must be presented to them. See table 2.5

- Verbal Consent
- Contact information
 - Cell phone number
 - Alternative Numbers/Emergency Contact Number
 - Mailing Address
 - Email Address
- Completion of surveys/Questionnaires over the phone, email or mail
 - 6 Months
 - 12 Months

Table 2.5

	Enrollment	6 Month	12 Month
Consent	X		
Contact Information	X	X ¹	
Surveys	X	X	
Interview Questions			X ²
Compensation		\$25	\$100 ²

¹Verification of Contact Information Only

²Only for Supporters in the Intervention Arm

2.5.1 Obtaining Verbal Consent

Verbal consent must be obtained before any study procedures begin. RAs need to follow the Supporter Information Sheet to clearly delineate the Supporters role in the study. Refer to the Manuel of Operations (MOP) Section 4 for the information sheet.

Once information sheet and study requirements were explained to potential supporter, individuals will need to clearly express their desire to participant in study.

Information sheet will need to be either mailed out or handed to supporter on site. Mailed out Information sheet will be completed by lead RAs.

2.5.2 Red Caps Creation

Correct and precise data entry is of high importance in this step. Date of Birth, Names, and Address NEED to be entered correctly into the system. Refer to Appendix 3.4 to for specific Redcaps creation

When entering Supporters First and Last Name use EXACTLY what was verbally indicated during consent process. For supporters with two Last Names, Enter both of them names indicated by individual. If subject goes by a nickname document alias name in quotes.

Example:

Pt goes by the name Meño. Orchid indicates Juan Manuel, Guzmán López

RedCaps should indicate the following:

First Name: Juan Manuel "Meño"

Last Name: Guzman Lopez

RedCaps passwords or log in information should not be shared under no circumstances. Failure to do so results in falsification of RA entering information into the system. RA will need to log off and clear browser to avoid incorrect data discrepancies.

Example: Survey indicates RA-1 completed section and multiple mistakes were done when entering data. However, RA-1 was not on shift. RA-3 was on shift during survey and data was completed.

2.5.3 Contact Information

Correct contact information is of high importance for the long term success of this study. Any incorrect information entered affects the study's follow up time point visits.

2.5.3.1 PHONE NUMBER/ADDRESS

Under no circumstances enter bogus information

Example: 555-555-5555 or 323-123-4567

Completely write out the city full name and zip code. No abbreviations should be used.

Clearly indicate if residence is an apartment or a house.

Verify with subject that the information was correctly entered in RedCaps

Example: Incorrect: 1200 N. State St. LA, CA

Correct: 1200 N. State Street Los Angeles CA 90033

2.5.3.2 EMAIL

Email address is an essential component to this study. It is used to create a MyAgile Account and as a method of follow up. If subject does not have an establish email address one will need to be created for them (see Appendix 3.5). If an email was created for Subject and or Supporter clearly indicate a comment in RedCaps.

DO NOT enter fabricated Emails

Example: doesnotknowwhottouseone@noemial.com

na@k.com

camen.sanchezUSCdiabetes@gmail.com

2.5.4 Surveys

Enrollment, 6 Months, and 12 Months surveys need to be completed in order. There is no reason why surveys should completed out of order.

DO NOT rush supporter when completing survey. Questions can be sensitive to supporter and such they do have the right to not answer specific survey questions. If supporter declines to answer specific questions a note must be entered in the comment section of that specific question.

RA needs to thoroughly ask all questions as seen in the survey regardless of previous answers. In other words, DO NOT make assumptions bases on previous responses. Be courteous, respectfully and professional with supporter

2.5.5 Compensation

All gift cards are tracked and accounted for. Note that during enrollment NO compensation is provided to Supporter.

2.6 RANDOMIZATION

Envelopes are located in the Research Lab Room drawer. All envelopes are accounted for and under no circumstances should be tampered with. This process is **ONLY** to be completed at the time Supporter verbally consents and agrees to participate in study. All envelopes are in order and thus need be used sequentially.

Once Supporter verbally consents to participate, grab a sealed unused envelope. Randomization will occur after Supporter completes enrollment survey and study requirements. Randomization Form in RedCaps will need to be completed delineating which arm was the Supporter assigned to.

Open envelopes will be placed with the enrollment package, to allow staff to determine participant's supporter was enrolled. Under no circumstances throw away envelop and its context.

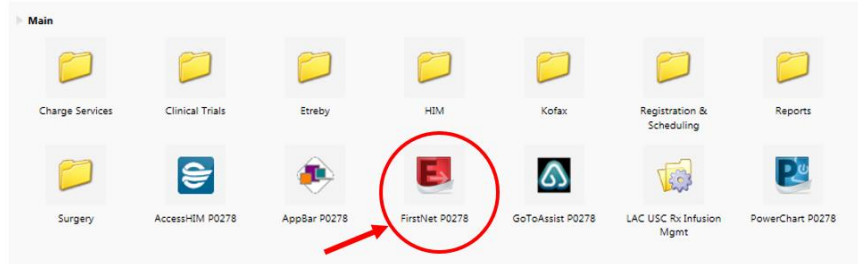
3.0 APPENDIX

3.1 ORCHID/FIRST NET

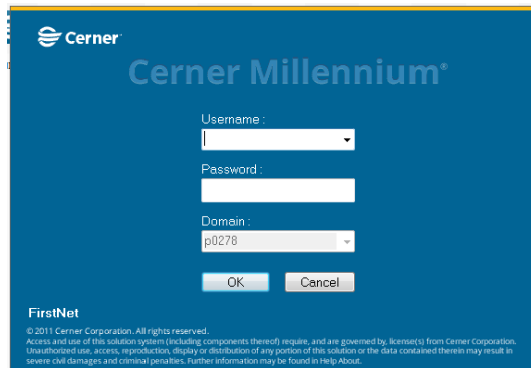
- Double-click on ORCHID icon



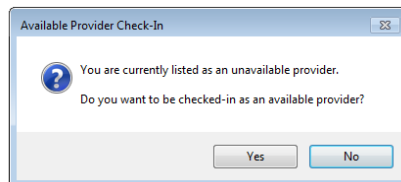
- Double-click on FirstNet icon



- Enter your log in information



- Click No when a message appears stating “You are currently listed as an unavailable provider do you want to checked in as an available provider”

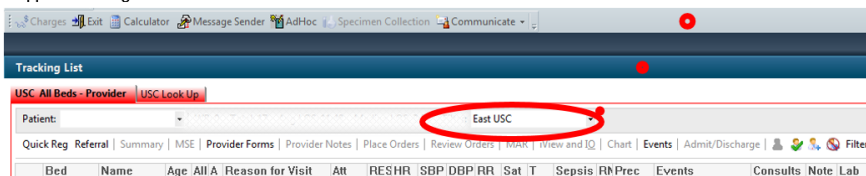


- Click on the filter tab as seen bellow and scan through the following areas
 - North USC
 - East USC
 - West USC
 - Resus USC
 - Obs USC
 - Supertrack

Note: West Patients should be screened/approached first due to rapid turn over



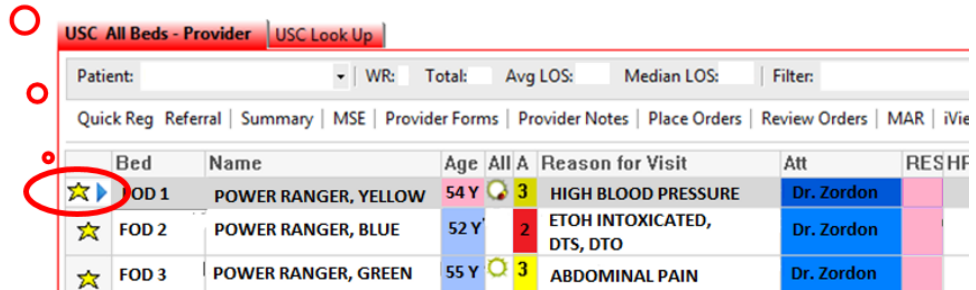
Appendix 3.1 Figure



3.2 OPENING A PATIENTS CHART

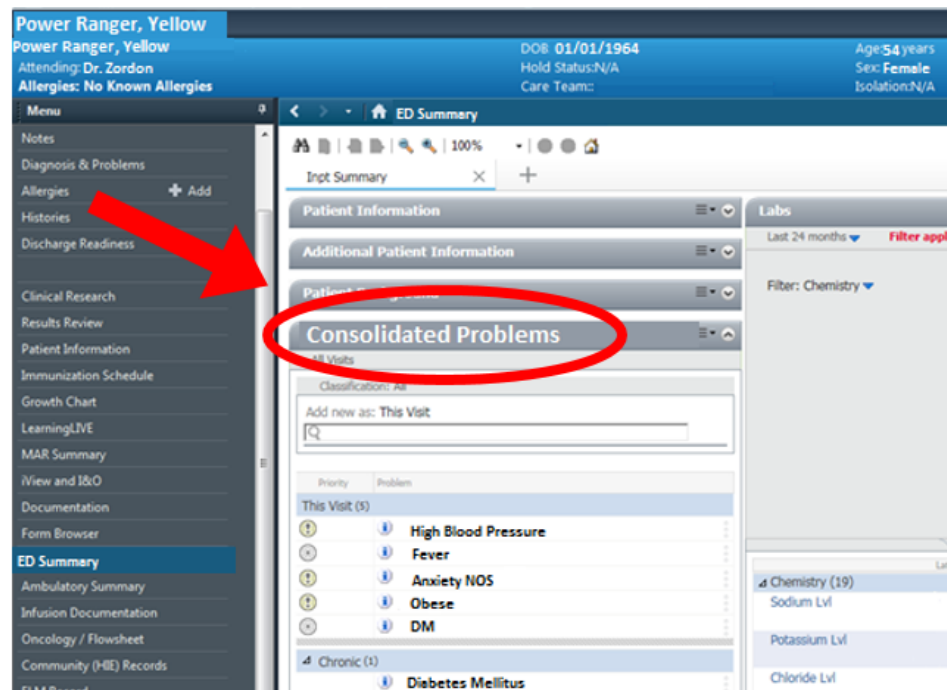
- Double click on the blue triangle to examine patient charts for age greater than or equal to 18 and PMH of diabetes.

CLICK ON BLUE
TRIANGLE



Bed	Name	Age	All A	Reason for Visit	Att	RESHF
★▶ FOD 1	POWER RANGER, YELLOW	54 Y	3	HIGH BLOOD PRESSURE	Dr. Zordon	
★ FOD 2	POWER RANGER, BLUE	52 Y	2	ETOH INTOXICATED, DTS, DTO	Dr. Zordon	
★ FOD 3	POWER RANGER, GREEN	55 Y	3	ABDOMINAL PAIN	Dr. Zordon	

- Sections should be reviewed in the following order:
 - Confirm that the patient is ≥ 18 years of age.
 - Review the ED summary page and locate the 'Consolidated Problems' section for this visit and previous visits.
 - If previous visits are not displayed, click the 'Show Previous Visits' box.
 - Check for the following codes: Diabetes mellitus type 1 & 2, DM1, DM2



Power Ranger, Yellow
Power Ranger, Yellow
Attending: Dr. Zordon
Allergies: No Known Allergies

DOB: 01/01/1964
Age: 54 years
Hold Status: N/A
Sex: Female
Care Team:
Isolation: N/A

Menu

- Notes
- Diagnosis & Problems
- Allergies + Add
- Histories
- Discharge Readiness
- Clinical Research
- Results Review
- Patient Information
- Immunization Schedule
- Growth Chart
- LearningLVE
- MAR Summary
- iView and I&O
- Documentation
- Form Browser
- ED Summary**
- Ambulatory Summary
- Infusion Documentation
- Oncology / Flowsheet
- Community (HIE) Records
- EMM Record

ED Summary

Inpt Summary

Patient Information

Additional Patient Information

Consolidated Problems

Classification: All

Add new as: This Visit

Priority Problem

This Visit (5)

- High Blood Pressure
- Fever
- Anxiety NOS
- Obese
- DM

Chronic (1)

- Diabetes Mellitus

Lab

Last 24 months Filter applied

Filter: Chemistry

- Chemistry (19)
- Sodium Lvl
- Potassium Lvl
- Chloride Lvl

- Review the 'Labs' section (also found in the ED summary page) for glucose levels.
 - Glucose levels can be found under the Chemistry Heading in the Labs.

- Patients with a glucose over 200 or HbA1c level above 8.5 should be approached first.
- This increases the probability of having an eligible patient.

Power Ranger, Yellow
Power Ranger, Yellow
Attending: Dr. Zordon
Allergies: No Known Allergies

DOB: 01/01/1964
Hold Status: N/A
Care Team:

Age: 54 years
Sex: Female
Isolation: N/A

Menu

Notes
Diagnosis & Problems
Allergies + Add
Histories
Discharge Readiness

Clinical Research
Results Review
Patient Information
Immunization Schedule
Growth Chart
LearningLVE
MAR Summary
View and I/O
Documentation
Form Browser

ED Summary
Ambulatory Summary
Infusion Documentation
Oncology / Flowsheet
Community (HIE) Records
ELM Record

ED Summary

Inpt Summary

Patient Information

Additional Patient Information

Patient Background

Consolidated Problems

All Visits

Classification: All

Add new as: This Visit

Priority Problem

This Visit (5)

- High Blood Pressure
- Fever
- Anxiety NOS
- Obese
- DM

Chronic (1)

- Diabetes Mellitus

Labs

Filter applied

Chemistry

Glucose	200
BUN	10
Creatinine Lvl	0.8
Sodium	145
Potassium	5.1

4. Review the 'ED notes' section.

- While in the ED notes section you can check the Nurse notes and ED Triage notes from this visit and previous visit.
- Look for information in relation to a diabetes related incident or any information that would possibly exclude the patient from the study (dementia, homelessness, psychiatric health issues, etc.)

Power Ranger, Yellow
Power Ranger, Yellow
Attending: Dr. Zordon
Allergies: No Known Allergies

DOB: 01/01/1964
Hold Status: N/A
Care Team:

Age: 54 years
Sex: Female
Isolation: N/A

Menu

Notes
Diagnosis & Problems
Allergies + Add
Histories
Discharge Readiness

Clinical Research
Results Review
Patient Information
Immunization Schedule
Growth Chart
LearningLVE
MAR Summary
View and I/O
Documentation
Form Browser

ED Summary
Ambulatory Summary
Infusion Documentation
Oncology / Flowsheet
Community (HIE) Records
ELM Record

ED Summary

Inpt Summary

Patient Information

Additional Patient Information

Patient Background

Consolidated Problems

All Visits

Classification: All

Add new as: This Visit

Priority Problem

This Visit (5)

- High Blood Pressure
- Fever
- Anxiety NOS
- Obese
- DM

Chronic (1)

- Diabetes Mellitus

Labs

Filter applied

Chemistry

Glucose	200
BUN	10
Creatinine Lvl	0.8
Sodium	145
Potassium	5.1

Documents

Last 24 months

Note Type	Author	Date/Time
ED Note-Provider	Dr. Zordon	
History and Physical	Dr. Alpha	
Cardiology Consultation	Dr. Mechiko	
Consultation		

Outstanding Orders (5)

New Order Entry

- All patients with diabetes should be added to the TextMed Screening Log.
- If a patient is homeless, has a psychiatric issue, or has a primary language other than Spanish or English then be sure to STILL record the appropriate information in the TextMed Screening Log, while using the correct enrollment code for exclusion.
- Approach all your patients on the completed screening log.
- If none of the patient's approached qualify for the study, then continue to screen until your shift is over.

3.3 HOW TO USE THE HbA1c ANALYZER

Proper handling of the HbA1c analyzer is necessary for the accurate assessment of patient HbA1c levels. The following sections outline how to properly run controls and measure a patient's HbA1c levels using the AfinionS100 HbA1c Analyzer.

Remember to always turn the analyzer ON at the beginning of your shift if you are the first shift of the day, and to turn it OFF if you are the last shift of the evening before leaving the FOD.

3.3.1 FINGERSTICK INSTRUCTIONS

Before collecting a blood sample for the HbA1c test, patient's need to be informed what the test consists of. Patient's will receive their HbA1c levels within 10-15 minutes after sample collection. Advice and medical recommendations of Patient's HbA1c level or DM care is not permissible. Report HbA1c value to patient once. For Patient specific questions regarding HbA1c results and or DM Care, please direct them to their primary care provider, care provider in the ED, and or nurse. A1C Level Information sheet can be provided to them. Refer to section 8.2. A1c Information Sheet -English & Spanish in Manuel of Operations.

- Gather ALL of the following supplies after patient agrees to have their HbA1c measured:
 - Kidney Bin
 - Gauze sponge 2x2
 - Alcohol preps
 - Finger bandage
 - Gloves
 - Extra-Absorbent pad
- Hands must be washed/sanitize before encountering any patient
- Gloves must be worn at all times while collecting an HbA1c sample
- All the supplies needed for collecting blood specimen must be placed on top of the extra-absorbent pad to prevent any contamination
- Identify selected site for finger stick (See Figure 3.3A)

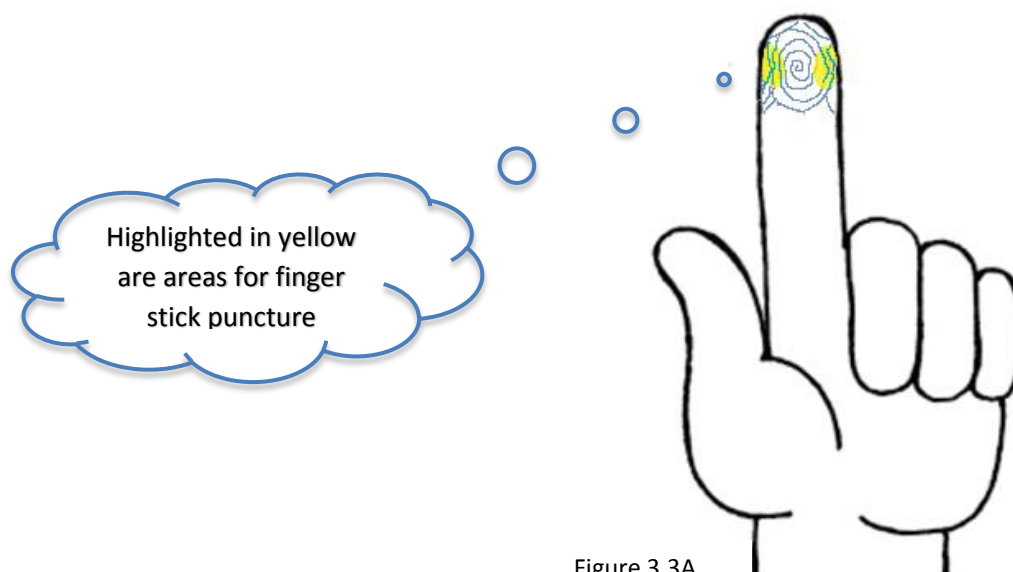


Figure 3.3A

- Wipe patient's finger with alcohol prep in CIRCULAR motion moving germs away from selected site (See Figure 3.2 B)
- DO NOT wipe side to side

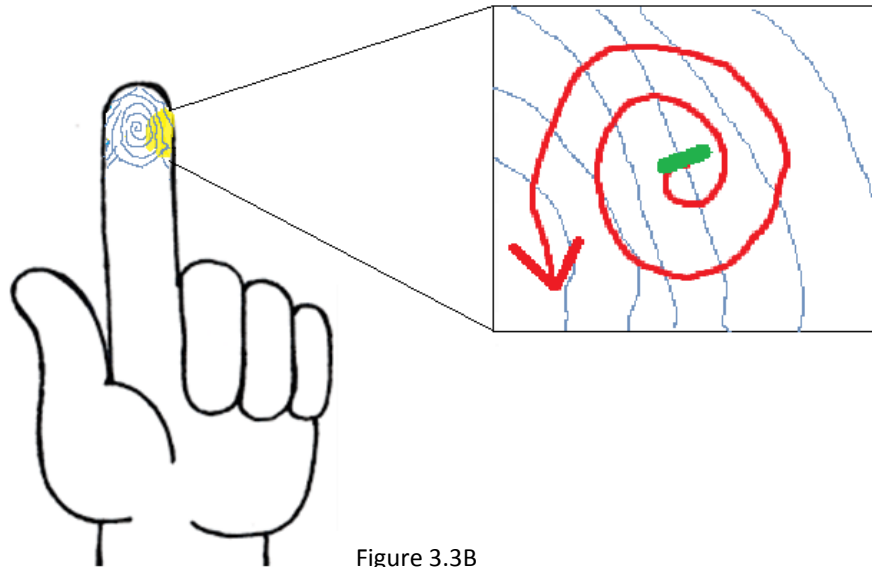
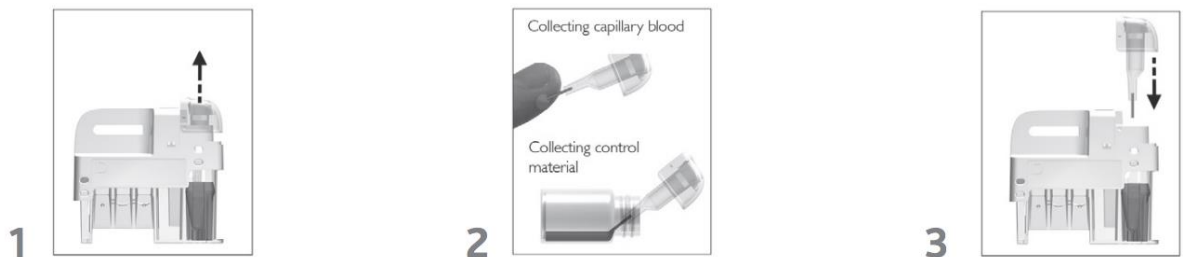


Figure 3.3B

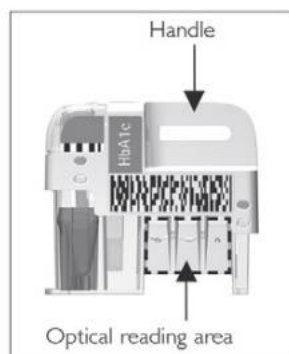
- Let alcohol dry off before proceeding to the finger stick
- For a finger stick, the cut should be PERPENDICULAR to the fingerprint line (See Figure 3.2 B). This will provide the best possible drip and blood flow. Be sure to squeeze finger if blood flow is minimal.
- Wipe off the initial sample of blood with the gauze, and collect the following sample.

3.3.2 COLLECTING CAPILLARY SPECIMEN

To collect sample, remove the capillary from the Test Cartridge, fill the capillary (holding the patient's finger almost horizontal bringing the tip of the capillary in contact with the sample), and immediately place capillary back into the test cartridge. Do not wipe off the capillary after collecting the sample. (See Figure 3.3C)




Do not lay the cartridge on its side, and be sure to hold the cartridge from its handle. Do not touch the optical reading area. This can influence the reading measured. (See Figure 3.3D)




Properly dispose of the finger stick needle, alcohol swab, and gauze in the biohazard container.
(Anything that comes into contact with patient's blood)

The time from filling the capillary until analyzing the Test Cartridge should be as short as possible. Politely excuse yourself to analyze the sample as quickly as possible.

Touch  on the HbA1c analyzer and insert the cartridge with the barcode facing left.

Close the lid manually. The analyzer will start processing the sample automatically.

Record the result, then touch  to accept.

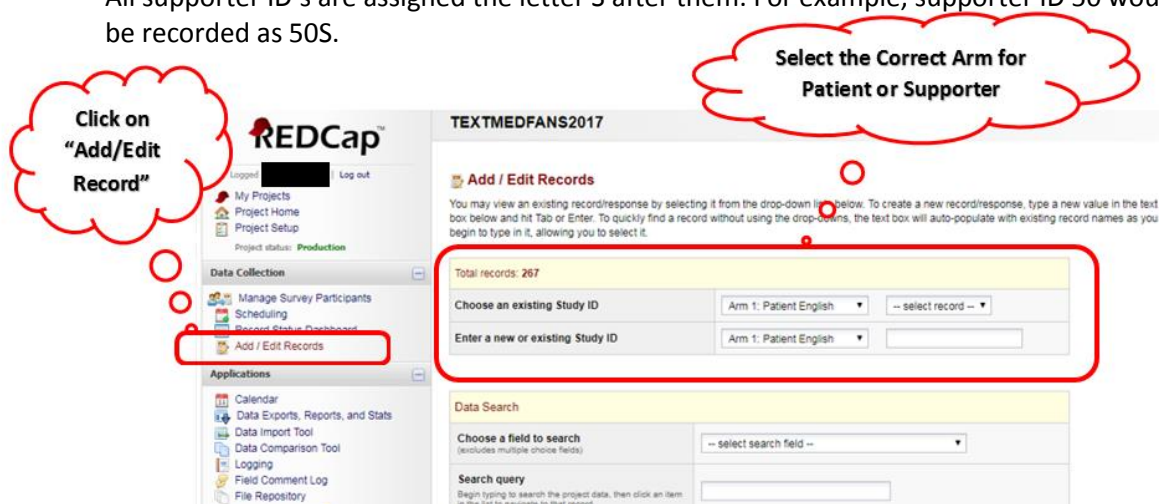
Remove the test cartridge from the cartridge chamber and discard it in the biohazard container in the FOD.

Keep the lid of the analyzer closed after in order to protect the analyzer from any damage.

3.4 CREATING PT/SUPPORTER PROFILE

Visit <https://redcap.sc-ctsi.org/> and login with your account information to create a RedCap Patient/Supporter Profile.

1. Click on the 'My Projects' tab and locate TEXTMEDFANS2017. You are now ready to create a new patient profile.
2. Click on Add/Edit Records under the Data Collections section. Select the correct arm for the patient/supporter. (English Patient/Supporter or Spanish Patient/Supporter)
 - Enter the correct study ID in the empty box highlighted below.
 - The next sequential ID can be found in the Manual of Operations in the section 7.1. PID Log Copies.
 - Once you enter the ID and click outside of the highlighted box the profile will be automatically created.
 - BE CAREFUL when creating the ID make sure to be accurate.
 - All patient ID's are assigned the letter P after them. For example, patient ID 50 would be recorded as 50P.
 - All supporter ID's are assigned the letter S after them. For example, supporter ID 50 would be recorded as 50S.



3. First, record the e-mail for a patient/supporter. If the patient/supporter does not have an e-mail, then you must create one for them using the iPad. At the end of each section, change the form status to 'Complete' and click on 'Save and go to Next Form'.

The screenshot shows the REDCap form for 'Email' under the 'Enrollment (Arm 1: Patient English)' event. The 'Study ID' field is highlighted with a red box. A thought bubble points to the 'Study ID' field with the text 'Refer to MOP Section 7.1 for the next sequential PID Number'. The 'Form Status' is set to 'Complete'.

4. Next, complete the physiologic measurements. (weight, height, abdominal circumference, and BP)
5. In the Demographics section, 'Healthy Start Date' for all patients is the 3rd Monday after Patient Enrollment
 - Be sure to record all phone numbers and addresses accurately. This is imperative for future appointment contacts with our enrolled patients.

The image shows a screenshot of a patient enrollment form. The form is divided into several sections. The top section is yellow and contains the text "Event Name: Enrollment (Arm 1: Patient English)". Below this is a grey section for "Study ID". The next section is green and contains the "RA Name" field, which is highlighted with a red box and has a red callout bubble above it that says "RA's complete name DO NOT initial". Below the RA Name field is a grey section for "Date subject signed consent", which has a red callout bubble above it that says "3rd Monday from Patient Enrollment". The final section is grey and contains the "Healthy Start Date:" field, which also has a red callout bubble above it that says "3rd Monday from Patient Enrollment". The form includes various input fields, dropdown menus, and a "Today" button for date selection.

RA's complete name
DO NOT initial

Event Name: Enrollment (Arm 1: Patient English)

Study ID

RA Name
* must provide value

Date subject signed consent
* must provide value

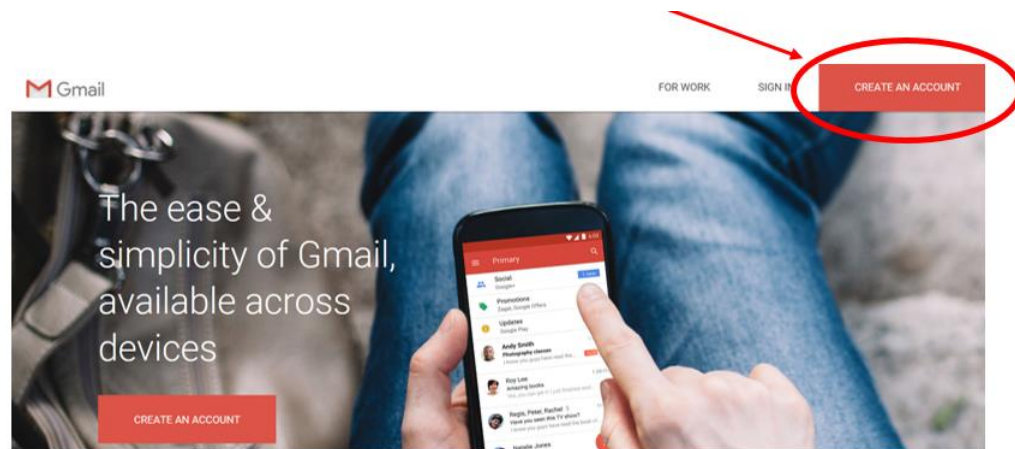
Healthy Start Date:
* must provide value

3rd Monday from
Patient Enrollment

3.5 CREATING AN EMAIL

Use the following steps to create an account for participant or supporter

1. Open the following link <https://www.google.com/gmail/about/#>
2. Click on “Create an Account”



3. Complete required fields seen below and Click on “Next Step”

Create your Google Account

One account is all you need
One free account gets you into everything Google.

Take it all with you
Switch between devices, and pick up wherever you left off.

Name

First Last

Choose your username

@gmail.com

Create a password

Confirm your password

Birthday

Month Day Year

Gender

I am...

Mobile phone

Your current email address

Default homepage

Set Google as my default homepage.

Your default homepage in your browser is the first page that appears when you open your browser.

Location

United States

[Next step](#)

[Learn more](#) about why we ask for this information.

4. Privacy and Terms Window will appear. Click on “I Agree”

Privacy and Terms

By choosing "I agree" below you agree to Google's [Terms of Service](#).

You also agree to our [Privacy Policy](#), which describes how we process your information, including these key points:

Data we process when you use Google

- When you set up a Google Account, we store information you give us like your name, email address, and telephone number.
- When you use Google services to do things like write a message in Gmail or comment on a YouTube video, we store the information you create.
- When you search for a restaurant on Google Maps or watch a video on YouTube, for example, we process information about that activity – including information like the video you watched, device IDs, IP addresses, cookie data, and location.
- We also process the kinds of information described above when you use apps or sites that use Google services like ads, Analytics, and the YouTube video player.

Depending on your account settings, some of this data may be associated with your Google Account and we treat this data as personal information. You can control how we collect and use this data at [My Account](#) ([myaccount.google.com](#)).

Why we process it

We process this data for the purposes described in [our policy](#), including to:

- Help our services deliver more useful, customized content such as more relevant search results.

CANCEL

I AGREE

5. Help participant record their username name and password for their records
6. Do NOT keep a copy of participant's log-in information
7. Provide participant with a copy of email safety tips form