PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR

Karen Sepucha, PhD

PROTOCOL TITLE

Refining the Shared Decision Making Process Survey Instrument

FUNDING

Agency for Healthcare Research and Quality

VERSION DATE

March 18, 2020

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

We plan to study the Shared Decision Making (SDM) Process survey and make improvements to the survey, as needed, to improve the reliability, validity and extend its generalizability. The overall project funded by Agency for Healthcare Research and Quality will accomplish the following three aims, however, this protocol only covers the activities for Aim 1 and 2. We separated these activities out from those in Aim 3, as we believe that these would be considered either not human subjects research or would be considered exempt from human subjects research. The activities in Aim 1 involve the analysis of existing datasets that do not contain any individually identifiable information and for Aim 2 the activities may be exempt according to guideline 45 CFR 46.104(d)(2) Educational tests/survey/interview procedures, or observation of public behavior.

Aim 1: Produce a comprehensive summary of the existing evidence of the reliability and validity of the SDM Process Score, and compare performance across a range of clinical situations (e.g. screening versus medication versus surgical) and types of decisions (e.g. symptomatic versus non symptomatic). Hypotheses related to discriminate, concurrent and predictive validity will be tested such as: (a) patients with higher baseline SDM Process scores were more likely have high decision quality (b) patients with higher baseline SDM Process scores will have less decisional conflict and (c) Patients with higher baseline SDM Process scores will have less regret at follow up.

Aim 2: Analyze de-identified data collected by Center for Survey Research at University of Massachusetts Boston from cognitive interviews and from four online field tests. The field test data will examine new and revised SDM Process items in previously studied populations (i) adults making cancer screening decisions and (ii) adults making medication decisions, and will also examine use with new populations (iii) younger adults (aged 21-40) and (iv) parents making decisions for their young children (e.g. treatment of attention-deficit/hyperactivity disorder). The analyses will examine reliability and will also test several hypotheses related to validity will be SDM Process scores will be associated with higher decision quality, lower decisional conflict and less regret.

Aim 3: Gather evidence of reliability, validity and feasibility in clinical settings targeting patients 65 and older who are scheduled for elective surgery to examine the quality of the surgical decision making process. As part of this study, nurses and caregivers will also be asked to complete short surveys to provide their perspective on the quality of decision making. These data will provide evidence of the acceptability, reliability, and validity of the measure.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Giving patients a voice and ensuring that decisions reflect patients' informed goals, needs, and preferences is the goal of shared decision making (SDM). In 2004, the investigators started work on survey items that focused on three elements—the extent to which the patient (1) is meaningfully involved the decision-making process (2) understands their options and the pros and cons of each, and (3) receives tests or treatments that reflect their goals [1-2]. Since then, the investigators have produced a generic SDM Process survey that covers item 1, and fourteen decision-specific Decision Quality Instruments (DQIs) that cover items (2 and 3). Two performance measures based on these surveys recently received endorsement by the National Quality Forum for six surgical decisions.

The investigators have amassed a large amount of data on the SDM Process survey in different medical contexts, with different patients, using different modes of administration. The different studies used slight variations in the wording of items and in the scoring of responses; however, there has not yet been any systematic examination of data to determine the best ways to word items, the best approach to scoring the items, and whether or how the items should vary based on aspects of the study (e.g. prospective versus retrospective sampling) or aspects of the clinical decision (e.g. screening, treatment of symptoms). Further, the use has been limited to adults in outpatient settings, with a major focus on elective surgery decisions. As a result, there is still much work to be done to extend generalizability of the SDM Process survey across clinical contexts and examine its performance in different populations.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

The following briefly describes the three main projects that will help achieve the study aims1 and 2. The projects are a mix of secondary analyses of existing data sets and online field tests.

Project 1 Secondary Data Analyses. This project consists of secondary data analyses from existing sources to that used the SDM Process survey to evaluate the quality of decision making. All of the existing datasets are de-identified and do not contain any identifiable information. One data set (DECISIONS) is publicly available through ICPSR, an open-access service. Dr. Sepucha has existing, active IRB protocols that cover access to and analysis of data for the datasets are listed below. The original purpose of these studies was to examine the

quality of decision making across different clinical situations with and without interventions. The secondary analyses, to examine shared decision making is aligned with the original purpose of each study. Dr. Sepucha currently has active IRBs that cover the secondary data analysis activities outlined in the first aim for the following data sources and added the funder AHRQ to each IRB. The IRB protocol numbers, title, and data sources covered are as follows:

- Partners Protocol #2006P002025 *Analysis of Data From the Foundation for Informed Medical Decision Making*, Sepucha (PI), data sources 1-4 below:
    1. DECISIONS study (2007): a retrospective *telephone survey study* of a national sample of 3,000+ adults age 40 and older, who had recently faced decisions about cancer screening, medication or surgery. The study was funded by the Foundation for Informed Medical Decision Making. The data are publicly available through the inter-university consortium.
    2. DQI Field tests (2005-2012): *online and clinic-based studies* of 2700+ patients facing decisions for breast cancer, knee or hip osteoarthritis and herniated disc, menopause, depression or colon cancer screening funded by Foundation for Informed Medical Decision Making.
- Partners Protocol #2013P001794 *Making Orthopedic Referrals Enhanced with Technology and Education*, data source 5: prospective, clinic-based sample of 652 patients with hip or knee osteoarthritis, herniated disc or spinal stenosis were surveyed shortly after visit with a surgeon, and again 6-12 months later.
- Dana Farber/Harvard Cancer Center Protocol #07-340 *Measuring the Quality of Decisions in Breast Cancer*, Moy (PI), data source 6: prospective, clinic-based sample of 267 patients with early stage breast cancer at four clinical sites about their surgery and systemic therapy decisions shortly after their first medical oncology visit and again about one year later. Sepucha (PI).
- Partners Protocol #2016P000229 *Comparative Effectiveness of Decision Support Strategies for Joint Replacement Surgery*, Sepucha (PI), data source 7: prospective, clinic-based study 1,100+ patients recruited to a multi-site randomized trial comparing different decision aids for hip and knee osteoarthritis
- Partners Protocol #2005P002282: *Improving patient involvement in decision making in primary care*, Sepucha (PI), data source 8: retrospective, mailed and online survey study 800+ patients who underwent elective surgery for hip osteoarthritis, knee osteoarthritis, herniate disc, and spinal stenosis.

- Medicare Surgery Study (2009): A retrospective *mailed survey* study of a national sample of 2000+ Medicare beneficiaries who had recently had prostate cancer surgery, breast cancer surgery, coronary bypass surgery or stents. Study run by investigators at Dartmouth Medical School, in collaboration with Foundation for Informed Medical Decision Making, funded by National Institutes on Aging. De-identified data sets are available through the principal investigator. Access to the data for analyses and advancing the measurement of shared decision making and decision quality was reviewed and considered exempt 2010-P-002766 *Secondary analysis of Medicare survey data*.

There are two additional data sets that Dr. Sepucha has been granted access to for the purposes of this study:

- TRENDS study (2011): a retrospective *online survey study* of a national sample of 2900+ adults age 40 and older were recruited to complete an online survey covering the same topics in DECISIONS study conducted and funded by the Foundation for Informed Medical Decision Making. In 2014, the ownership of the data transferred to Healthwise (when the Foundation for Informed Medical Decision Making and Healthwise merged). The data were

collected via an online survey company and the data set does not contain any individual identifiable information. A Letter from the Healthwise CMO granting the PI access to this data for the current study is included as an attachment.

- Demonstration Site Program data: survey data from 34 sites that were funded through the Informed Medical Decisions Foundation to use patient decision aids and survey patients about their decision making processes. The data set does not contain any individually identifiable information. The investigators will not have access to any codes or links that would enable an individual to be identified.

Project 2: Cognitive Interviews. MGH has a formal subcontract with Center for Survey Research to conduct these activities. Investigators at the Center for Survey Research (CSR) at University of Massachusetts Boston will conduct cognitive interviews to evaluate new items and existing items with new populations before each of the online field tests (see Project 3). The recruitment of participants for cognitive testing will be conducted by the Center for Survey Research (CSR) at University of Massachusetts Boston. They expect to enroll 8-10 participants before each online field test, for a total of 32-40 interviews. Table 1 contains the eligibility criteria for the subjects each of the field tests. Subjects who are part of the CSR database who have agreed to be contacted for research studies will be screened for eligibility. CSR will also place ads in online outlets and will screen respondents to the ads for eligibility.

CSR will provide MGH with de-identified results from the interviews. No identifying information will be presented in reports of findings. The results of this will be a set of evaluative comments about how well different questions are understood and what types of phrasing is preferred – and not preferred. This dataset will not contain any sensitive or confidential respondent information. The cognitive interview activities have been reviewed by the Institutional Review Board at UMass Boston and have been determined to be exempt according to guideline 45 CFR 46.104(d)(2) Educational tests/survey/interview procedures, or observation of public behavior. The letter indicating the IRB determination and the submitted protocol that includes copies of the advertisements is attached.

Table 1: Project 2 Eligibility Criteria

a. Cancer screening decisions	
Eligible	**Ineligible**
• Adults 40-75 years old • English speaking • Have discussed breast, prostate or colorectal cancer screening with a health care provider in the last 2 years	• Prior diagnosis of prostate, breast or colorectal cancer
b. Medication decisions	
Eligible	**Ineligible**
• Adults 30-75 years old • English speaking • Have talked with health care provider about treatment for high cholesterol, high blood pressure or depression within past 2 years	• History of heart attack or stroke
c. Depression in young adults	
Eligible	**Ineligible**

• Adults 18-39 years old • English speaking • Talked with health care provider about treatment of depression within past 2 years (either prescription medicine and/or counseling)	

d. ADHD decisions

Eligible	Ineligible
• Adults 21 and older • English speaking • Have talked with a health care provider about treatment for ADHD for a child (aged 3-13) in the past 1 year	

Project 3: Online Field Tests. We will conduct four online field tests to examine the psychometrics of the new and revised items. CSR will oversee the design and will program the surveys into Qualtrics. CSR will obtain anonymous responses from a web panel through Marketing Systems Group (MSG). The online panel members opt-in to take surveys and respondents can unsubscribe at any time. The sampling firm will send an email invitation to potentially eligible panel members informing them that a survey is available that they are eligible for. Respondents choose to participate or not. The sampling firm's database does not hold sensitive or confidential panelist information. MSG will stop emailing web panel members once they have received 500 completed surveys per round according to the criteria in Table 1. CSR will receive a participant ID from MSG and will never have access to participants' emails or any of their personal information.

The field tests will randomly assign participants to complete different versions of the items, and/or to complete other surveys in addition to the SDM Process survey to establish validity. For the cancer screening and medication decisions, participants may be randomly assigned to receive educational information (e.g. a patient decision aid) before completing the questions. The sampling will attempt to balance the respondents based on gender and geographic region (Northeast, Southeast, Midwest and West). A subset of respondent for each field test will complete the SDM Process items again shortly after the initial assessment to establish short term test-retest reliability. CSR will receive a completely anonymous, de-identified datafile that has responses to the survey questions.

No identifiable information will be collected or shared. MGH will receive a copy of the survey responses from CSR. The online field test activities have been reviewed by the Institutional Review Board at UMass Boston and have been determined to be exempt according to guideline 45 CFR 46.104(d)(2) Educational tests/survey/interview procedures, or observation of public behavior. The letter indicating the CSR IRB determination is attached.

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

Project 1: This is secondary data analyses only. The data are de-identified and the investigators do not have access to any personal health information nor do they have the ability to identify any individual in the samples. The purpose of the analyses are to examine the quality of the survey instrument used in the initial studies for which the patients originally provided consent.

Project 2: Cognitive interviews

1. MGH investigators will assist in developing the interview guide.
2. CSR will recruit the participants from online and newspaper ads.
3. CSR staff will conduct the interviews and participants will complete the survey items using a 'think aloud' technique and will react to formatting, wording and design of the survey instrument.
4. CSR will send MGH a summary of the results of the interviews with recommendations for editing the survey to improve comprehension and reliability. The summary report will not contain any individual identified data.
5. Investigators and staff will review the results and make recommendations for changes or edits to the survey items, instructions and formatting based on the results.

Project 3: Online field tests

1. The MGH investigators and staff will work with CSR to finalize the survey items based on results from Project 2.
2. CSR will program the surveys and obtain de-identified responses to the four online field tests from MSG's web panel.
3. CSR will send MGH study investigators and study staff deidentified results of the surveys. These datasets will include only de-identified information, no identifiable information will be collected or shared.
4. MGH investigators will analyze the data and prepare manuscripts summarizing the results.

All study staff are CITI certified and will receive training from the PI and program manager in the study protocol. We will hold regular meetings to review screening, enrollment and completion data.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

No diagnosis or treatments will be offered or administered as part of this study. The standard of care is that physicians discuss appropriate treatment options, including their benefits and risks with the patient.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

Project 1: The original studies were focused on examining the quality of medical decisions across a range of clinical areas. The proposed secondary analyses are aimed at improving the

survey instruments used in those original studies. The datasets do not contain any individually identified information. These analyses do not change the risk of the original studies.

Projects 2 and 3: The datasets shared with study staff/Partners will not contain any individually identifiable, confidential or protected/sensitive health information from responders. There are minimal risks associated with participating in the cognitive interviews and online field tests that will be conducted by CSR. Participants may refuse to answer any question and may stop their participation at any time during the interview. The respondents to the online panel have already given permission to be contacted by signing up for the panel. The participants in the online panel may stop their participation at any time.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

Project 1: The secondary analyses of de-identified data. The data sets do not contain any individually identifiable information and the investigators and staff will not make any attempt to identify any participant.

Projects 2 and 3: The summary report from the cognitive interviews (Project 2) and the datasets from the online field tests (Project 3) will be deidentified and no confidential or protected/sensitive health information will be shared with MGH study staff. The datasets will not contain confidential or protected/sensitive health information from responders. There are minimal risks associated with participating in the cognitive interviews. The staff at CSR will destroy all tapes after the summary reports have been finalized and will destroy all notes and files with personal information once the study is completed. For the online field tests, there is minimal risk to participants and neither CSR nor the MGH staff will never have any access to individually identifiable information.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

There are minimal risks to participating individuals in this project. For the secondary data analyses, there are no identifiable information included in the data sets, and the researchers will not attempt to identify any participant. For the cognitive interviews and online field tests, the main discomfort is the time and effort involved to complete the interview or survey.

The main risk for the cognitive interviews is the potential for loss of privacy. To address privacy and confidentiality issues, the summary reports shared with MGH by CSR investigators will not contain any identifying information and will be coded by unique study ID number only. The online field tests will not have any identifiable information.

To address issues of psychological discomfort, the instructions will clearly state that participants may refuse to answer any question and may withdraw from the study at any time.

No confidential or PHI will be collected as part of this study.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

There is no direct benefit from participating in the cognitive interviews or online field tests.

However, some people may view their participation as beneficial because they will be assisting in the evaluation of a measurement instrument that may be used to help patients. The results will help the field understand the best way to inform and engage patients in significant medical decisions.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

The majority of medical topics included these studies are only relevant for adults. The projects enrolling parents who have made decisions about treatment of their children's ADHD will target younger children so that parents are the primary decision maker. As a result, no children will be enrolled.

For Projects 2 and 3, participants will be limited to those who can read and speak English.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

Translation of the information sheets is not adequate to support the full participation of non-English or non-Spanish speaking patients for the study activities.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Non-English_Speaking_Subjects.1.10.pdf

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

Project 1: Secondary data analyses

1. This project is analyzing data that has already been collected. There are no recruitment activities involved.

Project 2: Cognitive interviews

1. Investigators at CSR will identify participants through advertisements (e.g. Craig's list ads and through their database of participants willing to be contacted for research).
2. CSR staff will screen interested participants for eligibility.
3. At the beginning of the interview, participants will review and sign a consent form.
4. MGH study staff will receive de-identified summary report of the results of the cognitive interviews from CSR.

Project 3: Online field tests

1. Members of the web panel will be contacted and recruited through email by Marketing Systems Group (MSG). The firm will send an email to invite targeted sample members to participate in the survey.
2. Panel members will review the information sheet before proceeding to the survey.
3. Study staff will receive anonymous, deidentified results of the online field tests from the firm. Study staff will conduct study analyses from these datasets;

All study staff are CITI certified and will receive training from the PI and program manager in the study protocol. We will hold regular meetings to review data.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

The respondents who participate in the cognitive interviews will be paid $80 for their participation, according to the standard policy for the Center for Survey Research.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Recruitment_Of_Research_Subjects.pdf

Guidelines for Advertisements for Recruiting Subjects
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Guidelines_For_Advertisements.1.11.pdf

Remuneration for Research Subjects

https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Remuneration_for_Research_Subjects.pdf

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

The secondary data analysis activities do not involve interaction or intervention with human subjects, are limited to existing data sets that do not contain an individually identifiable information, and there is no way for investigators to link data to an individual.

The cognitive interviews and online field tests involve survey and interview procedures for the purposes of examining the development and validation of a survey instrument. Participation is completely voluntary. CSR will use their standard informed consent form for the patients participating in the cognitive interviews. Before the cognitive interview starts, the interviewer will give the respondent an opportunity to ask questions about any aspects of what is expected of them or the project as a whole and they will be given the consent document to read and sign (See Appendix C in the attached protocol from CSR).

For the online survey, respondents will be presented with a digital copy of the information sheet and will acknowledge that they have read it before moving on to complete the survey items.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects:
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Informed_Consent_of_Research_Subjects.pdf

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the

study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

Oversight of the trial is provided by the MGH Principal Investigator (PI), Drs. Sepucha and the UMass Center for Survey Research PI, Dr. Fowler and Ms. Cosenza. The trial is minimal risk and the data and safety monitoring plan is commensurate with the potential risk level.

The existing data sets that will be used for secondary analyses will be kept on Partners password protected servers and only IRB-approved Partners study staff members will have access to the shared folder.

The data from the cognitive interviews and the online field tests will not include any identifiable information. There are no adverse events expected for this minimal risk survey study. Study staff will review the data sets and will notify the site PI about any serious or moderate potential adverse events (AEs) immediately and any minor or potential ones at weekly meetings. The PI will review AEs individually real-time and in aggregate on a weekly, basis at team meetings. The PI and clinician co-investigators will review potentially serious adverse events (SAEs), as soon as they are discovered. The PI ensures all protocol deviations, AEs, and SAEs are reported to the IRB according to the standard requirements.

There are no formal stopping rules for this minimal risk study.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

AEs are identified by study staff through interactions with study participants and upon review of completed surveys. SAEs and specific study-associated AEs are reported to the IRB within 24 hours. In addition, all AEs are reported according to the Partners and University of Massachusetts Boston Human Subjects Committee AE reporting guidelines.

No serious or moderate adverse events are expected based on the minimal risk in the studies. However, if a serious adverse event occurs then the principal investigator will report the event to the IRB within 24 hours and will file an HRC Adverse Event Form within 10 working days. If a mild or moderate adverse event occurs, the principal investigator will summarize the event in the progress report at time of the annual continuing review.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

All research staff are CITI certified and will be trained on the importance of data confidentiality. The study staff will not have any identifiable information on respondents and will not make any effort to identify an individual in the existing data sets.

All study data sets will be kept on a separate password-protected Partners shared folder and only the IRB approved study staff and investigators will have access to this folder. These will be kept as long as required by the research project. After the study has been completed, the external data sets that were used for this project will be deleted.

The study staff and the principal investigator will have routine meetings during the study period to ensure the project proceeds as intended per the protocol. The study staff will complete all required documents for the study binder and this will be reviewed quarterly by one of the principal investigators.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/DSMP_in_Human_Subjects_Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Reporting_Unanticipated_Problems_including_Adverse_Events.pdf

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

In projects 1-3, the study staff will only have access to de-identified survey and interview data. We will not have any individual identifiable information. We will not attempt to identify any individual in the existing data sets used for the secondary analyses.

All research staff are CITI certified and will be trained on the importance of data confidentiality.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

We are committed to making resources and data from the proposed research available to other investigators in the research community. The data collected in the online field tests will be made available to others for analysis and research. The study team will create a complete, cleaned, de-identified copy of the final data set for each online field test. Information for investigators interested in using this data will be made available on the Health Decision Sciences Center website and in publications of the data. Dr. Sepucha will share a de-identified data set with outside investigators at no cost, according to approved MGH/Partners policies for data sharing. Investigators from other sites will be able to request the data and will be required to complete a data use agreement that ensures that all local IRB requirements are met before using the data, that they will not attempt to identify any data in the dataset, and that they will not share the data set with anyone outside their project team.

We will also make information necessary to interpret the data, such as study protocols, data dictionaries, and survey tools available to interested investigators.

After the primary manuscripts are published, the MGH investigators will post the data and supporting materials in an open access service such as, ICPSR (https://www.icpsr.umich.edu/icpsrweb/). On ICPSR, individuals must register and agree to ICPSR's Responsible Use statement prior to accessing datasets. Additionally, before a dataset is made available for access, ICPSR completes a detailed review of all datasets to assess disclosure risk. If necessary, ICPSR modifies data to reduce disclosure risk or limits access to datasets for which modifying the data would substantially limit their utility or the risk of disclosure remains high. No information that contains identifiers or that could be used to link an individual to the data will be included in the de-identified data set.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

N/A

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

The data sets being used in project 1 are either publicly available, or the PI has obtained permission to use the data for the purposes of the current project. The data sets are de-identified and individuals cannot be identified by the MGH investigators.

For projects 2 and 3, CSR will conduct the cognitive interviews and online field tests. MGH has set up a formal subcontract with CSR to conduct these activities. MGH will receive data from CSR. The data will not contain any personal or identifiable information. MGH will conduct primary data analysis on online field test survey data collected by the Center for Survey Research.

References:

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