Appendix 6. Final Study Protocol

Appendix 6. Final study protocol

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

Adil Haider, MD MPH

PROTOCOL TITLE

Patient Centered Approaches to Collect Sexual Orientation and Gender Identity Information in the Emergency Department – Phase 3 Trial

FUNDING

Patient-Centered Outcomes Research Institute (PCORI)

VERSION DATE

01/27/2016

SPECIFIC AIMS

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

Goal: To determine the most patient-centered approach to collect sexual orientation and gender identity (SO/GI) information in the emergency department (ED)

Specific Aim 1: To implement two different approaches to SO/GI collection in the ED

Specific Aim 2: To compare the patient-centeredness of two different approaches to SO/GI collection in the ED

BACKGROUND AND SIGNIFICANCE

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

Lesbian, Gay, Bisexual and Transgender (SGM) populations experience significant health disparities associated with social stigma and discrimination, including higher risk of depression, suicide, substance abuse, and HIV.[1-3] Gay men, particularly within communities of color, have a higher risk of HIV and other sexually transmitted infections (STIs).[4] Lesbians and bisexual women are more likely to be overweight or obese,[5] and lesbians are less likely to get preventive services for cancer.[6,7] Older SGM individuals are particularly affected by barriers to high quality health care due to isolation and a lack of culturally competent health care providers.[8] Transgender individuals arguably experience the most acute health care access and outcomes disparities. Transgender people have a high prevalence of HIV and other STIs,[9] victimization,[10] and mental health issues.[11] The overwhelming array of health disparities experienced by the SGM community, compounded by the lack of available data, led the U.S. Department of Health and Human Services to identify SGM individuals as a target group for improvement in Healthy People 2020 and prioritized the need to identify appropriate data collection systems for SGM health.[12] Recently, the Center for Medicare and Medicaid Services have released Meaningful Use Stage 3 guidelines, which require all certified Electronic Health Record (EHR) systems to have that capacity to record SO/GI data.[13]

Lack of data on SO/GI is a major challenge to understanding and addressing SGM health disparities.[14] Furthermore, awareness of a patient's SO/GI information is important for health care providers to know, as it may be clinically relevant.[15] For instance, a female-to-male transgender patient (someone who was born a female, but whose gender identity or expression is now male) who presents to the ED with pelvic pain and does not disclose his gender identity – and most importantly, is not asked – is in danger of receiving poorer quality or delayed health care simply due to his providers' lack of awareness.

Every year in the United States, there are nearly 130 million visits to hospital EDs.[16] Few hospital EDs routinely collect SO/GI information;[17] however, the potential impact of doing so would be tremendous given this high volume of patients. In the preliminary findings of the study, it was found that while ED healthcare providers did not feel SO/GI collection was relevant, patients perceived collection to be important regardless of their medical concern. Although there are significant challenges to asking SO/GI information in a patient-centered way, the failure to inclusively and sensitively address SO/GI information in the hospital emergency setting effectively creates conditions for a kind of invisibility among SGM individuals – both within the examining room and within health outcomes data.

De Santis JP. HIV infection risk factors among male-to-female transgender persons: a review of the literature. *Journal of the Association of Nurses in AIDS Care.* 2009;20:362-372.

Dworkin SH YH. SGM identity, violence, and social justice: the psychological is political. *International Journal for the Advancement of Counseling* 2003 25:269-279.

Lombardi EL, Wilchins RA, Priesing D, Malouf D. Gender violence: transgender experiences with violence and discrimination. *Journal of homosexuality.* 2001;42(1):89-101.

Centers for Disease Control and Prevention (CDC). *HIV and AIDS among gay and bisexual men.* Atlanta: CDC;2010.

Struble CB, Lindley LL, Montgomery K, Hardin J, Burcin M. Overweight and obesity in lesbian and bisexual college women. *Journal of American college health : J of ACH.* 2011;59(1):51-56.

Buchmueller T, Carpenter CS. Disparities in health insurance coverage, access, and outcomes for individuals in same-sex versus different-sex relationships, 2000-2007. *American journal of public health.* Mar 2010;100(3):489-495.

Dilley JA, Simmons KW, Boysun MJ, Pizacani BA, Stark MJ. Demonstrating the importance and feasibility of including sexual orientation in public health surveys: health disparities in the Pacific Northwest. *American journal of public health.* Mar 2010;100(3):460-467.

Cahill S SK, Spade J. *Outing age: Public policy issues affecting gay, lesbian, bisexual and transgender elders.* Washington: National Gay and Lesbian Task Force 2009.

Herbst JH, Jacobs ED, Finlayson TJ, McKleroy VS, Neumann MS, Crepaz N. Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review. *AIDS and behavior.* Jan 2008;12(1):1-17.

Whitbeck LB, Chen X, Hoyt DR, Tyler KA, Johnson KD. Mental disorder, subsistence strategies, and victimization among gay, lesbian, and bisexual homeless and runaway adolescents. *Journal of sex research.* Nov 2004;41(4):329-342.

Diaz RM, Ayala G, Bein E, Henne J, Marin BV. The impact of homophobia, poverty, and racism on the mental health of gay and bisexual Latino men: findings from 3 US cities. *American journal of public health.* Jun 2001;91(6):927-932.

U.S. Department of Health and Human Services. *Healthy People 2020*.

U.S. Department of Health and Human Services. *2015 Edition Health Information Technology Certification Criteria, 2015 Edition Base Electronic Health Record Definition, And ONC Health IT Certification Program Modifications*. Oct 2015.

The Joint Commission. *Advancing Effective Communication, Cultural Competence, and Patient– and Family-Centered Care for the Lesbian, Gay, Bisexual, and Transgender (SGM) Community: A Field Guide.* Oak Brook, IL, 2011.

Alper J FM, and Sanders JQ. *Collecting Sexual Orientation and Gender Identity Data in Electronic Health Records - Workshop Summary.* Washington, DC: Institute of Medicine 2012

Centers for Disease Control and Prevention (CDC). Emergency Department Visits 2013 http://www.cdc.gov/nchs/fastats/ervisits.htm.

Snowdon S. *Health Care Equality Index 2013: Promoting Equitable & Inclusive Care for Lesbian, Gay, Bisexual and Transgender Patients and Their Families* Washington, D.C. : Human Rights Campaign Foundation 2013.

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.

This trial is the final phase of a three phase PCORI-funded study to develop and test patient-centered approaches to collect SO/GI information in the ED. This trial involves a three-mode design to be implemented at four hospitals: Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, The Johns Hopkins Hospital and Howard County General Hospital. From the results of Phase 1 qualitative interviews and national quantitative survey and Phase 2 Delphi rounds with the Stakeholder Advisory Board, we have determined two methods of collection favored by patients and providers to implement in the trial. The first method, nurse verbal collection, is in alignment with Partners recommended clinical practice and is therefore a quality improvement (QI) evaluation. The second method, non-verbal registrar form collection with nurse verbal confirmation, is a research intervention to evaluate and compare a new patient-centered approach to SO/GI collection. To compare the patient-centeredness of the two different approaches, satisfaction surveys will be administered to ED patients and staff members involved in collection.

In summary, the study design (1) evaluates recommended current practice (QI), (2) evaluates a quality improvement project to increase recommended current practice, and (3) evaluates a new method of collecting SOGI (research intervention). The study design includes three modes described below:

<u>Mode 0: Staff Education on SO/GI Data Collection</u>

This serves as a baseline period prior to any interventions. During this mode, research staff will facilitate educational sessions with ED registrars, nurses, and physicians to provide background on SO/GI collection, SGM health, and the study design, using a standardized curriculum. Registrars and nurses will be trained to collect SO/GI information using a standardized protocol across all four hospital sites. To establish a baseline for the proportion of ED patients reporting SO/GI, we will conduct a retrospective review of EPIC medical records to determine the proportion of patients who had SO/GI recorded and the proportion of ED patients that identify as SGM.

<u>Mode 1 (0-6 months): Nurse Verbal Collection of SO/GI</u>

Nurse verbal collection of SO/GI information is currently standard of practice at our participating Partners-affiliated hospital sites.[18] This mode of the study is a quality improvement intervention to improve current practice. First nurses will undergo training on SO/GI collection facilitated by study staff members. In Mode 1, ED nurses will verbally ask patients for this information as a part of social history collection, and then enter it into the corresponding data field within the EPIC EHR. We will use standard quality improvement techniques to improve compliance with data gathering by nurses including identifying clinical champions, sending reminder emails to staff, and audit and feedback of overall

departmental performance. Periodically throughout the 6 month period, study staff will work with nursing leadership to facilitate progress meetings to allow nurses to engage in discussion and provide feedback on the SO/GI collection process. All of these techniques are standard approaches to improve compliance with recommended clinical care.

We will conduct a triggered follow-up survey with SGM, non-SGM and non-responding patients before discharge from the ED. The survey, designed to be completed in 5-10 minutes, aims to assess patient satisfaction and comfort with the method of SO/GI collection and overall climate of the hospital.

Mode 2 (6-12 months): Registrar Form Collection of SO/GI

During patient registration, registrars will administer an electronic form to patients via tablet. This will include the following variables:

Sexual Orientation

Question #1: What is the patient's sexual orientation?

Options: Straight/Heterosexual, Gay/Lesbian/Homosexual, Bisexual, Queer, Questioning/Unsure, Pansexual, Prefer to speak with nurse, Declined to State, Other

Gender Identity

Question #3: What is the patient's gender identity now?

Options: Female, Male, Transgender Female-to-Male, Transgender Male-to-Female, Queer/Genderqueer, Questioning/Unsure, Prefer to speak with nurse, Declined to State, Other

Sex at Birth

Question #2: What was the patient's assigned sex at birth?

Options: Female, Male, Declined to State, Other

As it is not currently possible to directly integrate data from the tablet into the EPIC EHR, a nurse will be given the tablet. Nurses will check for the completion of the form and enter the data into the EHR. If the patient has not completed the form or indicates a preference for discussing with a nurse, the nurse will verbally confirm the SO/GI of the patient.

We will conduct a triggered follow-up survey with SGM, non-SGM and non-responding patients prior from discharge from the ED, as described above in Mode 1.

A staff satisfaction survey will be administered to registrars and nurses participating in SO/GI collection in the ED, during the last four weeks of each mode. The surveys will be conducted using the web-enabled RedCap application. Participants will receive unique log-in information via email for accessing the secure online survey.

The primary outcome of the study is patient satisfaction. The secondary outcomes are (1) ED staff satisfaction; and (2) the proportion of patients reporting SO and GI in each mode.

Eligible participants will include adult ED patients and ED nurses and registrars. All participants in the study must be age 18 and older and cognitively and physically capable of participation and informed consent. Adult ED patients include those seeking ED evaluation at a participating hospital site. Adult ED employees include staff members currently working as nurses or registrars in the ED of participating hospital sites directly involved in the collection of SO/GI.

The anticipated enrollment study-wide (including all four sites) for the follow-up satisfaction survey is 764 participants, further detailed below:

SGM Patients: 142

Non-SGM Patients: 142

Non-responding Patients: 142

Blank Field Patients: 142

ED Staff: 196

Total Participants: 764

We have established a secondary endpoint in order to power each hospital site individually. After achieving our primary endpoint of 764 participants, we will submit an amendment to continue enrollment to the secondary endpoint of 2,468.

SGM Patients: 568

Non-SGM Patients: 568

Non-responding Patients: 568

Blank Field Patients: 568

ED Staff: 196

Total Participants: 2,468

At the Partner hospital sites, we will enroll 284 patients and 98 staff members for the primary endpoint and 1136 patients and 98 staff members for the secondary endpoint.

18. BWH Bulletin. The Importance of Being Known: Incorporating SO/GI Data into Patient Care. 2015. Available at: http://bwhbulletin.org/2015/10/23/the-importance-of-being-known-incorporating-sogi-data-into-patient-care/. Accessed November 10, 2015.

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.

Conduct:

The trial will take place according to the following procedures:

Mode 0: Qualified study staff members will train registrars and nurses to collect SO/GI information using a standardized protocol across all four hospital sites. The in-person trainings will be approximately 20 minute interactive sessions. Topics to be covered include SO/GI terminology, importance of SO/GI collection, SGM health disparities, and best practices for collection.

Mode 1 (0-6 months): Following the current standard practice, nurses will verbally collect SO/GI information from patients. Nurses will ask patients for this information during the collection of social history, where the SO/GI data fields are currently located in the EPIC system.

Following collection, there will be triggered follow-up with SGM, non-SGM, and non-responding patients. Before patients are discharged from the ED,-we will administer a brief satisfaction survey to eligible patients electronically.

Mode 2 (6-12 months): This mode of the study will be implemented as research, using a new tool to collect information in the emergency department. Registrars will use an electronic form to non-verbally collect SO/GI information from patients. Upon arrival to the ED, patients undergo initial registration as part of which basic information, including name, insurance status, and social security number is collected. Later, registrars perform full registration at the bedside. During bedside registration, registrars will give patients an electronic form to complete via tablet. On the form, patients will be allowed to opt-in to discussing their SO/GI verbally with a nurse or opt-out from providing SO/GI information. The nurse will review the data and verbally confirm the SO/GI of the patient if the data field is unfilled or if the patient has indicated a preference for nurse verbal collection on the form.

Following collection, there will be triggered follow-up with SGM, non-SGM, and non-responding patients prior to their discharge from the ED. RAs will identify patients for follow-up using a Workbench Report, an internal EPIC report that will allow RAs to view the SO/GI data fields within patient charts in an efficient, secure manner. RAs will administer a brief satisfaction survey to eligible patient via electronic tablet.

Outcomes:

The primary outcome of the study is patient satisfaction. Patient satisfaction will be assessed using a survey consisting of the Leadership Commitment subscale of the Communications Climate Assessment Toolkit, and questions regarding acceptability, satisfaction and comfort with the information collection process. Survey data will be matched to the EHR entry using one-to-one linking based on encounter number, and de-identified prior to analysis. This data management process will be facilitated by institutionally approved data stewards on the research study team.

The secondary outcomes are (1) ED staff satisfaction; and (2) the proportion of patients reporting SO and GI in each mode. The ED staff satisfaction survey will consist of basic demographics (age, race, role in ED, SO/GI) and questions regarding the feasibility, acceptability, and utility of each method of information collection.

Analytic Methods:

Quantitative data collected during the survey process, including responses to questions graded on Likert-scales will be examined across various groups of interest as raw and standardized scores using Student's t-test, Wilcoxon Rank-sum tests and where appropriate across multiple groups, analysis of variance (ANOVA). Differences of proportion arising from questions requiring dichotomous or categorical responses will be examined using Chi-square and Fisher's exact tests. These analyses will be principally descriptive in nature. Regression models (linear, logistic, ordered logistic, etc.) will also be used to examine relative differences between group responses controlling for factors such as SGM strata, health care provider type (physician, nurse, etc), respondent age, gender and race (where available). All analyses will be conducted using STATA and/or SAS statistical packages.

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.

This study does not involve a treatment or diagnosis.

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.

Collection of SO/GI information is standard care adhering to recommendations from the Institute of Medicine and The Joint Commission, and recent Meaningful Use Stage 3 guidelines from the Center for Medicare and Medicaid Services. In addition, preliminary research demonstrates that patients are willing to have SO/GI collected and believe that is important for ED providers to know SO/GI in order to provide the best individual care. Therefore, collection of this information presents minimal risk to the patient. The research staff's training and experience will ensure that the intervention is administered in a way that minimizes psychological risks to study participants. The educational component of Mode 0 serves to train ED providers and staff to collect SO/GI information from patients in a safe and respectful manner and includes appropriate responses to frequently asked patient questions. RAs will be advised to be alert for signs of subject discomfort during the follow-up survey and notify the PI of any concerns.

There are no physical risks to the participants in this study. Participants will be informed that all responses to the survey are confidential and will be used for research purposes only, that their care at the particular healthcare facility will not be affected by their decision regarding participation, and that they may choose not to answer a question and stop participation at any time. Patients will be provided with contact information for the Patient/Family Relations Department at Brigham and Women's Hospital and Patient Advocates at Brigham and Women's Faulkner Hospital use as additional resources if

experiencing discomfort. Survey completion will be actively monitored by the research staff that will observe standard hospital policies and guidelines for patient safety and confidentiality.

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.

We anticipate no safety risks to subjects as a result of participation in the study. ED staff will be trained to routinely collect SO/GI information in a manner that creates a safe environment for patients to disclose sensitive information. Survey completion will be actively monitored by the research staff that will observe standard hospital policies and guidelines for patient safety and confidentiality. The principal investigator will oversee the conduct of all study activities. Any incidents or concerns regarding survey administration and data collection will be immediately addressed by the research staff. Research staff will be advised to refer a patient to the Patient/Family Relations Department at Brigham and Women's Hospital and Patient Advocates at Brigham and Women's Faulkner Hospital to address any further concerns or discomforts.

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.

The survey questions regarding SO/GI have the potential to cause minor psychosocial discomfort to study participants, and elicit emotions such as worry/fear, anger or confusion. However, the emotions evoked by collection are an important finding of this study. Research staff members have been trained in SGM cultural competency to promote sensitivity when engaging patients in conversations involving SO/GI. To ensure patient safety, the research team includes the Vice Chair of Quality and Safety for the Department of Emergency Medicine of the Brigham and Women's Hospital and Director of Patient Relations and Family Centered Care at Johns Hopkins Hospital, who will advise on concerns of participant risks and discomforts.

An additional risk associated with participation in this research would be the effects of an unforeseen and unintentional breach of confidentiality. Satisfaction surveys will be administered on a secure, password protected tablet by research assistants trained in standard hospital policies for patient safety and confidentiality. Breach of confidentiality will be minimized by using an internal Epic Workbench Report located on secure Partners computers to identify patients.

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.

Study participants will receive $10 gift cards as compensation for completion of the follow-up survey. Participants may receive better care due to the providers' awareness of their SO/GI information. The results of this study will benefit the SGM community by improving understanding of the most patient-centered and efficient ways to collect SO/GI information in the ED. Collection of this information will allow health providers to deliver more inclusive, quality care to all patients and allow researchers to better identify health disparities facing SGM patients.

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.

We will not exclude individuals based on race, ethnicity, or gender. For the triggered follow-up survey, we will target and oversample members of the SGM subgroups. This targeted recruitment will ensure that the study population will be representative of the SO/GI minority groups and greater population that stands to benefit from this research.

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.

We are going to conduct this study only in English. The surveys are currently validated only in English. We expect all providers to be fluent in English. If necessary, we will attempt to validate the patient survey in other languages, e.g., Spanish.

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.

Mode 1: Nurses will be instructed to collect SO/GI information from all patients receiving care at the ED as part of standard of care. RAs stationed within the ED will conduct targeted outcome surveys on eligible patients towards the end of their ED visit.

Mode 2: Registrars will administer an electronic form to collect SO/GI information from all patients in the ED; this electronic form is a new tool implemented as part of the research study. ED RAs will collect targeted outcome surveys from willing eligible patients prior to discharge.

An internal EPIC Workbench Report will be used to identify patients for triggered follow-up. The report will identify all patients admitted in the BWH Emergency Department and provide the following information: patient name, contact serial number, date of birth, ED location, level of service in the ED, department status, emergency severity index, attending physician, assigned nurse, race, ethnicity, marital status, religion, education, sexual orientation, sex assigned at birth, and gender identity. These variables are to be used for research purposes only, in the identification of patients for follow up outcome surveys in Modes 1 and 2, and for survey data analysis.

The staff satisfaction survey will be administered during the last four weeks of each mode to registrars and nurses participating in SO/GI collection in the ED. The surveys will be conducted using the web-enabled RedCap application. Participants will receive unique log-in information for accessing the secure online survey. Emails will be sent throughout the four-week period inviting them to participate in research. The participants can choose to opt out, if not interested in completing the survey.

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

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.

Mode 1: As this mode is a part of standard of care, consent is not necessary for nurse verbal collection of SO/GI. Informed consent for the follow-up patient satisfaction survey will take place in the ED prior to patient discharge. Completion of the survey will imply consent to participate. RAs will give a tablet to eligible patients on which they will be presented with an electronic consent form. Patients will be given the option to proceed with consent or decline to participate in the study.

Mode 2: Registrars will give a tablet to all patients during registration in the ED. Patients will be presented with an electronic consent form, and given the option to proceed with consent or decline to complete the form for SO/GI collection and participate in the satisfaction survey. Completion of the form and survey will imply consent to participate.

Staff participants will be provided with an electronic consent form at the start of the satisfaction survey. The consent form includes a written statement about the research followed by a button confirming that they agree to participate in this research study.

There are four consent forms included in the protocol:

Consent for EQUALITY Non-Verbal SO/GI Collection Form: An implied consent form for patients to be used in the Mode 2 non-verbal form collection. As electronic forms are not standard of care, a consent form is needed for research to implement this new tool of collection.

Consent for EQUALITY Phase III ED Staff Outcomes Survey: An implied consent form for staff members involved in SO/GI collection to complete the staff satisfaction survey.

Consent for EQUALITY Phase III Patient Baseline Survey: An implied consent form for ED patients to complete the baseline patient satisfaction survey. This survey will be administered before the beginning of Mode 1 to establish a baseline comparison point for patient satisfaction.

Consent for EQUALITY Phase III Patient Outcomes Survey: An implied consent form for ED patients to complete the baseline patient satisfaction survey. This survey will be administered before the beginning of Mode 1 to establish a baseline comparison point for patient satisfaction.

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.

Satisfaction surveys will be conducted through the secure RedCap data collection system that study staff will access via the web and their personal username and password. Data entered into forms will be de-identified and electronically encrypted using secure socket layering encryption technology. Data will be stored on a secure, password-protected server only accessible by designated research staff. Only the minimal amount of information needed to accomplish the study's aims will be maintained. Only the PI and the researchers doing the data analysis will have access to the server. The link to the identifiers and the data will be stored for a minimum period of 7 years. The PI will be responsible for reviewing the data and for the confidentiality of the data

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

Unanticipated problems and adverse events (e.g. complaints, breaches of confidentiality, etc) will be reported to the PI and discussed within the research team to determine a safe, effective course of action. The research team includes the Vice Chair of Quality, Patient Safety and Performance Improvement for the Department of Emergency Medicine at BWH and Director of Patient Relations and Family Centered Care at Johns Hopkins Hospital to ensure patient safety and institutionally approved data stewards to address any concerns with data usage and protection.

Unanticipated problems and adverse events will be reported to the IRB within 5 working days/7 calendar days of the PI becoming aware of the event via Insight/eIRB.

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.

The PI will be in regular communication with the Director of Quality, Patient Safety and Performance Improvement for the Department of Emergency Medicine at BWH, who is a co-investigator for the

study, in order to discuss enrollment, survey completion and any other issues. The research team will have weekly meetings to discuss the progress of the study. The principal investigator will ultimately be responsible for the conduct of the study.

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.

The anticipated risk to the privacy and confidentiality of subjects will be minimized through observance of institutional and research policies and procedures set in place for that purpose. Satisfaction surveys will be conducted through the secure RedCap data collection system that study staff will access via the web and their personal username and password. Data entered into forms will be de-identified and electronically encrypted using secure socket layering encryption technology. Data will be stored on a secure, password protected server only accessible by designated research staff. Only the minimal amount of information needed to accomplish the study's aims will be maintained. All research staff

members have undergone CITI and HIPAA training, and are well-informed of the importance of confidentiality of data.

Tablets used for research purposes will be password protected and only accessible by research personnel. All information on the tablet will be erased. De-identified research data and materials will be maintained by the BWH Department of Surgery for a minimum of 7 years, post-publication.

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.

No specimens are collected for this study. No data will be sent to research collaborators outside of Partners.

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.

Data will not be stored at collaborating sites outside Partners for future use.

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.

N/A