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

Promoting informed decisions about rescheduling colonoscopies delayed due to COVID-19 (PRIMED-2): randomized controlled trial

FUNDING

Patient Centered Outcomes Research Institute (PCORI)

VERSION DATE

January 6, 2021

SPECIFIC AIMS

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

Due to COVID-19 there has been a sharp reduction in the number of colonoscopies since Feb 2020. This is predicted to lead to delayed diagnosis in more than 18,000 patients across the US.[i] Recovery efforts are underway to plan for resuming these non essential health care services. However, if patients are not willing or able to come back to get routine cancer screening, then these testing delays may have a significant impact on cancer mortality rates. There is very limited data examining patients' attitudes and concerns about seeking cancer screening in this environment. The aims of this study are to:

Aim 1: Assess anxiety, COVID risk tolerance, cancer worry, willingness to screen, barriers to colonoscopy, and preference for alternative colon cancer screening options for patients aged 45-75 who had their screening or surveillance colonoscopy delayed due to the pandemic.

Aim 2: Examine effectiveness of using a shared decision making approach with patients on the waitlist to decide about rescheduling their colonoscopy. We will randomly assign patients to receive SDM tools or usual care. We will test hypotheses that compared to the control group, patients in intervention arm will (a) report higher shared decision making; (b) have stronger intention to follow through with colon cancer screening (whether colonoscopy, stool-based test or other approach); and (c) have less decisional conflict.

Aim 3: Follow all patients on the waitlist and examine wait times and completed colonoscopies to determine whether these differ by patient characteristics, including gender, age, race and ethnicity, adjusting for cancer risk.

BACKGROUND AND SIGNIFICANCE

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

COVID-19 has changed the health care landscape in profound ways in a few short months. Entire hospitals and practices have been refocused to screen for and treat patients with COVID-19. Routine visits, screening tests and elective procedures have been postponed. As the initial surge of patients with COVID-19 recedes, routine care will not simply be able to return to normal. One pressing issue is the large and growing backlog of screening tests and elective procedures at many hospitals. Nationally, data suggest that colonoscopies have dropped 90% since February.[ii] At Massachusetts General Hospital (MGH) alone, the Gastroenterology (GI) department estimates that about 8,000 colonoscopies have been postponed, more than 5,000 of these are routine screening colonoscopies. Recovery planning programs have been delayed further because of the shortage of PPE and because GI nursing staff have been redeployed to COVID care duties. The department anticipates 2-3 months to ramp up to about 66% of prior volume but does not anticipate getting back to 100% in the next year due to new requirements for infection control that will increase turnover time. To further complicate matters, public health officials warn that multiple waves of infection may occur over the next 12-18 months, and each may cause additional restrictions on capacity, increasing backlogs even more. Managing demand with reduced capacity while planning for additional shutdowns represents a key new challenge for health care systems delivering care during this crisis. Further, even if there is capacity, many patients may feel differently about the value of seeking healthcare, including cancer screening, during the crisis. A recent poll showed that the majority of patients are unlikely to visit a hospital (62%) or specialist (64%), regardless of whether they live in a COVID hotspot.[iii] There are many challenges to resuming healthcare during this crisis, and important research questions about how to do this in a safe, equitable and patient-centered manner. Some key questions include: How should patients be prioritized for routine screening procedures like colonoscopy? What role should patients' preferences play in the prioritization process? What do health systems need to do to ensure patients are comfortable accessing needed care? How can systems do this without furthering disparities or disadvantaging vulnerable populations?

The PI and co-investigators have an existing PCORI-funded project, the PRIMED study, that is examining the impact of training primary care physicians in shared decision making (SDM) on colorectal cancer screening decisions for patients aged 76-85. A PRIMED advisor, Dr. Richter, is on the task force to determine policies for resuming GI services at MGH and will serve as co-investigator on this study. Together with our stakeholders (including our patient partners and the Colon Cancer Alliance), we have designed two descriptive studies and a randomized controlled trial to examine whether shared decision making will improve colon cancer screening decisions for patients aged 45-75 who have had their colonoscopy delayed due to COVID-19. The findings will not only have direct implications for managing the backlog of colonoscopies, but will also help inform policies for other screening tests and elective procedures.

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."

Across all of the aims, we anticipate enrolling 645 participants study-wide. (Aim 1, n=195 patients completing a survey; Aim 2, n=450 patients completing a survey in the study).

For Aim 1 we will conduct a cross-sectional survey study targeting patients aged 45-75 who had their screening or surveillance colonoscopy postponed or delayed due to the COVID pandemic. We will survey a random subsample of these patients. Table 1 includes information on eligibility for the patient sample. We anticipate inviting 300 patients and estimate receiving 195 completed surveys.

Eligible patients will be sent a survey packet in the mail that will include a cover letter signed by the GI Director of Quality and Safety inviting their participation, an information sheet describing the study, an incentive ($10), and the survey. The cover letter will include information for participants to opt-out if they desire. Patients will be asked to complete the survey and return it back to study staff. Consent is implied with return of the survey.

For Aim 2, we will conduct a randomized controlled trial that will enroll patients who have to reschedule colonoscopies. We will randomly assign about 900 patients who are on the waitlist to either intervention or control arm. The intervention arm will receive a shared decision making worksheet that will cover (a) presenting pros and cons of three screening options (first available colonoscopy (wait time estimated to be ~6 months), stool-based test (with consideration that if positive, a follow-up colonoscopy may still be delayed ~3 months), and delay colonoscopy one year); (b) contact information for rescheduling their colonoscopy; and (c) contact information to connect with staff if they have questions or need more information. GI clinicians will be recruited and complete an online SDM training prior to their visit with patients who have more questions and request a GI visit. The control group will receive the standard department guidance and policies on scheduling. We will invite patients to complete a survey to track SDM, decisional conflict, overall anxiety and cancer worry, preference for colonoscopy, concerns about accessing health care-and we will also track any testing received within 6 months. We estimate sending a survey to about 700 patients across both arms and receiving 450 completed surveys.

For Aim 3, we will follow all MGH patients who had their screening or surveillance colonoscopy delayed for 12 months and will document receipt of colonoscopy or other colon cancer screening test, and if they got a colonoscopy, will calculate the wait time for colonoscopy for all of the patients on the waitlist. We will track demographic information, age, gender, race and ethnicity, primary language, zip code. We estimate that there are about 5,000 patients who have had their colonoscopy delayed that will be followed in this chart review portion of the study.

Table 1: Eligibility for patient participants

Eligible	Ineligible
• Adults, age 45-75 • Had screening or surveillance colonoscopy delayed due to COVID-19 • Either due for first screening colonoscopy or a routine screening or surveillance colonoscopy for low to moderate risk patients (as indicated by 3-10 year recommended follow up frequency on prior test)	• Diagnostic colonoscopy • High risk for colorectal cancer as indicated by 1 year follow up schedule • Prior history of colon cancer • Unable to read or write in English or Spanish (Aim 1 and 2 only) • Have not already rescheduled or completed their colonoscopy

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.

Working closely with co-investigators and staff in GI department, study staff will create a master waitlist of patients who had a previously scheduled colonoscopy postponed, who had a referral for a colonoscopy that has not been processed, and/or who should have been contacted by the GI department to schedule a colonoscopy but were not due to COVID-19 restrictions. Study staff will confirm that they meet the eligibility criteria as outlined in Table 1. Study staff will also use RDPR and Epic to confirm eligibility if needed.

For the patient surveyed in both the cross-sectional study and the randomized trial, study staff will send each subject a packet that includes a cover letter signed by the Director of Quality and Safety for the department inviting their participation and providing information to opt-out of the study, an information sheet describing the study, an incentive ($10), and the survey. Patients will also be given option to complete the survey via RedCap. Patients will indicate consent by returning the survey. Survey responses will be entered into RedCap and analyzed by the study team. On the survey, patients will be able to indicate if they are interested in participating in an optional short interview to follow-up on their survey responses. Staff will contact a selected subset of patients who agreed to set up the short interview.

The research staff will track the number of participants screened, reason for ineligibility, the number sent invitation by mail, the number who opted out or otherwise declined participation and any reasons given for the refusal to participate. Limited information collected during the eligibility screening process will be kept for non-responders to examine non response bias.

All study staff are Collaborative Institutional Training Initiative (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, to discuss protocol and standard operating procedures, and to identify and mitigate any issues that arise.

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 tests or treatments will be administered as part of this study.
For Aim 2, the standard of care is that patients may call the GI scheduling group to reschedule their colonoscopy or GI schedulers may reach out to patients to reschedule a cancelled or postponed procedure. In the intervention arm, patients may still call the GI scheduling group to reschedule their colonoscopy or GI schedulers may reach out to patients. In addition, patients will receive information about their options. The materials will direct patients who are interested in colonoscopy to call the GI scheduling group. Patients who are unsure or who would like to learn about other options will be

offered the opportunity to talk with staff from Health Decision Sciences Center who will then connect patients with the participating GI clinicians to obtain stool-based tests or to discuss other concerns.

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.

There are minimal risks to participating individuals associated with or attributable to this study. The main risks are associated with loss of privacy of their health information. To minimize risks, all electronic data files that include patient identifiers will be kept in a Partners protected server and only members of the research team will have access to the files. Files with PHI will only be accessed from Partners computers or encrypted laptops that are protected with SafeBoot. To ensure confidentiality, all paper surveys will be identified by study code number only and kept in a locked file cabinet. All paper surveys will be scanned and electronic files will be stored on password protected Partners server. Study papers (e.g. eligibility screeners, surveys) that have been scanned or entered into a database will be disposed of in the confidential shredder. To address issues of psychological discomfort, research assistants will inform patients that they may refuse to answer any question and may withdraw from the study at any time. To address privacy and confidentiality issues, analytic database with outcomes data will not contain any identifying information and will be coded by unique study ID number only.

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.

Although there are no written informed consent forms, Drs. Simmons and Sepucha are responsible for assuring that patient participants are adequately informed prior to engaging in any research procedures, that all subjects meet eligibility criteria, and that the study is conducted according to the IRB-approved research plan.

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

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 individuals participating in this project. The main risks are the time and effort involved in participating (for patients estimated to be about 20 minutes for survey and about 30 minutes for the optional short follow-up interview) and the potential loss of privacy.

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 are no direct benefits to patients from completing the surveys. The potential benefit to society is that the study will help inform policies for how to incorporate patient's preferences into prioritization process for resuming procedures and services once it is safe to do so.

Shared decision making (SDM) has been shown to increase patient knowledge, reduce decisional conflict and improve the match between patients' preferences and their choices. Those patients randomized to the intervention arm may benefit as having knowledge of other screening options may help them get the care that they prefer.

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 patient recruitment is limited to men and women 45 to 75 years of age as clinical guidelines recommend this age group to get routine colorectal cancer screening. We will target patients whose colonoscopy has been postponed or delayed due to COVID-19. Routine colon cancer screening is not recommended for adults younger than 45 or those older than 75.

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.

Patient survey materials will be available in English and Spanish. Most patients seen by MGH GI speak either English or Spanish (>97%).

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Non-English-Speaking-Subjects.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.

Patient recruitment, Aim 1:

- Study staff will work with the GI department to identify patients whose colonoscopy has been delayed due to COVID-19 and meet the eligibility criteria in Table 1.
- Staff will randomly select 300 eligible patients from the wait list to invite into the cross-sectional survey study. Study staff will also use RDPR and Epic to confirm eligibility if needed.
- The research coordinator will send a survey packet that includes: a cover letter signed by the GI Director of Quality and Safety inviting their participation, an information sheet describing the study, an incentive ($10), and the survey. The cover letter will have information for participants who wish to opt out of the survey. Patients will be given the option to complete the survey by RedCap and a link will be included in the cover letter. Patient consent for the study will be implied by return of the completed survey.
- Staff will make up to three reminder phone calls. Study staff will send all non responders, who did not opt out, one reminder paper survey packet about four weeks after the initial packet. Study staff will then make up to 3 additional reminder calls to non-responders.
- All participants who complete a survey will receive a thank you note.

Clinician recruitment, Aim 2:

- The department chair will send out an email notifying clinicians about the study and may share study information at regular faculty meetings.
- Dr. Richter will follow up on the Chief's communication and will reach out individually to clinicians via email and/or during regular meetings to describe the study and invite clinicians to join. The email will contain an information sheet for clinicians.
- Clinicians will indicate consent by sending an email to Dr. Simmons and/or Sepucha indicating their interest to join the study.
- Interested clinicians will complete a ~1 hour online shared decision making training session with study investigators and send availability for ~1 hour per week they may be available to meet with study participants who request a GI visit via the intervention.
- All clinician participants will complete a short phone debrief after the intervention is complete and receive a thank you email.

Patient recruitment, Aim 2:

- Study staff will work with the GI department to identify patients whose colonoscopy has been delayed due to COVID-19 and meet the eligibility criteria in Table 1.
- Study statistician will randomly assign patients on the waiting list to either the intervention or control group. Patients in the intervention group will receive information in the mail that describes available options for colon cancer screening and directions on who to call depending on patients' preference for screening. The usual care group will not receive the information.
- About 6-8 weeks after the mailing, the research coordinator will send a survey packet that includes: a cover letter signed by the Director of Quality and Safety for the department inviting their participation, an information sheet describing the study, an incentive ($10), and the survey. The cover letter will have information for participants who wish to opt out of the survey. Patients will be given the option to complete the survey by RedCap and a link will be included in the cover letter. Patient consent for the study will be implied by return of the completed survey.

- Staff will make up to three reminder phone calls. Study staff will send all non responders, who did not opt-out, one reminder paper survey packet about four weeks after the initial packet. Study staff will then make up to 3 additional reminder calls to non-responders.
- All participants who complete a survey will receive a thank you note.

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.

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

Patients will receive $10 with the initial survey packet. Patients who participate in the optional short interview will receive $20. Clinicians will receive $50 gift card for each completed survey and $50 gift card for completing the intervention. A Partners Corporate Card will be used to purchase the gift cards.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Recruitment-Of-Research-Subjects.pdf

Guidelines for Advertisements for Recruiting Subjects
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Guidelines-for-Advertisements.pdf

Remuneration for Research Subjects
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/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.

There are no formal written consent procedures in this project for patients or clinicians. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required.

Eligible patient participants will be sent a cover letter signed by the Director of Quality and Safety for the GI department inviting them to participate in the survey and an information sheet that describes the risks and benefits of the study. Consent will be implied by the return of the completed survey.

The principal investigator's and study staff's names and contact information will be available on the cover letter, information sheet and survey if participants have any questions or concerns about the study. The study staff will be available by phone or email to discuss the study and answer any questions.

Study materials will emphasize that whether or not patients participate will have no effect on the health care they receive.

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://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/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.

Study staff will protect the privacy of research study participants as described in the Privacy and Confidentiality section. It is possible that participants may be upset by a question in the survey, and survey instructions will emphasize that subjects may skip any question they do not wish to answer. Study staff will review completed surveys weekly and if any complaints or concerns are raised, will flag those and send to the PI and clinician co-investigators to address.

Study data will be accessible at all times for the PIs to review. The project manager and PIs will examine study conduct including enrollment, accrual, drop-outs, and protocol deviations on a weekly or every other week basis with the staff at each site. Study staff will review study related data including reminder phone calls to participants, participant surveys and will notify the PI about any serious or moderate potential adverse events (AEs) immediately and any minor or potential ones at regular meetings. No SAEs are expected based on the minimal risk trial. However, the co-investigators will review potentially

serious adverse events (SAEs), as soon as they are discovered. The PIs will ensure all protocol deviations, AEs, and SAEs are reported to the IRB within required time frame based on severity, and will file an HRC AE Form within 10 working days as needed.

The study is minimal risk and the DSMP is commensurate with the potential risk level. 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

No serious adverse events are expected. The name and contact information for the principal investigator will be included on study information sheet as well as contact for study staff and Partners IRB in case participants have a problem. We will have a clinical co-investigator for each topic who will be able to consult on any clinical issues that arise during the course of the interviews or surveys. However, if a serious adverse event occurs relating to the study, 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 continuing review.

Study staff will be instructed to review surveys within a week of receipt and to notify the PI about any potentially serious events immediately and all other events at regularly scheduled meetings. Study staff will keep records of any feedback, questions, concerns and/or complaints that are received and we will address them with the co-investigators and staff as needed.

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 study staff and the principal investigator will have routine meetings during the study period to ensure the project proceeds as intended per the protocol. All participant screening and enrollment will be tracked on password protected servers using an Access or RedCap database. The information is

stored behind a firewall and only study staff will have access to it as needed. We will track recruitment rates and response rates weekly and identify issues as they come up. The study staff will complete all required documents for the study binder and this will be reviewed quarterly by the project manager and one of the principal investigators.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/DSMP-in-Human-Subjects-Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/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.

Special efforts will be made to protect the privacy of subjects. We will have names and addresses of eligible participants and this information will be kept separate from the study data (e.g. survey responses). All patient participants will receive a code number and the surveys will only be identified by code number. A separate password-protected electronic file will contain the codes linked to identifying information. Only the study staff and investigators will have access to this file. These will be kept as long as required by the research project. After the study has been completed the personal contact information of all eligible participants will be destroyed.

The last page of the patient surveys for Aim 1 and Aim 2 will ask patients if they are interested in being recontacted to participate in future research studies with the MGH HDSC study team. Responses from these questions, whether from the paper survey, or from the online survey, will be kept in a separate database from survey responses.

All files (e.g. eligibility screeners) that contain PHI will be kept in a locked file cabinet or in a secure offsite file storage location or on a password protected Partners shared drive.

Patient confidentiality will be maintained as is routine for all patient care privacy guidelines. 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.

To promote research replicability, transparency and future use of the data, de-identified data sets will be created and will be available, by request, to outside researchers. After the study results have been published, de-identified data sets will also be deposited 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. The information sheets will contain the following language: After the study is completed, all identifiable information will be removed from the data and after removal, the de-identified information will be deposited in an open access service to promote use of the data by other researchers.

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.

No identifiable data on Partners patients will be stored outside MGH

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

[i] Institute for Human Data Science. Shifts in healthcare Demand, Delivery and Care During the COVID-19 Era: Tracking the impact in the United States. 2020 IQVIA. [https://www.iqvia.com/insights/the-iqvia-institute/covid-19/shifts-in-healthcare-demand-delivery-and-care-during-the-covid-19-era] Accessed May 7, 2020.

[ii] Institute for Human Data Science. Shifts in healthcare Demand, Delivery and Care During the COVID-19 Era: Tracking the impact in the United States. 2020 IQVIA. [https://www.iqvia.com/insights/the-iqvia-institute/covid-19/shifts-in-healthcare-demand-delivery-and-care-during-the-covid-19-era] Accessed May 7, 2020.

[iii] Franki, Richard. Pandemic Effect: All Other Healthcare Visits Can Wait. Medscape. May 5, 2020. (Accessed May 10, 2020 https://www.medscape.com/viewarticle/930036).