Mass General Brigham

Institutional Review Board
Intervention/Interaction Detailed Protocol

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1. Background and Significance

Lung cancer remains the leading cause of cancer-specific mortality. Despite recent advancements in lung cancer diagnosis and treatments resulting in decreasing mortality, lung cancer remains the leading cause of cancer mortality in the US. In 2021, there will be 235,760 estimated new cases and 131,880 estimated deaths. Furthermore, disparities in lung cancer mortality persist, with Black/African American individuals having a higher mortality compared to Non-Hispanic White individuals[1]. Despite the decreasing incidence in lung cancer among Latino/Hispanics, lung cancer remains the leading cause of cancer-related death among Latino individuals[2-6]. This is due to the stage at the time of diagnosis, as only 17% of Latino/Hispanics are diagnosed with localized disease and the 5-year survival rate for distant stage disease is 6%.

Smoking is an important public health issue in the Latino community, but access to resources lag in the Latino community. Cigarette smoking is the leading cause of preventable mortality in the US, accounting for more than 480,000 deaths every year[7]. Smoking-related cancer and cardiovascular disease, including heart disease and stroke, are among the top five leading causes of death among Latinos, and some Latino subgroups demonstrate a higher smoking prevalence, according to recent CDC data [8-12]. Furthermore, among Latino current smokers, 67.4% report that they want to quit and 56.2% report attempting to quit in the past year[13, 14]. Lower health insurance coverage among Latinos makes it less likely that they will have opportunities to provide accurate smoking history to their healthcare provider, receive smoking cessation counseling, or be advised to undergo lung cancer screening. We anticipate these smoking-related disparities will continue to be a leading cause of preventable mortality without targeted interventions.

Lung cancer screening (LCS) offers an opportunity to bridge disparities in lung cancer mortality through early detection, but LCS participation rates remain low despite its proven benefits. Multiple clinical trials have shown the benefits of LCS in reducing lung cancer mortality through early detection[15, 16]. Despite these proven benefits, LCS rates among high-risk eligible individuals remain low, with more recent studies showing an increase only up to 10-20%[2]. The low LCS uptake is complex and multifactorial, including difficulty understanding eligibility

criteria, readability level of available health information, cost concerns, and COVID-related safety concerns in return to care, among other reasons[17-21]. These factors are magnified among Latino individuals who already multilevel face systemic barriers to care resulting in much lower LCS rates[22].

The US Preventive Services Task force (USPSTF) is committed to addressing systemic racism through clinical Recommendations, and the expansion in LCS guidelines represent a foundational step[23]. A recently published article established the USPSTF commitment to bridging health disparities caused by structural societal barriers. The article provided a framework to proactively address these issues, including promotion of racial and ethnic diversity in research and evidence-based data, and fostering transparency in identifying and addressing healthcare disparities. The anticipated update in USPSTF guidelines for LCS provides a vital step in addressing disparities in lung cancer outcomes through early detection[24]. Underrepresented minorities tend to be exposed to other lung cancer risk factors that result in being diagnosed at an earlier age with a lower pack-year smoking history. The new USPTF guidelines lower the starting age to 50 and the smoking history to 20 pack-years, thus increasing the likelihood of Latinos to be eligible. However, tailored outreach efforts are needed to ensure the participation of the Latino community in this life-saving screening exam.

The COVID-19 pandemic has exacerbated health disparities related to social determinants of health (SDoH) among racial and ethnic minorities, and this effect is impacting LCS in the return-to-care phase[21, 25-28]. Racial and ethnic minorities, including Latino individuals, have experienced increased COVID-19 morbidity and mortality secondary to a combination of socioeconomic and medical factors that increase their exposure risk, and result in higher likelihood of delays in seeking care. It is estimated that the effect of care quality and access modify only 20% of the variation in clinical outcomes, while SDoH have a cumulative effect of up to 50%[29]. The ongoing pandemic exacerbated the influence of SDoH and has resulted in diversion of medical resources to address immediate needs and postponing non-urgent medical care, including LCS. This postponement of LCS can potentially result in widening the existing institutional disparities in LCS, where over 5,400 patients have been screened and 75% of those patients are Non-Hispanic White individuals. The National Institute on Minority Health and Health Disparities offers a multi-dimensional research framework that can be adapted to facilitate assessment of emerging disparities in LCS, identify opportunities, and measure progress in LCS[30].

Digital outreach programs are most effective when community-based participatory research (CBPR) principles are leveraged in the process[31-39]. Outreach interventions are most effective and sustainable when CBPR elements are integrated in all aspects of the intervention, from conceptualization to implementation and evaluation. Engaging diverse community stakeholders will provide direct knowledge to detect and understand barriers and facilitators to LCS across Latino communities. This approach also serves to promote trust by making the community an active participant in the implementation process. Building trust is key to foster long-term relationships and the longitudinal engagement necessary to improve health disparities among Latino communities. Without the development of targeted interventions that incorporate these elements, the existing healthcare disparities gap among Latino communities will continue to widen. Targeted interventions need to incorporate CBPR principles while leveraging new digital outreach opportunities that result from the recent proliferation of telehealth services, smartphone

message delivery, and patient portal expansion among Latinos to scale implementation and prevent widening the *techquity* disparities gap[40, 41].

Preliminary data: As of December 2020, 5,373 patients have undergone LCS at our institution. Among these patients, only 25% (1318/5373) are racial minorities, and only 16% (841/5373) are patients with MassHealth/Medicaid. This data exemplifies the disparities in LCS that our Latino communities and other underrepresented racial and ethnic minorities face when accessing services and underscores the need for targeted outreach. A published study by Dr. Flores and his colleagues showed that only 44% of Latino participants were aware about LCS, but almost all (90%) were interested in LCS if offered[22]. In this study, 22% of Latinos reported a cost concern about insurance coverage for LCS, and a recent study published by Dr. Flores shows that the out-of-pocket cost of LCS is highly variable among LCS centers across the US, with a mean cost of $583+ 607[19.] Dr. Flores' research has shown that a 3-phase LCS outreach intervention that incorporates CBPR principles, is tailored for individuals with serious mental illness (SMI) and was delivered in a community mental health clinic in collaboration with mental health clinicians was *feasible and acceptable*[42].

The COVID-19 pandemic has launched telemedicine into a central component of health care delivery and offers a key role for digital outreach to bridge existing and emerging LCS disparities. Current data has shown that 79% of Latinos own a smartphone and 25-35% of Latinos rely on their smartphone as their sole source of online access[43]. Dr. Flores has research experience with technology-based interventions, as his published study found that an LCS digital awareness campaign using social media and search engine outreach increased LCS awareness (number of visits to institutional LCS education web pages) and participation (number of scheduled LCS), thus showing the efficacy of digital outreach interventions. Therefore, targeted digital outreach interventions have the potential to increase LCS uptake, decrease disparities in lung cancer outcomes through early detection, and bridge the existing digital divide among Latinos[40].

Health Opportunities & Promoters of Equitable Screening for Lung Cancer (HOPES for Lung Cancer) offers an innovative approach to promote LCS uptake among Hispanic current and former smokersby elucidating barriers and facilitators to consistent documentation of smoking status to promote LCS uptake opportunities and leveraging the rise of digital health to assess the reach of the digital delivery of an educational video tailored to promote LCS uptake among Hispanic communities.

2. Specific Aims and Objectives

Aim 1: To elucidate barriers and facilitators to consistent identification and documentation of smoking status to promote LCS uptake among Hispanic current and former smokers. Employing a qualitative approach that leverages CBPR principles, we will conduct focus group discussions (n=5) with community stakeholders (n=6 per group). We will gather data on a) Hispanic patients' and community leaders' perspectives on socioculturally-sensitive nondisclosure reasons and b) providers' perspectives on smoking status ascertainment and electronic health record (EHR) documentation. The results will be shared with patients, community leaders, and hospital leadership as a framework to inform institutional strategies. Proposition: Elucidating barriers and

facilitators to disclosure and documentation of smoking status will promote opportunities to identify eligible Hispanic current and former smokers for interventions to increase LCS uptake.

Aim 2: To assess feasibility, acceptability, and reach of the digital delivery of an educational video to promote LCS uptake among Hispanic current and former smokers. An existing LCS educational video tailored for Hispanic communities will be digitally delivered to participants (n= 2000) via their preferred modality: 1) email, 2) patient portal, or 3) text messaging. Feasibility will be assessed by the proportion of participants with a digital delivery modality documented in EHR. Acceptability (overall satisfaction) will be assessed with brief surveys. Reach will be assessed by the proportion that interact and view the video among all participants. Hypothesis: Digital intervention delivery will be feasible and acceptable among Hispanic participants, and 20% of participants will interact with the digital delivery of the LCS educational video.

Aim 3: To explore the effect of the digital delivery of the educational video to increase interest, intent, and scheduling of LCS uptake among Hispanic current and former smokers. Brief surveys included in the digital delivery will assess participants' interest and intent to undergo LCS. Scheduling LCS (Y/N) will be assessed by EHR review 12-months after the video is sent and compared to historical controls. Hypothesis: Digital intervention delivery will increase LCS uptake among Hispanic participants. This K08 proposal builds on my research and community partnerships to improve documentation of smoking status and evaluate the digital delivery of an LCS educational video tailored for Hispanic communities.

3. General Description of Study Design

Approach: This study will use a hybrid-effectiveness design (*hybrid type 1*) to test the effect of a multimodal digital outreach intervention on increasing LCS rates among eligible Latino patients while observing and gathering information on implementation, delivery, dissemination, and sustainability of this outreach strategy[44]. This approach was selected as it allows incorporating CBPR principles and elements of efficacy studies and implementation research. We will assess the effect of improved identification and a digital outreach strategy on increasing LCS awareness and participation among eligible Latinos, while simultaneously assessing implementation fidelity to inform scalability of this outreach strategy.

Methods & Measures: Utilizing a user-centered design that leverages community-based participatory research principles through focus group (n=4) discussions with representative members of the Latino community served by our healthcare system, we will employ a rigorous mixed-methods design to explore how to improve the accuracy of up-to-date, inconsistent smoking history in EHR (**Fig. 2**), increase identification of LCS-eligible patients including, and improve experiences with digital outreach. The focus group discussions (n=4) will be conducted via Zoom, and we will recruit patients eligible for LCS, population health managers, primary care clinicians and patient advocates (n=6 per group). Through guided semi-structured focus group discussions (1 hour) and brief surveys prior to focus group participation, we will explore participants' perceptions of 1) patient reasons for nondisclosure of smoking status, 2) provider reasons for not assessing updated smoking history, and systems-based barriers to initial and ongoing documentation in EHR. Participants will be remunerated with $30 gift cards.

4. Subject Selection

Patient Participants:
The following inclusion criteria will be used:
- Age 50-80 years old
- Current or former Latino smokers (quit within the last 15 years, with ≥ 20 pack years)
- Not currently enrolled in LCS

The following exclusion criteria will be used:
- Those with cognitive inability to provide informed consent
- Those with inability to complete a brief survey
- Those with a current diagnosis of lung or any other active cancer
- Those who do not speak English, Spanish or Portuguese

Patient Advocate Participants:
The following inclusion criteria will be used:
- Age > 18 years old
- Verbal fluency in English
- Role as a patient navigator, community leader, other advocate position that has experience working with a Latino population

The following exclusion criteria will be used:
- Having cognitive impairment (e.g., severe dementia) severe enough to interfere with completing brief survey questionnaires or providing informed consent
- Refuse participation

Providers/Population Health Managers:
The following inclusion criteria will be used:
- Age > 18 years old
- Verbal fluency in English
- Role as a provider/clinician (i.e., community health center, hospital)

The following exclusion criteria will be used:
- Having cognitive impairment (e.g., severe dementia) severe enough to interfere with completing brief survey questionnaires or providing informed consent

Recruitment Procedures:

Aim 1. Focus Groups. Approximately 30 people will be recruited to participate (patients, population health managers, primary care clinicians, and patient advocates).

***Patient recruitment*:**
- Patients representing Hispanic groups with different English language proficiency (i.e., Spanish and Bilingual) eligible for LCS will be recruited to participate in the patient focus groups discussions done by teleconference (Zoom). We will utilize existing recruitment tools at MGH [Research Patient Data Registry (RPDR), Research Opportunities Direct to You (RODY), and Rally (research advertisement platform)]. To

provide an accurate estimate of the eligible patient population to recruit from, queries were conducted in the RPDR.

- Recruitment strategies will use HIPAA-compliant procedures, in which research staff will mail an opt-out letter to notify potential participants of their eligibility, with follow-up conducted in 7 days through telephone and email outreach. We will make a total of 4 calls per patient and two emails. All materials sent to patients will be translated into their primary language as indicated in their medical record, and a bilingual research assistant or study staff member will be available to consent patients and answer any questions. Participants will then be screened by a research assistant for eligibility prior to participating in the focus group.

Professional group recruitment (Population health managers, primary care clinicians, and patient advocates/community leaders):

- Clinicians, health care professionals and patient advocates/community leaders will be proactively recruited via email from an established clinical program at MGH, as well as through existing relationships with community health centers. Dr. Flores will leverage his existing network of collaborators from the community to recruit for the focus groups, a strategy that has yielded success in previous research.

All Focus Group participants will be remunerated with $30 gift cards as a token of appreciation for their time.

Aim 2 and 3. Digital Delivery of an LCS educational video.

- All participants will be remunerated $5 for completing the survey. Hispanic current and former smokers will be identified by querying the EHR research patient data registry (RPDR) from MGH. Eligible participants will be recruited and enrolled via an opt-out letter sent by mail or email.
- Aim 2: Participants will be assigned to receive an existing LCS educational video tailored for Hispanic communities using one of three digital modalities based on their preferred choice of contact documented in the EHR: 1) email, 2) patient portal, or 3) text messaging. Messages will be sent via an MGB approved survey platform (Qualtrics). A reminder message will be sent one week later to participants who have not interacted with the outreach tool.
- Aim 3: Participants will have the opportunity to answer a brief survey after watching the LCS educational video. The survey questions will be embedded within the same link as the educational video.

5. Subject Enrollment

- **Describe any pre-screening procedures as applicable:**
  - **Mass General Brigham Research Patient Data Registry (RPDR):** RPDR will be used to create the patient research invitation list. A query that excludes patients who have opted out will be created to send Research Invitations. Research

Invitations will be sent through Patient Gateway's personalized letters and targeted research announcements.

- **Recruitment through the Partners Rally Recruitment Portal**: We will submit a recruitment advertisement to the Partners Rally Recruitment Portal (see Attachment) to allow interested and potentially eligible patients to send their contact information directly to the study team. The study team will then reach out to interested patients to assess fit and eligibility for the study.
- **Flyer Recruitment:** Informational flyers (see Attachment) may be distributed by providers in the context of a medical encounter, posted at MGH and MGH Health Centers in pre-approved locations, and distributed at conferences/events geared towards the eligible population for this study. We will seek pre-approval before posting the flyer in any context. Flyers will describe the purpose of the study, what participation entails, remuneration, and contact information per the MGB protocol.
- **Patient Advocate/ Provider Recruitment:** Patient advocates and providers will be recruited with assistance from the MGH Community Health Centers and the Chelsea Health Center Research Roundtable. We will leverage our multidisciplinary network of collaborators (PCPs and patient navigators) and stakeholder boards to ask via phone calls, in-person, or via email for participants. The study staff will explain the purpose and details of the study and answer any questions that may arise.

- **Describe in a step-by-step procedure the consent process:** We will obtain verbal consent from the volunteers who agree to participate in the focus group sessions to provide feedback that will be utilized to refine and address LCS eligibility in the EHR. These individuals will be consented for audio recording of the focus group sessions, as these recordings will be utilized to gather feedback to systematically improve the educational intervention. The consent process will be performed by a research assistant or the principal investigator. All participants will be ensured that participation is strictly voluntary and confidential, and that it does not affect their care at any of the MGB Healthcare institutions. In addition, we will inform the participants about the confidentiality measures that the research group will take during the process. Only members of the research team will have access to the data, and the recorded responses will not contain identifiable or confidential information. The verbal consent process will include pertinent information on study design, risks and benefits, and voluntary nature of the research and confidentiality. The consent process will be executed in a manner consistent with the IRB approved protocol, and the most recent version of the IRB-approved protocol will be used. Participants will be encouraged to review the consent form, in its entirety, before verbally consenting. Participants will be given a copy of the consent form.
  - Children will not be a part of this study as they do not meet our eligibility criteria and do not meet current LCS guidelines for recommended screening populations
  - There will be non-English speaking participants included in this protocol, and a study team member who can provide translated questions and surveys.
  - Those who are incapable of consciously making the informed decision to participate in the study or require the assistance of a surrogate decision maker, fall

within our exclusion criteria, and will not be considered for participation in the study.

6. STUDY PROCEDURES

- **Description of each study visit and procedures at each visit**
  - This study will be conducted via virtual means. There will be no study visits or medical procedures.
- **Description of study drugs, devices or other interventions/ exposures administered**
  - We will not be providing/ exposing the study participants to any drugs, devices or other interventions.
- **Description of specific data variables to be collected, including data collection methods, assessments, data collection sheets, and/or schedule of assessments**
  - **Aim 1,** will consist of focus groups. Focus groups (6 groups, n=6/group). will be held via Zoom due to COVID-19. They will last approximately 60 minutes each and be held with patients, primary care clinicians, population health managers, and patient advocates. Through guided semi-structured focus group discussions (1 hour) and brief surveys administered prior to focus group participation, we will explore participants' perceptions of improving socioculturally-sensitive smoking status to promote disclosure among Hispanic communities, barriers and strategies to ascertain smoking status during patient encounters with Hispanic patients consistently, and scalable best practices for consistent electronic-health record (EHR) documentation of smoking status among Hispanic populations.
  - **Aim 2** will consist of sending out the outreach video via three digital modalities to participants. Participants will be assigned to receive an existing LCS educational video tailored for Hispanic communities using one of three digital modalities based on their preferred choice of contact documented in the EHR: 1) email, 2) patient portal, or 3) multimedia short messaging service (SMS). Messages will be sent via a Mass General Brigham (MGB) approved survey platform (Qualtrics) that allows the study team to assess interaction with the digital outreach tool, including if participants read the message, clicked to watch the video and duration, as well as incorporate a brief survey instrument. A reminder message will be sent one week later to participants who have not interacted with the outreach tool. Baseline demographic characteristics and smoking status will be obtained from EHR.
  - **Aim 3** will consist of a brief survey sent to participants with the digital delivery of the LCS educational video to evaluate the effect of the digital outreach intervention to increase LCS participation among Hispanic participants who received the intervention. Using the Likert scale in the brief surveys that will be included in the outreach intervention, we will assess the proportion of participants that express interest and intent in participating in LCS among all that receive the intervention. Interest will be assessed by asking participants if they are thinking of participating in LCS (*e.g., I'm interested in talking to my doctor about LCS*), and intent will be assessed by asking participants if they are planning in participating in LCS (*e.g., I intend to schedule a low dose CT scan for LCS*). Scheduling LCS will be assessed by reviewing the EHR 12-months post-intervention to assess the

proportion of participants that scheduled low dose CT for LCS among all participants that received the intervention.

For all aims sources of materials will include information collected from the EHR (i.e., lung cancer screening history, smoking status, ethnicity, age), focus group qualitative data, and survey response data. A trained research assistant or study staff will conduct the EHR review. All information collected will be for the purposes of research and will only be accessible to study staff.

- **Description of planned genetic research—** No genetic research is being conducted.

7. Risks and Discomforts

Participation in the focus groups involves minimal risk to participants as this is primarily a quality improvement process for accurate targeting of LCS eligible patients in the EHR. We anticipate no physical risks to participating in this study. The potential for loss of confidentiality of data collected is minimal. To further decrease the potential for loss of confidentiality, we will employ multiple safeguards. All data, including focus group recordings and transcriptions, will be stored in locked file drawers. Access to data files containing personal identifiers will be secured with a password filing system and will be restricted to authorized study staff. All project file cabinets and computer databases will be secured in offices that are locked when not in use. No data regarding individual's responses will be provided to any third party. Data will be aggregated, and summary reports will be generated without any personal identifying information. There is a small risk of psychosocial distress related to the discussion of lung cancer and smoking. We will invest every effort to keep any foreseeable risk to a minimum. For example, all participants will be reassured that data will be de-identified. Participants will be informed that they have the right to decline participation in the study, to refuse to answer any questions, or to withdraw consent at any time without retribution from research personnel or adverse consequences. Participation in the study is completely voluntary and will not impact their clinical care.

8. Benefits

The benefits to participants are moderate to high for all Aims. For Aim 1, Participants will have the opportunity to discuss their smoking behaviors and disclosure of smoking status, as well as provide feedback on current practices. Specifically, participants in the focus groups will have the opportunity to discuss relevant risk perceptions of cancer and any fear or uncertainty they have about their smoking and screening behaviors with others. Discussing these concerns within a group setting provides participants with valuable peer support, especially as the focus groups will include only participants who haven't screened for lung cancer. This shared experience can help foster self-confidence, self-efficacy, and emotional validation. For primary care providers, population health managers, and patient advocates, their perspectives in the focus groups will help validate that they have expertise in this area. Any potential risks to participants, which we believe are minimal, are reasonable and outweighed by these moderate to high potential benefits. To minimize participant burden, all focus group participants will receive $30 remuneration for their time and participation.

For participants in the digital intervention (Aim 2,3), every effort to protect their data will be made. Furthermore, we believe the benefits again outweigh the risks as participants will receive tailored outreach about lung cancer screening and also receive a $5 remuneration for their time.

9. Statistical Analysis

All focus group discussions will be audio-recorded and professionally transcribed verbatim. Qualitative analysis will be performed by three study team members in two stages: First, data will be reduced, coded, and organized in summary templates that reflected the six a priori domains of inquiry. Second, content from the summary templates will be synthesized and displayed in stakeholder-by-domain matrices to allow comparison across stakeholder types. Content analyses will be discussed with mentors to assess structural thematic framework and categories, and discrepancies will be resolved through discussion and comparison to raw data. The outcome will be a framework with strategies to improve updated smoking history EHR documentation.

10. Monitoring and Quality Assurance

Participants will not receive a treatment or invasive procedure during the study. Therefore, no adverse effect is expected during this study. The PI and study staff will ensure that procedures of the study are followed according to the IRB-approved protocol. Should there be any protocol deviations or unanticipated problems or adverse events, the PI will notify the MGB IRB. Any adverse effects reported to study personnel will be reviewed with the PI who will determine whether they are mild, moderate, or serious. The PI will notify the IRB of any major violations or at the periodic review for any minor protocol violations, as is outlined in the MGB Human Research Policy.

Data collection and security:

For Aim 1, all focus group qualitative data, including transcription data, will be entered into a study-specific REDCap database using participant study numbers rather than participant names. Additionally, each participant study number will have a pseudonym (e.g., participant 1, participant 2) that will be used during the focus groups given the provision of information in a group setting. Importantly, all participants will be instructed to refrain from using their names; if there is accidental use of their names, the audio will be edited prior to submitting the file for transcription. The professional transcription that will be used in the qualitative analysis software will identify focus group participants with pseudonyms. All survey data, including Qualtrics response data and electronic health record (EHR) information, related to Aims 2 and 3 will be entered into a study-specific REDCap database in the same de-identified and secure fashion as in Aim 1. Maintenance of the password-protected, secure log linking participant study identifiers to participants will only be conducted by the PI and the study team. No identifying information will be kept on any study forms. Consent will be obtained online or over the phone, so all consent tracking forms will be kept electronically on an MGB-encrypted secure computer that is password-protected and only accessible to study staff. All data will only be shared with Mass General Brigham (MGB) and IRB-approved study staff; data will not be shared with any entity outside of the MGB system.

11. Privacy and Confidentiality

- ☒ Study procedures will be conducted in a private setting
- ☒ Only data and/or specimens necessary for the conduct of the study will be collected
- ☒ Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas)
- ☐ Specimens collected will be maintained in a secure location with appropriate protections (e.g. locked storage spaces, laboratory areas)
- ☒ Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol
- ☒ Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.)
- ☒ All electronic communication with participants will comply with Mass General Brigham secure communication policies
- ☒ Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary members of the research team required to conduct the research
- ☒ All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens
- ☒ The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research
- ☐ Additional privacy and/or confidentiality protections

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APPENDIX A

Data Monitoring Committee / Data and Safety Monitoring Board Appendix

A Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) will be convened for safety monitoring of this research study. The following characteristics describe the DMC/DSMB convened for this study (Check all that apply):

☐ The DMC/DSMB is independent from the study team and study sponsor.

☐ A process has been implemented to ensure absence of conflicts of interest by DMC/DSMB members.

☐ The DMC/DSMB has the authority to intervene on study progress in the event of safety concerns, e.g., to suspend or terminate a study if new safety concerns have been identified or need to be investigated.

☐ Describe number and types of (i.e., qualifications of) members:
Click or tap here to enter text.

☐ Describe planned frequency of meetings:
Click or tap here to enter text.

☐ DMC/DSMB reports with no findings (i.e., "continue without modifications") will be submitted to the IRB at the time of Continuing Review.

☐ DMC/DSMB reports with findings/modifications required will be submitted promptly (within 5 business days/7 calendar days of becoming aware) to the IRB as an Other Event.