Mass General Brigham

Official Title: Evaluation of a Resiliency Program for Fathers of Children and Youth with Special Health Care Needs

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# Institutional Review Board
# Intervention/Interaction Detailed Protocol

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*For Intervention/Interaction studies, submit a Detailed Protocol that includes the following sections. If information in a particular section is not applicable, omit and include the other relevant information.*

## 1. Background and Significance

Parents of children with disabilities experience elevated levels of parental stress, distress, and poorer health outcomes compared to the parents of children without disabilities (Lindo et al., 2016 & Olodsen & Richardson, 2006). Currently, research has focused primarily on mothers, "educators," or "parents" who have children with disabilities, with little research pertaining to fathers specifically (Hastings & Beck, 2004 & Oelofsen & Richardson, 2006). However, studies including fathers have found that they experience more stress, parenting daily hassles, and health stress than fathers of children without disabilities (Darling, Senatore, & Strachan, 2012; Oelofsen, & Richardson, 2006; Seymour et al., 2017) and are more likely to show violence in times of distress (Kimberlee et al., 2014). Additionally, contrary to the perception that fathers of children and youth with special health care needs (CYSHCN) do not want to be involved in their child's life, some studies have found fathers report a desire to be involved and see involvement as highly important (Rankin et al., 2019). Despite findings indicating that the fathers of CYSHCN experience elevated levels of psychological and physical health problems compared to fathers of children without disabilities (Darling, Senatore, & Strachan, 2012), significant gaps in the literature regarding interventions for this demographic remain. Therefore, future studies that aim to increase resiliency and decrease stress among fathers of CYSHCN are needed.

Fathers of CYSHCN may be underrepresented in research, in part, due to the barriers, men, particularly men of color, report experiencing when accessing health care (ex., social influence/stigma, economic strain, cultural influences, and changing gender roles) (Khanalou et al., 2015; Addis & Mahalik, 2003; Sicouri et al., 2018; Tully et al., 2017). Further, it has been established that men are less likely to seek help compared to women (Addis & Mahalik, 2003; Liddon, Kingerlee, & Barry, 2018). Significant gender differences observed between men and women indicate the need to tailor interventions for the specific needs of fathers. Several studies have found that fathers reported preferring interventions and activities with their children that incorporated physical activity into their designs (Rankin et al., 2019; Kingerlee et al., 2014; Sicouri et al.,2018). Additionally, fathers of CYSHCN tend to prefer male-focused support groups over other intervention designs (Kingerlee et al., 2014; Batchelor, Maguire, & Sheran, 2021; Sicouri et al., 2018). Finally, some studies have found that fathers

reported a higher likelihood to participate in interventions that were delivered from a trusted facilitator in a stimulating, relevant, and non-academic way (Sicouri et al., 2018).
Given these preferences, it is crucial that clinicians understand the intersection between male gender roles and recruitment approaches to accommodate current interventions for fathers (Julion et al., 2018 & Batchelor, Maguire, & Sheran, 2021). Currently, little research focuses on reducing stress and increasing resiliency among fathers of CYSHCN, leaving few opportunities for in-person or virtual care (Kuhlthau et al., 2020). However, several studies have found that prioritizing cultural sensitivity, addressing the influence of masculinity in culture, and addressing systemic barriers have the potential to increase male involvement in interventions that target resiliency (Seidler et al., 2018 & Khanlou et al., 2015).

Additionally, a meta-analysis revealed six interventions that targeted the fathers of children with developmental disabilities, where two explored the influence of home-based behavioral parent training and the remaining four explored the influence of coping skills interventions in clinical environments (Lindo et al., 2016). In a more recent meta-analysis, ten papers were identified that examined interventions that included fathers of children with Autism Spectrum Disorder (Rankin et al., 2019). Of these studies, five were in-home training programs, two had control groups, and six compared mothers to fathers (Rankin et al., 2019). Finally, one study on Mindfulness found that fathers who were more mindful were also more involved in their child's life and that the level of mindfulness may predict father-child relationships and child outcomes (Macdonald & Hastings, 2010). Large gaps in the literature persist regarding interventions targeted toward fathers of CYSHCN, indicating a need for future studies to accommodate current intervention for the parents of CYSHCN to fathers.

Resiliency is a multidimensional construct that refers to the ability to maintain adaptation and effective functioning when faced with stressors. Resiliency provides a framework for understanding the adjustment to stress as a dynamic process. Allostasis refers to the capacity to maintain stability of physiological systems in the face of adversity. When the exposed to chronic stressors, such as care for a CYSHCN, individuals expend a great deal of energy attempting to maintain allostasis; this can lead to the metabolic wear and tear described as allostatic load. Evidence is accumulating that this wear and tear is mediated by changes in basal stress system activity and by effects of these changes on dependent systems. Allostatic load and resilience can therefore be assessed by measuring basal stress system activity (HPA axis and salivary alpha-amylase).

Research to improve fathers' responses to stress is warranted and may help improve the wellbeing of both fathers and their children. Yet, a treatment targeting the psychosocial needs of fathers of CYSHCN has not been developed. This study aims to design and develop a resiliency intervention to provide support to fathers of CYSHCN.

This intervention will be a modified version of Dr. Park's evidence-based 8-week multimodal treatment which is designed to promote adaptation to stress and resiliency. The original program (the SMART-3RP) is an 8 session, 1.5 hours weekly multi modal intervention that incorporates relaxation techniques, stress awareness discussion, and adaptive strategies to improve coping with stress. In Phase 1 (Protocol #:2021P002838), we conducted a series of interviews to adapt the original SMART-3RP to meet the unique needs of fathers caring for children with special health care needs. This protocol outlines Phase 2 of our approach, which includes a small open pilot trial to refine the adapted program. The overall goal of this study is to advance our ultimate objective to implement a national father resiliency program.

## 2. Specific Aims and Objectives

Based on findings from our prior trials with parents of children with learning and attentional disabilities and parents of children with autism spectrum disorder (Kuhlthau et al., 2020; Park et al., 2020; IRB approved: #:2016P001622 and 2016P002037 respectively), we propose to pilot test and refine the adapted SMART-3RP among fathers of children with special health care needs. In both of these trials, the majority of participants who completed an earlier version of the intervention were mothers. The current study has the following objectives:

**Aim 1:**
Through participation in an open pilot of the intervention, we aim to further refine the adapted SMART-3RP content and study procedures. Treatment and study adaptations will be informed by weekly feedback surveys, a post-intervention survey, and exit interview(s) with participants, which will be recorded and transcribed.

In addition to aim 1, we have one exploratory aims:

**Exploratory Aim 1:** We aim to explore the preliminary feasibility (by assessing the number of sessions attended and adherence to Relaxation Response practice) and acceptability (assessed using the Participant Feedback Survey) of an 8-session Relaxation Response Resiliency (SMART-3RP) program for fathers of CYSHCN.

## 3. General Description of Study Design

This is an open pilot study. Based on Phase I findings, we propose to enroll up to 12 fathers of CYSHCN in the adapted SMART-3RP intervention. The SMART-3RP is an 8-session mind-body resiliency intervention that will be conducted virtually. Participants will complete the study survey at baseline and immediately following the intervention. As this is a pilot, participants will also be asked to provide weekly feedback on program sessions and participate in exit interview(s) following the intervention. The intervention may be iteratively modified as we receive feedback from participants.

## 4. Participant Selection

*Inclusion Criteria:*
1) Self-reported identify as father or male guardian of at least one child with special health care needs (e.g., autism spectrum disorder, cerebral palsy, dyslexia)
2) Age 18 or older
3) Ability to participate in group, virtual sessions including access to computer, tablet, or smartphone and internet.

*Exclusion Criteria:*
Fathers will not be eligible if they are unable to speak or read English, are unwilling or unable to participate in the study, or are considered medically or otherwise unable to participate by the study PI. There are no exclusion criteria with respect to ethnicity or socioeconomic status. To inform feasibility and acceptability, we will document reasons for refusal and reasons why fathers are excluded (and will maintain this data in a de-identified way).

*Recruitment:*

Participants will be recruited through advertisements (e.g., flyers) placed throughout social media platforms and online support groups for parents and families of CYSCHN. Flyers will also be placed throughout clinical and community settings and on the Mass General Brigham (MGB) Rally website. These flyers are included in the IRB submission. We will also share the flyer with family leaders who may distribute it to their networks. Interested participants may call or email the study staff to learn more about the study.

We will also recruit through our contacts in the community including providers from Massachusetts General Hospital and Boston Medical Center, as well as through local and national support groups, such as Family Voices and clinics affiliated with the Children and Youth with Special Healthcare Needs Network. MGH psychologists may also refer potentially eligible participants. If individuals reached through this recruitment method are interested in the study, they will complete the screening process described below for participants responding to advertisements.

## 5. Participant Enrollment

Interested participants may call or email study staff to learn more about the study. A member of the study staff (e.g., a PI or trained Research Coordinator) will explain study procedures, answer any questions, and complete an eligibility screening over the phone or via REDCap. They will then complete the electronic consent process described below. We plan to enroll up to 12 participants with the goal of conducting up to 2 intervention groups; each group will consist of approximately 3-8 participants.

***Informed consent process***

Given that we will be recruiting participants from multiple instate and out-of-state locations, in-person consent will, in most cases, be unfeasible. Thus, for eligible and interested participants, a member of the study staff will obtain informed consent electronically. We will use the electronic REDCap consent module to record a digital signature for this project. Participants will be made aware of security concerns related to email communication and will be informed of how to use the REDCap Survey Login feature. If not already specified via the completion of an eligibility screen, the participant will be given the option of using the MGB send secure system or unencrypted email.

**Electronic Informed Consent Process (EIC):**

The participant will be emailed the informed consent portal via REDCap. The REDCap link will direct them to an encrypted REDCap portal; the Electronic/Paperless Consent Template Project will be used. Once the participant confirms receipt of the EIC form link, they will be prompted to enter in their full name and birthday to access the informed consent form and verify their identify. This portal will have the electronic (paperless) consent form, to guide them through the consent discussion with study staff over the phone. The participant will be given ample opportunity to ask questions and take their time to consider their participation. If a participant would prefer, they may return to the EIC portal as many times as they would like to review the consent form on their own time. When ready, participants will digitally sign and date/time the consent form. Additionally, the participant will be prompted after signing to indicate the method through which they would like to receive a copy of the consent form for their record: digitally or through hard copy. If a patient would like to receive a copy of the consent form digitally, they will be asked of their preference to receive the email as encrypted, the default, or opt-out and receive the email unencrypted. These options allow participants to be informed of what an encrypted (Send Secure) email would appear as in their inbox and the steps to get into the email, or alternatively, to give permission receive the email without this extra layer of security but in a more accessible format. MGB language concerning the Send Secure feature is included to assist in this decision. Study staff will confirm receipt of

the digital signatures and will sign and date the consent form as the consenting study staff member. Participants will be informed that remuneration for completion of surveys will be sent in the form of a check. The participants social security number will be collected over the phone during the informed consent call by the study coordinator. This information will be stored only with the study ID number in a secure database on a password protected computer. The SSN will only be shared with the Partners Accounts Payable office and will be removed from research records when the check is generated. The SSN and a valid US address (collected on demographic form in "Contact Information" section) will be reported in the eCheck submission, which will be used for participant remuneration.

The consent forms will include a description of all study procedures, information about potential risks and benefits of participation, and study contact information (including that of the IRB) in case questions arise at a later time. The consent form will also explicitly state that study participation is voluntary, and that participants may refuse to answer any questions that make them uncomfortable and may discontinue participation at any time. The consent forms will also describe what participants will be asked to do in participating in the study. Participants will also be made aware that confidentiality would be broken if participants reported thoughts of harming themselves or others, in order to obtain appropriate care for the person. Lastly, the consent form will ask participants to consent to audio-recording of the exit interview(s) following the intervention.

In addition, special attention will be given during the consent process to the implications of receiving an intervention online via a videoconferencing platform. Participants will be explicitly informed that the video conferencing service, Zoom, provides secure web-based HIPAA-compliant videoconferencing software. Zoom is routinely used at MGB institutions and participants do not need to sign an end-user license agreement in order to use it. Zoom is a cloud-based solution, so participants need only click on the meeting link to participate on the platform, and they do not need to install the software onto their personal devices. All use of Zoom throughout the duration of this study will be with a MGB Zoom account. Participants will also be advised to wear headphones and sit in a quiet place to protect their own, and other group members' privacy. We will explain to participants that although we will do our best to ensure confidentiality on our end, we cannot guarantee 100% that other group members will not share the content of the group. Participants will also be advised to wear headphones and sit in a quiet place to protect their own, and other group members' privacy.

Participation will not be recorded in medical or employment records. All procedures and protocols will be approved by the MassGeneral Brigham (MGB) IRB. The participant will be given as much time as they need to review the consent and ask any questions.

Following consent, the participant will be asked to complete a demographic survey. The participant will also have the option to complete a brief test call with a study staff member using the videoconferencing software in order to ensure proficiency with the software.

## 6. STUDY PROCEDURES

**Participant communication**

Participants will be asked to provide contact information via the demographic survey and specify their preferred contact modalities following informed consent.

Study staff will attempt to engage in contact via phone, paper mail, email and/or text message to schedule group sessions and send study reminders, that will be sent up to twice a week. At minimum, participants will be asked to provide a home address and telephone number to allow for supplemental contact and delivery of study materials (e.g., intervention guide, study materials, etc.). Participants will be informed of MGB policies regarding text-messaging and email, per the information below.

**Text Message:** Participants will be given the option of communicating with study staff via text-message. Study staff will send brief text messages, containing limited information related to session scheduling as well as group session and survey reminders. Text-messages will be sent through a dedicated study phone plan, reviewed and administered by MBB Information Security. Text-messages will instruct the participants to refer to their email for more information. Participants will be given the opportunity to review the MGB texting language within the consent form. If a participant chooses to receive text messages from study staff, they given the option to receive encrypted or unencrypted text message and will be read the following language:

"The MBH standard is to send secure text messages. If you prefer, we can send you "unencrypted" texts that are not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted texts despite these risks, MGB will not be held responsible. Text message and data rates may apply based on your cell phone service plan. Your preference to receive unencrypted texts will apply to text messages sent to you from research staff in this study. If you wish to communicate with other research staff at MGB regarding additional studies, your preference will have to be documented with each research study."

Under no circumstances will study staff ever screen or discuss personal medical history, exchange personal health information, or other sensitive information via SMS message. If a participant introduces sensitive information, including but not limited to the examples just listed, into a SMS message conversation, the study staff member will direct the participant to call them to discuss it further over the phone on a dedicated secure phone line. Participants will be able to opt out of receiving SMS text message, at any time, for any reason, by informing study staff that they would no longer like to receive SMS text message. We intend to use a dedicated study phone plan, reviewed and administered by MGB Information Security to communicate with participants via text message.

**Email:** Participants will also be given the option to communicate (receive reminders, schedule, etc.) with study staff by email. If participant chooses email as their preferred method of communication, study staff will explain the encrypted, Send Secure default feature of emails sent from within the MGB Healthcare network. Study staff will verify that no sensitive or patient health information will be disclosed in emails but ensure that the patient understands that by opting-out of the send secure feature, information will not be as secure.

**Assessments**
Study assessments will include a battery of questionnaires via REDCap. At baseline, participants will be administered baseline questionnaires. Immediately following the intervention, participants are administered a second set of questionnaires (see attached "Participant Survey).

The assessments are itemized below. In addition, participants will be asked to complete weekly feedback surveys via REDCap throughout their intervention.

**Administered at Baseline:**
Battery of questionnaires
Contact information and Demographic Intake Form

**Administered during Intervention**
Weekly feedback survey

**Administered at Post-intervention:**
Battery of questionnaires
Participant Feedback Questionnaire

**Intervention**
In the intervention, sessions focus on developing an understanding of stress physiology and the physiology of the relaxation response (RR), on developing a regular practice of eliciting the RR, and on learning cognitive behavioral and positive psychology/resilience skills. In addition to the weekly group sessions, participants will receive the manual, via paper mail and/or an emailed pdf, which describes the content of the sessions, and audio recorded guided meditations for independent relaxation practice. Participants are expected to practice eliciting the RR for approximately 20 minutes a day throughout the course of the study, using the audio recording provided and/or any other meditative or mind body techniques. Participants will complete a daily log reporting how often and by which methods they are practicing the RR. (Please see attached practice log).

The intervention will be delivered virtually, via Zoom, a secure videoconferencing platform. The intervention will not be delivered clinically and will be a psycho-educational intervention. Participants will be asked to wear headphones and sit in a quiet room by themselves for each of the sessions.

Participants in all groups will be given questionnaires at the same timepoints (baseline, post intervention). Study staff will email these questionnaires to the participants via the REDCap system. Participants who have not responded within two weeks of each time point will be contacted to ensure receipt of study data.

**Exit Interview**
Following the intervention, we will conduct individual and group exit interviews with participants. Participants will be offered the option of participating in a group interview and an individual interview – they may participate in either or both formats, depending on their preference and availability. Group interviews will 30-60 minutes and individual interviews will last 10-30 minutes. We will utilize a semi-structured interview guide and will audio-record and transcribe the conversation (see "Exit Interview Guide")

**Remuneration**
Participants will receive a check of which the amount is based on the number of surveys completed. Participants will receive $25 per survey completed (baseline, post intervention). If they complete both surveys, they will receive an additional $25. Additionally, participants will receive $5 per each weekly feedback survey (8 surveys in total) and $25 for participating in the exit interviews ($25 for each interview: group and individual) following the intervention. In total, participants may be able to receive a check of up to $140 upon completion of all surveys.

## 7. Risks and Discomforts

Participants may feel uncomfortable completing various psychosocial questionnaires. As in any research study, there is a small risk that confidentiality may be breached; all efforts to minimize this risk will be taken, as outlined below. In addition, participants may find it time consuming to practice techniques learned in the intervention or tracking behavior such as elicitation the relaxation response.

As previously described, all participant information will remain confidential unless there is a reasonable concern for the safety of a participant. Depending on the nature of the situation, study staff will provide a clinical referral and/or contact the appropriate authorities to ensure the safety of the participant. Specifically, the leader(s) of the intervention sessions will be study staff members who are licensed psychologists and have experience delivering the program. If, at any point throughout the delivery of the intervention, staff members recognize a participant as distressed, they will ask the participant if they would like to take a break or continue and remind them they can terminate being part of the study at any time or opt out of a portion of the study. The interventionist will inform the study PI and/or fellow co-investigators of the conversation with the participant and discuss how to proceed. If, in the judgment of the PI and/or fellow co-investigators, the participant appears to be too emotionally distressed by participating, we will recommend that the participant to leave the study. If, at any point during the intervention, the participant appears to be at risk or harming themselves and/or others, study staff will provide a clinical referral and/or contact the appropriate authorities to ensure the safety of the participant.

## 8. Benefits

Participants may not benefit from this study. Participants in the current study may observe a reduction in symptoms of stress related to being a father of CYSHCN. It is hoped that the intervention will result in a statistically significant reduction of symptoms of stress and an increase in resiliency.

The current study may provide support for fathers. This intervention may enhance our understanding of the role of psycho-educational interventions such as the SMART-3RP in fathers of CYSHCN. This intervention may have widespread implications for types of resources available that may ultimately improve wellbeing of CYSHCN.

## 9. Statistical Analysis

We plan to conduct a pilot trial of a virtual-based SMART-3RP for fathers of CYSHCN. Our main goal is to gather feedback from program participants through weekly descriptive surveys in order to iteratively adapt the SMART-3RP manual for fathers. Data from these surveys, in addition to the post-intervention survey and the exit interviews, will be used to inform any adaptations to program content and structure. We will utilize rapid analysis to analyze qualitative feedback collected in the surveys and thematic content analysis to analyze qualitative data collected in exit interviews. In addition, we hope to assess the questions below as exploratory outcomes.

**Exploratory Outcomes**

**1) Is the virtual intervention feasible and acceptable for fathers of CYSHCN?**

Feasibility will be assessed using attendance (i.e. 6/8 sessions).
Feasibility will also be assessed by the number of participants completing study surveys.

Acceptability will be assessed using a Participant Feedback questionnaire (See Feedback questionnaire attached).

## 10. Monitoring and Quality Assurance

**Data Management and Quality Control Procedures**

All study staff will complete required MGB human participants trainings prior to the start of study procedures. All interventionists and assessors will have advanced training in interviewing and assessment. Participants will be informed that they may refuse to answer questions that make them feel uncomfortable. Participants will be advised to wear headphones and sit in a quiet place during each virtual session. Participants will also be asked not to share the contents of the group with anyone else.

Electronic information will be stored in REDCap (Research Electronic Data Capture), a free, secure, and HIPAA-compliant web-based application hosted by the Partners HealthCare Research Computing Enterprise Research Infrastructure & Services (ERIS) group (based at the PHS Needham corporate datacenter).

REDCap (Research Electronic Data Capture) is a free, secure, HIPAA compliant web-based application hosted by the Partners HealthCare Research Computing Enterprise Research Infrastructure & Services (ERIS) group. The system offers easy data manipulation with audit trails, reports for monitoring and querying participant records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus).

Participants will complete surveys using a REDCap link that will only be sent to them. They will be instructed to complete the survey in one sitting, within two weeks of receiving the survey link. Not all survey questions require completion. Participants will have the option of stopping survey completion at any time, and they will not be able to go back to the survey at a later time. If not all of the questions are answered, the survey will simply be left as incomplete. Rate of survey completion will be used to measure the feasibility of the pilot intervention. Only participants themselves will be able to edit survey responses.

The REDCap project will use the logging feature to track data entry. Data will be monitored weekly by a study coordinator. The coordinator will meet regularly with the study PI to review all enrollment and survey data saved in REDCap.

Data will be stored on password protected computers that will be stored in secure locations at all times. Only research staff will have access to these data locations.

A unique anonymous identifier will be assigned to each participant; subsequently, all data collected will be associated exclusively with this identifier. This includes all questionnaires administered over the course of the study, as well as home practice logs.

All groups will meet using Zoom, a secure, HIPAA compliant web-based videoconferencing platform. All group sessions will be password protected, and the password will only be shared with trained study staff and study participants.

**Data and Safety Monitoring Plan**

Adverse Event Monitoring: Throughout the study participants will be monitored for the occurrence of events defined as any undesirable experience or unanticipated risk. Lack of effect of treatment is not considered an event. All adverse events will be reported on an adverse event form.

The principal investigator is ultimately responsible for data and safety monitoring. If study staff becomes aware of any adverse events, the event will be reported immediately to the Principal Investigator. The Principal Investigator has the responsibility of reporting serious adverse events (death, life threatening illness or injury, serious injury, or permanent disability) to PHRC within 72 hours of notification. All other adverse events and/or other events will be reported by the PI to the Office of Research Compliance via Insight/eIRB within 5 working days/7 calendar days of the date the investigator first becomes aware of the problem

**Participant Safety**
All participant information will remain confidential unless there is a reasonable concern for the safety of the participant. Depending on the nature of the situation, study staff will provide a clinical referral and/or contact the appropriate authorities to ensure the safety of the participant. Specifically, the leader(s) of the intervention sessions will be study staff members who are licensed psychologists and have experience delivering the 3RP program. If, at any point throughout the delivery of the intervention, staff members recognize a participant as distressed, they will ask the participant if they would like to take a break or continue and remind them they can terminate being part of the study at any time or opt out of a portion of the study. The interventionist will inform the study PI and/or fellow co-investigators of the conversation with the participant and discuss how to proceed. If, in the judgment of the PI and/or fellow co-investigators, the participant appears to be too emotionally distressed by participating, we will recommend that the child leave the study. If, at any point during the intervention, the participant appears to be at risk or harming themselves and/or others, study staff will provide a clinical referral and/or contact the appropriate authorities to ensure the safety of the participant.

## 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

All comments and information gained through the exit interviews will not be attached to individual participants. Moreover, specific details about individuals or individual situations will be omitted or slightly changed (e.g. deleting the name of a hometown or changing specific occupation of a family member) when reporting findings. This will be done to assure confidentiality. As noted above, recordings and transcripts will be labeled only with the focus group ID, participant ID and date, and will be accessible only by approved study staff who will maintain confidentiality standards and will not discuss names or any identifying information associated with the focus group findings.

Audio-taping and transcription

Confidentiality for exit interviews will be maintained by standard procedures, including the storage of all data including audiotapes and transcripts in password protected computer files.

All audio files will be transferred off of recorders onto a password protected drive immediately following each interview or focus group.

## 12. References

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# APPENDIX A

## Data Monitoring Committee / Data and Safety Monitoring Board Appendix

- *To be completed for studies monitored by Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) if a full DMC/DSMB charter is not available at the time of initial IRB review.*
- *DMC/DSMB Charter and/or Roster can be submitted to the IRB later via Amendment, though these are not required.*

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.