SUPPORTING OUR CAREGIVERS IN ADRD LEARNING (SOCIAL): REDUCING STRESS FOR CAREGIVERS OF PERSONS WITH DEMENTIA, AN OPEN PILOT STUDY

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1. Background and Significance

Background

Over 11 million adult caregivers care for someone who has Alzheimer's disease (AD) and AD-related dementias (ADRD), and 40% report caregiver stress that interferes with their ability to care for themselves and their loved one. Caregiver stress is exacerbated by managing challenging patient behaviors such as aggression, agitation, and apathy, and is associated with heightened emotional distress (symptoms of depression and anxiety), decreased well-being, and increased risk for morbidity and mortality in both caregivers and care-recipients. **Decreasing caregiver stress is a public health concern, and many caregivers are actively looking for feasible and effective ways to manage high caregiver stress and associated emotional distress.**

Available services do not meet the psychological needs of stressed caregivers of persons with ADRD with challenging behaviors for 3 main reasons. First, while helpful, support groups often do not teach behavioral management skills which caregivers report needing to successfully manage challenging patient behaviors. Second, behavioral management skills interventions while available, do not teach: 1) emotional regulation skills which are necessary to foster caregiver ability to actively use these skills to manage patient behaviors, and 2) self-compassion skills which are necessary to bypass guilt and loneliness which are common caregiver challenges. Third, mindfulness and self-compassion interventions are theoretically based, effective solutions for managing stress and distress among caregivers, but are rarely applied to managing challenging behaviors, and are burdened by long sessions, need for intense home practice regimen, and complex language which limit uptake and reach. **Our preliminary data shows that ADRD caregivers desire real-time guidance and support that weaves together emotional regulation, self-compassion and behavioral management skills to successfully navigate the stress of the caregiving experience.**

Our guiding hypothesis is that combining evidence-based mindfulness and self-compassion skills with behavioral management skills is an effective and efficient solution to the problem of high stress among ADRD caregivers.

We will use the NIH stage model and principles from the Science of Behavior Change (SOBC) to develop, optimize and establish proof of concepts for the Supporting Our Caregivers In ADRD Learning (SOCIAL) for stressed caregivers of persons with ADRD with challenging behaviors, with a strong focus on mechanisms of action. SOCIAL structure and components will be designed to facilitate uptake (video delivery, shorter program, simple, lay language), skills practice (web platform downloaded as an app with all program skills; focus on incorporating skill practice within the caregiver activities) and sustainability of effects (continued access to the web platform with skills after the group sessions end). We will enroll stressed caregivers (PSS-4≥ 6) who self-report managing 1 or more patient behaviors in the past month from the Dementia Care Collaborative Program at MGH (Ritchie director), Massachusetts Alzheimer's Disease Research Center community partners, and from national dementia care programs (>38% racial and ethnic minorities as benchmark).

Significance

Informal caregivers are the backbone of our health care landscape. A caregiver—sometimes called an informal caregiver—is an unpaid individual who provides assistance (physical and/or emotional) to one or more individuals with chronic illness, frailty, disability, or a mental health disorder.[1] Over 11 million caregivers provide unpaid care to an older adult with Alzheimer's Disease or Related Dementia (ADRD).[2] The lifetime cost of caring for one person with ADRD exceeds $350,000 and family care accounts for 70% of this toll.[3] Despite their critical role in supporting persons with ADRD, caregivers are often described as "hidden patients" because they are at risk for negative health outcomes but are underrecognized and undertreated.[4]

Caregiver stress, emotional distress (symptoms of depression and anxiety) and reduced well-being are common among caregivers of persons living with ADRD, are exacerbated by care recipient behavioral symptoms and negatively impact morbidity and mortality for both themselves and the person they care for. Although some caregivers adjust well to their role of caring for an individual with ADRD, approximately 40% report stress that negatively impacts their health and well-being.[5,6] Caregiver stress (also known as caregiver stress syndrome) is defined as the strain or load borne by a person who cares for a chronically ill, disabled, or older family member.[7]

Addressing stress, emotional functioning, and well-being in caregivers of persons with ADRD is a public health concern. Addressing caregivers' stress is important not only for decreasing own risk for chronic health problems, morbidity, and mortality, but also because it affects the quality of care they provide and thus their loved one's emotional and health outcomes.[5,6] As such, there is a need for feasible, acceptable, effective, and scalable stress management programs to prevent the deleterious effect of stress on both caregivers' and their loved one's overall health. Studies show that on average, 42- 55% of ADRD caregivers are actively looking for non-pharmacological interventions to decrease caregiver stress.[8]

Available programs do not meet the psychological and practical needs of stressed caregivers of persons with ADRD; we need better solutions. First, while helpful, most support groups do not systematically teach behavioral management skills which caregivers report needing in order to manage challenging patient behaviors.[9] Second, behavioral management skills interventions exist, but do not teach: 1) emotional regulation skills which are necessary in order to foster caregiver ability to access and use these skills to manage patient behaviors, and/or 2) self-compassion and compassion skills which are necessary to bypass guilt and loneliness and navigate behavioral symptoms which are common caregiver challenges. Third, mindfulness and self-compassion interventions are effective solutions for managing stress, and distress across multiple populations, but engagement and efficacy among diverse ADRD caregivers are limited.[10-15]

Available programs also have several practical limitations that impede potential for routine implementation and scalability. First, traditional mindfulness and self-compassion programs are time-intensive (90-minute sessions, 8-12 weeks long) and many caregivers of persons with ADRD are unable to commit to attending given their caregiving responsibilities. Second, these programs have been historically delivered through in-person visits. This delivery modality is not feasible for caregivers who spend substantial time on caregiving tasks in addition to their own life responsibilities. Third, traditional mindfulness and self-compassion program content is general and not tailored to the specific case-based scenarios of ADRD caregivers. Fourth, these programs require an intense regimen of home practice with up to 2x20 minutes of practice per day, which often is not realistic for caregivers. In sum, shorter programs and sessions, virtual delivery, tailored content to case-based scenarios encountered by ADRD caregivers, and incorporation of home practice within the caregiving routine are necessary in order to foster potential implementation and sustained skill practice.

The guiding hypothesis of this proposal is that combining evidence-based mindfulness and self-compassion skills with behavioral management skills within a multi-component program increases intervention potency and efficiently supports caregivers of persons with ADRD. Accounting for practical challenges to engagement (nr. sessions, delivery modality, skill practice) will also enhance uptake and reach.

Our preliminary data[16] shows that caregivers of persons with ADRD desire real-time guidance and support that weaves together emotional regulation, self-compassion, and behavioral management skills to successfully navigate the stress of the caregiving experience. To date, no such programs exist for ADRD caregivers.[17]

Current study

Building on the limitations of prior research, we proposed to develop the **Supporting Our Caregivers In ADRD Learning (SOCIAL)** to help caregivers of persons with ADRD manage the stress associated with the general caregiver experience including stress stemming from managing challenging patient behaviors. In AIM 1 of the SOCIAL study (Protocol#: 2022P002037) we obtained feedback on the program's proposed content and format from caregivers of individuals living with ADRD. What we learned from those responses was used to inform this open pilot (aim 2) of the study which aims to teach: (1) mindfulness skills; (2) compassion and self-compassion skills; and (3) behavioral management skills. The SOCIAL open-pilot also provides psychoeducation and group-based training and skill practice to facilitate skill uptake and integration within the caregiver experience and tasks.

2. Specific Aims and Objectives

We will conduct a live video open pilot of the SOCIAL intervention with exit interviews (N=up to 2 groups, up to 20 caregivers). We will use this information to revise SOCIAL and our conceptual model, as needed to maximize feasibility and target engagement. Hyp. 1: SOCIAL will show evidence of feasibility, acceptability, credibility, and fidelity. Hyp. 2. SOCIAL will show evidence of improvement in intervention targets and outcomes and these improvements will be correlated.

3. General Description of Study Design

We will conduct an open pilot of our active intervention, SOCIAL, delivered via live video (Zoom) to ADRD caregivers who meet eligibility criteria. We will recruit and enroll up to 20 stressed informal caregivers of ADRD individuals who also report challenges managing patient behaviors. Participants will be adults (18 years or older) who care for an individual with ADRD and who endorse caregiver stress on the Perceived Stress Scale-4 (score of 6 or higher) and have managed 1 or more behavioral symptoms in the past month. We will recruit caregivers from an array of sources, including, but not limited to, local caregiver support programs, dementia research centers, and community partners. All recruitment efforts will be captured in a secure database and will allow us to solidify our recruitment plan for the subsequent pilot clinical trial.

Potential participants (recruited nationally) may hear about the study through a flyer given to them from clinical staff, posted on social media or websites, or through community outreach efforts. Potential participants will either a) verbally agree to clinical staff for study staff to contact participants directly, indicate interest directly into RedCAP through the QR code or by reaching out to study staff based on information they have obtained from websites or community outreach.

Potential participants will indicate their interest by completing the REDCAP screener using the QR code on the flyer or by emailing the research assistants who will provide more information about the study and schedule a screening phone call. CRCs will reach out to eligible caregivers, and engage in an informed consent discussion where they will be informed of study procedures, expectations, potential risks and benefits of participation, and information regarding who they can contact regarding further questions. They will also be informed that participation is voluntary, that they can refuse to answer any questions, and they can withdraw from the study at any time. All caregivers who verbally consent and can attend the designated time and date for the group cohort will be emailed a link with the baseline questionnaire over REDCap; a research assistant will help with questionnaire completion if needed. All baseline data collection will be completed prior to the first group session. All caregivers will also have the opportunity to attend a Zoom practice session with the Research Assistant to problem solve any technical challenges. Caregivers will complete the same questionnaires after the conclusion of the intervention. Additionally, caregivers will have access to a web-based platform. The web platform for SOCIAL will include voice over videos and recordings of skills in addition to the program manual.

Participants will have the option to receive secure and encrypted text messages sent via Twilio, a third party, MGB-approved web service that integrates with REDCap to send reminders, survey invitations, and collect home practice participation over SMS text messaging. If participants prefer, study staff can send "unencrypted" texts that are not secure and could result in the unauthorized use or disclosure of their information or email reminders sent directly through REDCap If participants want to receive communication by unencrypted texts despite these risks, they will be informed that MGB Healthcare will not be held responsible for any data breaches. These texts will not contain any protected health information. Text message and data rates may apply based on participants' cell phone service plan Participants have the right to refuse these texting reminders. This decision will not impact their ability to participate in the study. Participants can opt out of these text messages at any time.

Outcome Measures

Primary Outcome Measures

1. Feasibility of Recruitment

We will examine feasibility of recruitment through tracking of the number who respond through flyer (QR Code), email, website or direct clinical contact.
[Time Frame: Baseline]

2. Feasibility of Assessments

We will calculate the proportion of caregivers completing the study questionnaires.
[Time Frame: Baseline, Post-intervention]

3. Feasibility of Quantitative Measures

We will assess the proportion of quantitative measures missing within the questionnaires.

[Time Frame: Baseline, Post-intervention]

Other Pre-specified Outcome Measures

4. Symptoms of Depression

We will use the Center for Epidemiological Studies-Depression Scale (CES-D). This is a 20-item scale widely used with ADRD caregivers.

[Time Frame: Baseline, Post-intervention]

5. Mindfulness

We will use the Five Facets Mindfulness Questionnaire FFMQ (15 items) to assess caregivers' mindfulness based on 5 subscales (observing, describing, awareness, non-judging, non-reactivity).

[Time Frame: Baseline, Post-intervention]

6. Perceived Stress

We will use the PSS-10 (10 items) to assess perceived stress.

[Time Frame: Baseline, Post-intervention]

7. Symptoms of Anxiety

We will use State Trait Anxiety Inventory (STAI) state subscales (20 items) to assess anxiety symptoms in response to stressful situations. STA has been successfully used with ADRD caregivers.

[Time Frame: Baseline, Post-intervention]

8. Self-Compassion

The Self-Compassion Scale-Short Form (SCS-SF), (12 items)assesses self-kindness.

[Time Frame: Baseline, Post-intervention]

9. Compassion

The Compassion Scale (CS) (16 items) assesses common humanity, kindness toward others and ability to understand the suffering or challenges of others.

[Time Frame: Baseline, Post-intervention]

10. Caregiver self-efficacy
The Revised Caregiver self-efficacy instrument (10 Items) assesses domains of self-efficacy including obtaining respite, responding to disruptive patient behaviors, and controlling upsetting thoughts.

[Time Frame: Baseline, Post-intervention]

11. Loneliness
The UCLA loneliness scale (3-item) assesses relational connectedness, social connectedness, and self-perceived isolation.

[Time Frame: Baseline, Post-intervention]

12. Social Support
Interpersonal Support Evaluation List short form, ISEL(12 items) assesses appraisal, belonging and tangible social support.

[Time Frame: Baseline, Post-intervention]

13. Well-being
The World Health Organization-Five Well-Being Index (WHO-D) (5 items) assesses emotional well-being.

[Time Frame: Baseline, Post-intervention]

14. Distress Due to Patient Challenges Behaviors
The Neuropsychiatric Inventory Caregiver Distress Scale (12 items) assesses distress associated with dementia patient's behaviors such as apathy, elation, disinhibition.

[Time Frame: Baseline, Post-intervention]

15. Satisfaction with the Intervention
We will use the Client Satisfaction Questionnaire (CSQ-3) to assess caregivers' satisfaction with the intervention.

[Time Frame: Post-intervention]

16. Perceptions of improvement
We will use the Modified Perception of Global Improvement (MPGI), (2 items) to measure a participant's interpretation of changes in perceptions of stress following intervention.

[Time Frame: Post-intervention]

17. Therapist Fidelity
We will assess both therapists' ability to deliver the content of each session (through therapist completed adherence checklists) and therapist fidelity (through independent review of recorded sessions by Co-I's)

[Time Frame: Baseline through Post-intervention]

18. Perceptions of Questionnaire Battery
We will assess how appropriately the caregivers fill the questionnaires through documenting completion rates of all questionnaires.

[Time Frame: Post-intervention]

19. Adherence to Home practice
We will report the proportion of caregivers who complete weekly home practice.

[Time Frame: Weekly]

20. Perceptions of Email and Text Reminders
We will assess caregivers' perception of emails and text messages reminders by asking, "Do you think that the amount of emails/texts you received was: too little, just enough, too much?"

[Time Frame: Post-intervention]

21. Credibility and Expectancy
We will use the Credibility and Expectancy Questionnaire (CEQ), (6 items) to assess caregivers' perceptions that the treatment will work after participating in the intervention.

[Time Frame: Pre-intervention]

The self-report measures and assessment domains align with the purpose of the study and with recommendations for feasibility trials. Feasibility of recruitment and retention will be assessed using proportions (see Table 1). Satisfaction and credibility will be assessed with proportions of scores over the midpoint of the Client Satisfaction and Credibility and Expectancy questionnaires.

4. Subject Selection

Study Population Characteristics

Conditions or Focus of Study

- Informal caregivers of people with ADRD who endorse caregiver stress and challenges managing patient behaviors

Eligibility Criteria

Caregivers will be 18 years or older, fluent in English, who meet the criteria for an informal caregiver (e.g., family or friend of a care recipient who providers unpaid care) and lives with and cares for an individual with ADRD. The informal caregivers must have lived with the patient for more than 6 months and must currently provide more than 4 hours of supervision or direct assistance to the care recipient per day (average). Caregivers will need to endorse stress (PSS-4>=6) and self-report that they had managed 1 or more behavioral symptoms in the past month. Exclusion criteria include planned change in psychotropic treatment for the duration of the study, use of mindfulness apps or any meditation (more than 60 min/week in past 6 months), major illness known to drastically worsen or require surgery for the duration of the study, active treatment for cancer, involvement in another clinical trial for caregivers, a score >=4 on the PMSQ and no stated concerns or distress related to care recipient's disruptive behaviors.

Inclusion Criteria

- 18 years or older
- English fluency and literacy
- Meeting criteria for being a caregiver (e.g., family or friend of a care recipient who provides unpaid care)
- Must live with and care for an individual with ADRD.
- Must have been in a caregiver role for more than 6 months
- Must provide an average 4 hours of supervision or direct assistance per day for the care recipient
- Perceived Stress Scale-4 (4-item) version >= 6
- Had managed 1 or more behavioral symptoms in past month

Exclusion Criteria

- Recent change in psychotropic treatment for depression or anxiety.
- Use of mindfulness apps or any meditation (more than 60 min/week in past 6 months).
- Involvement in another clinical trial for caregivers, a score >= 4 on the Portable Mental Status Questionnaire (PMSQ).
- No stated concerns or distress related to care recipient's disruptive behaviors.
- Involvement in another clinical trial for caregivers

Recruitment and Retention Plan

We will conduct a live video (Zoom) open pilot group with exit interviews (N=up to 2 groups, up to 20 caregivers). We will use this information to revise SOCIAL and our conceptual model, as needed to maximize feasibility and target engagement.

5. Subject Enrollment

Potential participants recruited nationally will indicate their interest by completing the REDCap screener using the QR code on the flyer or by emailing the research assistants who will provide more information about the study and schedule a screening phone call. CRCs will reach out to eligible caregivers and engage in a discussion where they will be read the study fact sheet which including an explanation of study procedures, potential risks and benefits of participation, and information regarding who they can contact regarding further questions via a phone call, and if they would like to consent to participate. They will also be informed that participation is voluntary, that they can refuse to answer any questions, and they can withdraw from the study at any time. All caregivers who consent and can attend the designated time and date for the next group cohort will be emailed a link with the baseline questionnaire over Redcap and offered assistance with questionnaire completion from the research assistant. Caregivers who provide consent but are unavailable to participate in the next available group will be placed on a waitlist for the next group cohort. All baselines will be completed within 1 week of the first group session. Due to the remuneration amount, participants will be prompted to complete an MGB secured REDCap survey along with the initial pre-intervention (baseline) survey that will ask for their SSN per MGH's compensation policy. If participants do not want to provide their SSN, an option will be provided to them of receiving $50 through two gift cards (see Renumeration below). Additionally, prior to the first intervention session, caregivers will have the opportunity to attend a zoom practice session with the Research Assistant to problem-solve any technical challenges.

6. Study Procedures

Study enrollment

We will recruit up to 20 caregivers for up to 2 groups in this study. Participants will be asked to complete a baseline assessment that asks questions on physical and mental wellbeing as well as questions about their experiences as a caregiver for someone living with dementia. Upon completion, caregivers will be invited to participate in a weekly 60-minute virtual group training session for 6 weeks that is led by a trained Clinical Social Worker. The content of each session varies week-to-week: Week 1: U*nderstanding Caregiver Stress and Distress; Week 2: Mindful Caregiving; Week 3: Caring Without Losing Ourselves; Week 4: Behavior Management Skills; Week 5: Mindful and Self-Compassionate Caregiving; Week 6: Mindful and Self-Compassionate Life.* At the end of the 6 weeks, we will conduct individual live video exit interviews to gather detailed feedback on SOCIAL intervention components, applicability of study measures, general protocol issues including barriers and facilitators to participation and skill practice, perception of the web platform, and perception of the live video intervention delivery. Exit interviews will last 30 minutes and will be recorded via zoom, transcribed using Landmark Associates, and analyzed in NVivo to refine study procedures and finalize SOCIAL before the pilot RCT.

7. Risks and Discomforts

Potential risks

It is unlikely that participants will incur any risk of physical harm because of study participation. Participants may find some questionnaire items to be emotionally upsetting or may experience psychological discomfort while discussing their experiences during intervention sessions. The study MPI Vranceanu is a licensed psychologist and the study MPI Ritchie is a geriatrician. Both have expertise with ADRD caregivers and will triage and refer individual participants to an appropriate level of clinical care, as needed.

<u>Communication-related risks:</u> Text messages by mobile/cellphones are a common form of communication. The SOCIAL research study involves sending participants text messages using the Twilio app. Participants do not have to agree with receiving text messages in order to participate. These text messages will include information about session reminders, reminders to complete homework logs, and activity prompts to complete before upcoming sessions. We will send these messages daily during the 6-week group intervention. Texting over mobile/cell phones carries security risks because text messages between mobile/cellphones are not encrypted. This means that information you send or receive by text

message could be intercepted or viewed by someone other than staff involved with this research study, or by your mobile/cellphone provider or carrier.

Meditation-related risks. Meditation may cause study participants to feel emotions more intensely on a temporary basis (during practice) as the practice of meditation teaches participants to become more mindful of their thoughts, feelings, and emotions. Participants will learn through the instruction materials that this increase is temporary and is associated with an actual decrease in symptoms over time, due to habituation. If subjects report ongoing emotional dysregulation, the MPI, Dr. Vranceanu will triage and refer individual participants to an appropriate level of clinical care, as needed.

8. Benefits

Potential Benefits of the Proposed Research to Human Subjects and Others

Participants may benefit from the numerous evidence-based advantages associated with engaging in meditation, self-compassion and training in managing challenging care recipient behaviors. Caregivers may experience reduced caregiving stress, emotional distress, and improved well-being. Caregivers may be able to better regulate their emotions, have fewer ruminating thoughts, and provide higher quality care to their loved ones.

Importance of the Knowledge to be Gained

The larger goal of this research is to provide ADRD caregivers with feasible and scalable resources they need to navigate the stress and challenges managing patient behaviors. The current R01 pilot feasibility RCT represents the first step toward this larger goal, by allowing us to ascertain feasibility, mechanism and proof of concept necessary in order to conduct a scientifically rigorous stage II efficacy trial.

Remuneration

Participants will be remunerated $20 at base line for enrollment data collection and $40 at completion of intervention at their Exit Interview. Participants can receive up to $60 by check. If participants do not want to provide their Social Security Number, they will be provided the option to receive $50 in gift cards, distributed as a $20 baseline and then $30 gift card upon study completion in compliance of the MGH policy, “Payment to Human Subjects for Participation in Research.”

9. Statistical Analysis

Sample Size and power analyses

Traditional power analyses are also not appropriate for activities within NIH stage 1A, where the goal is to “explore” feasibility and mechanistic target engagement for the sole purpose of refining the intervention and protocol. Although these studies are inherently underpowered for detecting statistical significance, they provide essential information on feasibility, signal of improvement in targets and outcomes, and signal of association between change in targets and outcomes.[18]

Optimize SOCIAL

Qualitative exit interview data will be analyzed using Nvivo12, which assessed reliability (kappa) of coding for themes and patterns of responses. A postdoctoral fellow and/or the RAs, under the supervision of the MPIs, will code qualitative data into superordinate themes and subthemes. The research assistant will complete reliability coding. Discrepancies will be resolved through discussions until reliability is obtained (kappa >.80). We will use qualitative thematic analyses with a hybrid deductive-inductive analyses plan. Inductive analyses will be guided by the Framework method.

We will also explore pre-post changes in our intervention targets (mindfulness, self-compassion, caregiver self-efficacy and social support) and outcomes (stress, depression, anxiety, and well-being) using t-tests and explore correlations between change scores and outcomes. We will revise our procedure, conceptual model and measures based on quantitative and qualitative data as needed. Consistent with recent recommendations we will report whether the MCID for each quantitative measure is included within the 95% confidence interval for all quantitative analyses as a go/no go benchmark rather than statistical significance.

10. Monitoring and Quality Assurance

Data Safety and Monitoring Plan

Participant Confidentiality. All study materials will identify participants only by study ID, visit number, and visit date. The study research assistant will be trained in procedures to protect study participant confidentiality. Recordings of each session will be immediately de-identified (e.g., only ID, visit number and date) and stored on a password protected computer; the recording will be subsequently and immediately deleted from the recording device.

Group sessions will also be audio-recorded and transcribed. The names of the people who volunteer for this study will not be discussed outside of this project. Identities will be kept confidential. When the audio recordings are being transcribed, participants' names will be replaced with a code. Only trained members of the research team will have access to and know which code belongs to whom. These codes will be stored within the Mass General Brigham firewall, which is secure, and password protected.

Data Validity and Security. The research team will develop standard operating procedures for data collection, data management, and quality control. The project manager, under the supervision of the MPIs will oversee all procedures related to secure data collection and management. Data activities will be conducted using Research Electronic Data Capture (REDCap), a software and workflow tool for research data collection and management, with assistance from Partners HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS) group. REDCap provides secure web-based applications with an intuitive user interface data and real time validation rules.

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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