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Protocol Form for Non-Exempt Research

Complete each question. If a question is not applicable, put N/A in the shaded text box.

1. GENERAL INFORMATION

☐ **Initial Submission**

☒ **Revised; HSL Protocol #:** 14-014 NCT02346136

Version Number & Date	**Version #: 9** **Date: 10/27/2017**
Principal Investigator	Lewis A. Lipsitz, MD and Peter Wayne, PhD
Protocol Title	Health Outcomes of Tai Chi in Senior Supportive Housing (Mi-WiSH Study Mind Body - Wellness in Supportive Housing Study)
Sponsor/Funding	National Institute of Aging

2. BACKGROUND

2.1 Background and rationale for research based on existing literature:

The rapid growth of the US population over age 80 that is expected to occur over the next 20 years will create enormous challenges to our health care system. Many of these elderly individuals will develop physical and cognitive disabilities that will make it difficult for them to live independently. Moreover, as a result of their medical needs, loss of income, and/or limited pensions, many will be poor and dependent on government support for their housing and health care needs. Currently, approximately 15% of seniors or 3.5 million people in the US live at or below the poverty level (Salkin). Many of these people are "dually-eligible" Medicare and Medicaid beneficiaries and live in Federal or State subsidized supportive housing facilities. Dually eligible beneficiaries are generally poor and frail with worse health status than other Medicare beneficiaries. They also tend to use more health care services, and account for a disproportionate share of Medicare spending, particularly for inpatient hospitalizations.1, 2 For example, dual eligible beneficiaries are 1.6 times more likely to be hospitalized than non dual eligible beneficiaries.[From Misha Segal, Policy Insight Brief, 9-2011]1, 3 Older adults living in public housing are twice as likely — 57.3 percent vs. 26.9 percent — to report fair or poor health compared to those with no public housing experience. (Ethnicity and Disease.)

Impact on scientific knowledge and clinical practice: Previous clinical trials have included highly selected populations of different ages, and interventions that have typically been limited to 12-24 weeks in duration and conducted in academic medical centers. Very few of these studies have involved poor, frail, and ethnically diverse elderly populations or employed long-term interventions based in community settings. Moreover, we are not aware of any studies that have directly evaluated impacts of Tai Chi on overall medical costs. The proposed study will determine whether Tai Chi is an effective and practical intervention to improve overall function and lower health care costs in an expensive, vulnerable population of seniors that is more representative of many US communities than those previously studied. If the results are favorable, our study will also provide the

necessary training and protocol manuals to replicate Tai Chi programs in senior housing facilities across the nation to help prevent, better manage, and overcome frailty among seniors.

Unlike several other practices that have beneficial effects on health and well-being, Tai Chi has several features that are particularly attractive in frail elderly populations and can improve compliance. First, previous studies, including our own, demonstrate that it is safe in patients with chronic disease. 8,45,53,57 The exercises can be tailored to the capabilities of the participant, yet still have beneficial effects. In addition, many studies report higher adherence to Tai Chi than the comparison group or conventional exercise. This is important, particularly when dealing with populations of patients with chronic disease who have difficulty engaging in and sustaining conventional exercise. The relaxing effects, social interactions, self-efficacy, and continually reinforcing physical and psychological benefits of Tai Chi are intrinsic features that will likely promote long-term adherence.65-67

It is often challenging to enroll sedentary older adults in exercise programs, especially those who are economically disadvantaged or not well educated. Moreover, once recruited, it requires concerted effort to maximize participation and retention rates in the program. This is especially the case for our Tai Chi trial, which includes a year-long intervention, making it the longest Tai Chi intervention investigated in the context of a clinical trial in the United States. Therefore, the goal for the new amendment is to document effective strategies for increasing activity levels among older adults with a sedentary lifestyle, as a means to reducing disability and improving overall health.

2.2 **Previous** (non-clinical, pre-clinical or clinical) **studies leading up to and supporting the proposed research:**

Given the large and growing problem of supporting the health and health care needs of frail seniors living in subsidized housing, it is particularly important to identify interventions that can combat frailty, improve residents' functional abilities, and ultimately reduce their health care costs. Tai Chi is a particularly promising intervention that has enormous promise for ameliorating many of the conditions that lead to poor health and excessive health care utilization. In our previous studies, we have shown that it can be practiced successfully and without adverse effects by frail seniors living in supportive housing facilities and can result in significant improvements in balance, gait, and functional ability after only 12 weeks. However, it remains to be determined whether a longer period of Tai Chi exercise can improve the health of poor, frail seniors and reduce their health care utilization and cost.

Tai Chi is a mind-body exercise that originated in China, and that is growing in popularity in the West. It is based on slow intentional flowing movements, often coordinated with breathing and imagery, that aims to strengthen, relax and integrate the physical body and mind, and according to traditional Chinese medicine, enhance the natural flow of 'qi' (or life energy), improve health, and personal development.1,2 Surveys suggest that approximately 5 million Americans have practiced Tai Chi, and this number is increasing.3,4 Because of its reputed health benefits, apparent safety, low cost, and growing popularity, Tai Chi has become an increasingly recognized preventative and rehabilitative modality. Studies have shown that Tai Chi exercise can improve a number of medical conditions, including CHF,5-10 hypertension,11-13 hyperlipidemia,11,14,15

coronary artery disease,16-21 COPD,22-25 cardiorespiratory fitness,26-34 poor balance,35-40 reduced musculoskeletal strength and flexibility,26,31,32,35,41-44 Parkinson's disease,45 rheumatological conditions,46-55 cognitive decline,56-62 and overall mood.63 Several Tai Chi review articles have been published.64

2.3 Describe why this research is important and how it will contribute to existing knowledge:

The proposed clinical trial will reinforce the concept that multi-system interventions are particularly beneficial in overcoming the chronic diseases and disabilities of older adults and will demonstrate the value of Tai Chi, as an effective, low cost, easily tolerated, universally available, yet currently underutilized intervention to improve the functional health of elderly people. The study will also help dispel the myth that aging is associated with an inevitable and irreversible functional decline, by demonstrating the ability of frail seniors to engage in and benefit from Tai Chi exercise.

Innovation: The proposed research is innovative, in our opinion, because: 1) it is based on a unique conceptual model derived from complex systems theory, 2) it engages a previously understudied, underserved, and expensive population in a unique academic-community partnership, and 3) it examines important economic and physiologic outcomes that have not been previously investigated, yet can lead to a better mechanistic understanding and downstream impact of our results.

Unlike previous studies, we will examine health care utilization and costs as outcomes of our Tai Chi intervention, in addition to traditional physiological and functional indicators of health. We will also examine novel measures of physiologic complexity of gait and balance developed to determine whether the effect of Tai Chi on overall functional ability is associated with improvements in the complex dynamics of these underlying control systems. Finally, we will determine features that will help us scale and sustain the program in the future – factors that influence compliance and ways to empower the community itself by training future Tai Chi trainers who work and live in the housing facilities we study.

Our results will add to the growing scientific literature to evaluate subjects' experiences in clinical trials/programs to inform facilitators and barriers to adherence, engagement, and program satisfaction, and the processes that mediate health behavior change.

3. STUDY LOCATION

3.1 Study Site(s):

The study will emanate from HSL-IFAR, and the study will take place in multiple senior supportive housing sites in Boston, Brookline, Somerville and Lynn. The Housing Authorities of three communities have provided letters of support, included in this application.

3.2 Principal Investigator's experience conducting research at study site(s), if outside of HSL facilities:

The Principal Investigator was the lead investigator for the MOBILIZE Boston Study, which recruited and followed longitudinally 765 volunteers over aged 70, who resided in the local communities, many of whom were residents of senior facilities in Brookline and elsewhere.

Dr. Lipsitz has also worked collaboratively with the co-investigators in the past and each has significant expertise to contribute to the success of the current protocol. Dr. Peter Wayne has lead many community Tai Chi Studies over the past several decades and collaborated previously with Dr. Lipsitz on a successful Tai Chi Intervention Study: The TEACH Study HSL IRB protocol 10-005

4 STUDY OBJECTIVES

Provide study objectives/aims/hypotheses:

Overall Aim: To conduct a cluster randomized controlled trial (RCT) of Tai Chi classes twice weekly (with interim video reinforcement), or health promotion educational classes and monthly social calls for 1 year in low-income elderly housing facilities in Brookline, Somerville, and Lynn Massachusetts.

Specific Aim 1: To determine the effects of the Tai Chi intervention on functional performance over a one-year period in poor, multiethnic, and functionally-limited elderly residents of low income housing facilities. To provide a similar level of attention and social engagement, the control group will participate in educational classes and monthly social calls. The primary functional outcome will be overall physical function as quantified by the Short Physical Performance Battery (SPPB). Secondary outcomes will include person-centered measures, including specific aspects of physical function, cognition, psychological well-being, falls, exercise self-efficacy, and satisfaction with the intervention. We hypothesize that participation in the Tai Chi classes will improve outcomes within each of these domains as compared to educational classes and monthly social calls.

Specific Aim 2: To determine the effects of the Tai Chi intervention on health care utilization and cost during the one-year periods during and following Tai Chi or educational classes in poor, multiethnic, elderly residents of subsidized housing facilities. The primary utilization outcomes will be emergency visits, hospitalizations, doctor visits, skilled nursing and nursing home admissions, and the total number of encounters. Cost outcomes will be total Medicare spending for hospital, emergency room, post-acute care, and physician or nurse office visits. We hypothesize that compared to the control intervention, the Tai Chi intervention will significantly reduce health care utilization and costs during the intervention period and one year afterward.

We will work within the ongoing Tai Chi clinical trial to address the following 2 aims:

Specific Aim 3: Determine demographic, social, psychological, and other factors that influence continuing participation in a year-long Tai Chi exercise intervention by residents of subsidized senior housing facilities in Boston through a series of focus groups for residents participating in and dropping out of the Tai Chi exercise program.

Specific Aim 4: Examine the predictors of long-term adherence to the Tai Chi exercise program by assessing the relationship between baseline demographic, health, functional, and psychosocial subject characteristics, which are being collected in the trial, with subsequent adherence to the intervention. We will quantify adherence by the number of Tai Chi sessions attended and will determine the characteristics of those most likely to complete the program.

5 STUDY DESIGN

5.1 Study design (e.g., double-blind, placebo-controlled, parallel design)**:**

We will address our aims by conducting a cluster randomized controlled trial (RCT) of twice weekly group Tai Chi exercise sessions plus self-practiced video-directed supplemental sessions vs. an organized healthy aging educational program plus monthly social telephone calls, in low income senior housing facilities located within three diverse communities surrounding Boston. This is a pragmatic trial, rather than a comparative effectiveness or mechanistic study, which aims to determine the functional and health care utilization outcomes of Tai Chi compared to one's customary daily practices, while controlling for attention through the educational sessions. The added focus group sessions and withdrawal interviews are designed as a qualitative and descriptive study.

5.2 Study duration (total)**:**

The study duration is expected to be 5 years in total.

A REVISED STUDY TIMELINE FOR COMPLETION OF FIELD ACTIVITIES AND DATA ANALYSIS IS ATTACHED.

5.3 Duration of study for participants:

Participants will be enrolled for about 26 months; The baseline assessment will occur within 4 weeks of the telephone screen; the study intervention of Tai Chi or health aging educational program sessions will last for 12 months; followed by a follow up assessment to occur within 4 weeks of completing the study intervention (a midpoint assessment will occur at 6 months from the start of the intervention). Participant visits will end at the follow up assessment, but Health Care Utilization data will be collected for the one year during the study intervention, and for one year following the completion of the intervention.

For each of the group (Tai Chi or health educational program), we will conduct three 30-45 min. focus groups, one within the first four months of the intervention, one within the second four months of the intervention, one within the last four months of the intervention.

For those who withdraw from the study, we will conduct individual interviews as close to the time of drop-out as possible.

6 PARTICIPANT SELECTION AND WITHDRAWAL

6.1 Source of study participants:

Participants will be individuals aged > or = 60, living in a participating senior housing site

6.2 Total target number of participants to be enrolled:

320

Facility/Institution	Unit (if applicable)	Number of Participants
Senior Supportive Housing in Boston, Brookline, Somerville and Lynn MA		Approximately 20 participants per site will be enrolled in 16 sites.

6.3 Inclusion criteria:

These include: living in low income senior housing facilities, age > or = 60, able to understand instructions in English, able to participate safely in Tai Chi exercises at least twice a week, expected to remain in the facility for 1 year,

Inclusion criteria for the focus group: any participant stays in the study.

Inclusion criteria for the withdrawal group: any participant drops off from the study.

6.4 Exclusion criteria:

Exclusion criteria will be: already participating in Tai Chi exercises, any unstable or terminal illness (e.g., unstable cardiovascular disease, active cancer, unstable COPD, advanced dementia, psychosis), inability to maintain posture sitting or standing, and the inability to hear, see, or understand Tai Chi instructions and assessment questions. We will briefly screen volunteers for their cognitive capacity over the telephone and accept those who can recall at least 2 of 3 words in 3 minutes, and 2 of 3 highlighted elements of the study protocol.

6.5 Participant recruitment (describe recruitment methods and submit any materials to be used to recruit participants)**:**

This study calls for recruiting 320 elderly individuals living in 16 subsidized senior housing facilities. The facility managers have all agreed to cooperate with this study, provide us with access to their residents, inform them about the study, and encourage participation. In addition, we will post information promoting the study, conduct public information sessions in each facility, place notices in all resident mailboxes and newsletters, and inform residents that they will be visited personally by research staff. We have contracted with the Center for Survey Research of the University of Massachusetts-Boston (CSR) to conduct door-to-door recruitment by having trained interviewers speak directly with potential study participants. CSR has experienced interviewers who are themselves older adults and can relate to and establish trust from older adult populations. Using similar door-to-door recruiting, CSR helped us recruit 765 seniors > 70 years of age from the local Boston metropolitan area for the MOBILIZE Boston study between 2006-2008.

Subjects will be recruited and studied in 2 waves. Recruitment will occur during the first 6 months of each wave. If a resident agrees to participate, the recruiter will conduct a brief screen for inclusion and exclusion criteria. If the volunteer passes the screen, their baseline assessment will be scheduled as soon as possible.

WE WILL INTRODUCE THE FOCUS GROUP DURING THE REGULAR SESSION FIRST. WE WILL THEN SEND OUT AN INTRODUCTORY MAIL FOLLOWED BY A PHONE INVITATION TO RECRUIT THE PARTICIPANTS.

FOR THOSE WITHDRAWAL FROM THE CLASS, WE WILL SEND OUT AN INTRODUCTORY MAIL FOLLOWED BY A PHONE INVITATION TO RECRUIT THE DROP-OUTS.

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RECRUITMENT FOR THE STUDY IS NOW DISCONTINUED, AS DETERMINED BY THE NIA, FOLLOWING THE DSMB MEETING AND FOLLOW UP DISCUSSIONS OF 10/25/17.

6.6 Procedures for obtaining informed consent, including who will obtain consent and the timing of consent from recruitment**:**

Informed consent will be obtained at the first study visit. The Project Director or Research Assistant will review the details of the study and will review the entire informed consent document with the participant, either by asking the participant to follow along as the document is read or by having the document read to them. After each section of the consent form, the participant will be asked if he/she has any questions. Once the staff is confident that the participant understands all aspects, the participant will be asked to sign the form and will be given a copy to keep. The participant will be given the contact information of the study team members and be encouraged to call at any time for any additional questions that may occur during the participant's participation in the trial. Informed consent will be obtained in a private place in the housing facility in which the potential participant resides, either their own apartment, or another identified private location within the facility.

The participant will be allowed to take as much time as they would like to decide about their participation in the study and may discuss the study with anyone that they wish before making a decision to participate. Only participants capable of providing individual consent will be enrolled in the study.

FOR THE FOCUS GROUP AND THE WITHDRAWAL GROUP, WE WILL RECEIVE THEIR VERBAL CONSENT.

6.7 Withdrawal of participants (anticipated circumstances when participants will be withdrawn without their consent, how participants will be withdrawn, including use of any collected data and follow-up with any new/pertinent information)**:**

The criteria for discontinuing a participant's participation include any Iife-threatening or potentially disabling event, including hemodynamic collapse, stroke, transient ischemic attack, dysrhythmia, renal insufficiency, angina, myocardial infarction, anaphylaxis, acute hemorrhage, or hospitalization for acute illness. If the participant recovers from a potentially serious event, he/she may re-enter the study if they are assessed safe to return. In this situation, we will ask the participant's primary MD to assess the participant's medical fitness to return to the study. To do this, we will send the attached letter to the participant's MD with the participant's permission, and request that the MD sign off that it is medically safe for the participant to resume their participation in the study.

PARTICIPANTS WHO HAVE BEEN ENROLLED IN WAVE 2, PAIR 3, WILL BE WITHDRAWN FROM THE STUDY, DUE TO THE DECISION OF THE NIA TO STOP THE TRIAL. THESE PARTICIPANTS HAVE COMPLETED A BASELINE ASSESSMENT BUT WERE NEVER ENROLLED IN THE STUDY INTERVENTION. A LETTER OF EXPLANATION TO BE SENT TO THESE PARTICIPANTS IS ATTACHED. FOR PARTICIPANTS ENROLLED IN WAVE 2, PAIRS 1 AND 2, IN WHICH THE INTERVENTIONS WERE UNDERWAY, THE INTERVENTIONS WILL BE STOPPED, AND PARTICIPANTS WILL RECEIVE A LETTER OF EXPLANATION, ATTACHED.

6.8 **If the participants may have diminished capacity to provide informed consent or to understand study procedures (now or in the foreseeable future),** describe additional safeguards to protect their rights and welfare, including how and when you will engage legally authorized representatives**:**

Only participants capable of providing individual consent will be enrolled in the study. To be sure the subject is capable of providing informed consent, we will briefly screen volunteers for their cognitive capacity before enrolling them and will accept those who can recall at least 2 of 3 words in 3 minutes and 2 of 3 key elements of the study protocol. for participants with little or no formal education we will read the informed consent form with a family member present if the participant wishes, and an appropriate witness (the housing sites have a care advisor/social services advisor on site who can serve as the witness) . For individuals with little or no formal education, we will ask participants to answer the following questions to assess their understanding and assure they are informed.

1. Can you tell me in your own words what this study is about, and what is involved if you participate? 2. Is the study voluntary or do you have to participate? If you choose to participate, do you have to stay in the study until it ends or can you withdraw whenever you would like or need to? 3. Are there any benefits to you for participating in the study? (If yes, can you explain the benefits?) Are there any risks to you for participating in the study? (If yes, can you explain the risks?) 4. Have you had enough time to make your decision to participate? 5. Do you have any questions about the study? 6. Please explain how you will contact the study staff if you have any questions or problems during the study.

6.9 **Will non-English speakers will be enrolled in the study?** ☐ **Yes** ☒ **No**

If yes, confirm what language will be used to consent prospective study participants. If the language used to consent is not the same language used by study participants or their legally authorized representatives, describe what methods and materials will be used to confirm their understanding of the study:

7 STUDY PROCEDURES

7.1 **Study visits including procedures/tests involved** (e.g., blood test, x-rays, questionnaires. If numerous study visits and procedures are involved, include a study procedure timeline)**:**

The participant's Housing Site will be assigned by random, such as the flip of a coin, to participate in either a Tai Chi or Health and Wellness Activity study group. The participant will be asked to take part in whatever group his/her housing site has been assigned. Participants in the Tai Chi Activity group will be asked to attend for one hour twice a week for twelve months, or a total of 96 classes. Participants in the Health and Wellness Activity group will be asked to attend for one hour, once a month for a total of 12 classes.

Study Groups: The Tai Chi study group will be led by a certified Tai Chi instructor. It will consist of warm-up exercises, stretches, and Tai Chi movements developed for use with older adults. The participant will be asked to attend all of the classes in the assigned study group over the one year period. He/She may also be asked to watch and follow along with a Tai Chi instructional video in his/her apartment at his/her convenience one or two times each week for 15-30 minutes. If he/she does not have a video player, one will be provided

to use during your study enrollment. The video will consist of warm-ups, seated stretches, and simplified Tai Chi movements. The participant will be asked to keep a log of practice dates and times and bring this to class with them for review with the instructor, and will be regularly collected. The Health and Wellness Activity study group will also be led by a trained instructor. Activities will include lectures and discussions on healthcare topics of interest to older adults. All sessions will take place in a common room of the housing facility. The instructors will have access to water for participants and a phone in case of emergency. PARTICIPANTS WHO ENROLLED IN WAVE 2, PAIR 3 WILL NOT TAKE PART IN EITHER OF THE STUDY INTERVENTIONS.

Assessments: Participants will be asked to complete an assessment described below on 3 separate occasions. The first assessment will occur before beginning the assigned activity group of either Tai Chi exercise sessions or Health and Wellness sessions, twice a week for one year. The second assessment will occur six months (+/- 3 weeks) after beginning the sessions and the third assessment will occur twelve months (+/- 3 weeks) after beginning the sessions. (Wave 2 , participants from Housing site pairs 1 and 2, participation will end following the second assessment at six months. These participants will not be asked to complete a third assessment at twelve months. This is due to the recent decision by the NIA and DSMB to stop the study intervention at this time. Only these Wave 2 site pairs will have reached the point of the six month assessment at the time that the study intervention is stopped.) It will take about two hours to complete each of these three assessments. A trained research assistant will carry out the assessments which will take place in the participant's apartment or a private place at the housing facility.

1. Health Interview - At each of the three assessments, the participant will be asked questions about his/her health, medications, history of falls, whether he/she has had any hospitalizations or emergency room visits. Height, weight, blood pressure and heart rate will be measured. Participants will be asked questions about daily activities, mood, sleep, memory and balance.

2. Balance and Walking Test - Participants will be asked to perform several activities such as walk a few yards, stand up from a chair, and stand with one foot beside or in front of the other. Participants will also be asked to walk at his/her own pace several times in a quiet hallway while a trained research assistant walks with him/her for safety. Participants will be asked to wear small wireless accelerometers, the size of a wristwatch (Mobility Labs™) to capture gait, walking and balance data. The monitors will be placed at the ankles and the waist, and attach quickly and easily like a wristwatch with a velcro strap. During one of the walking trials, the participant will be asked to count outloud while they are walking. Participants will be able to rest if needed during the test, and a chair will be available to sit down if he/she becomes tired. He/She will be asked to stand for one minute, up to six times. During two of the one minute stands the participant will be asked to count out loud. The wireless accelerometers will measure how much he/she sways as he/she are standing still. An experienced research assistant will be at his/her side at all times to ensure safety during all balance tests. Participants will be able to rest as needed.

3. Handgrip strength - Participants will be asked to squeeze a handgrip device with his/her dominant hand three times. Participants will rest between each trial. The handgrip device will measure strength in the handgrip and forearm.

Pilot Testing: Prior to the start of data collection at the housing sites, we will pilot test the above procedures, that is, the Health Interview, the Balance and Walking Tests, and the Handgrip strength test. The purpose of the pilot testing is to train and certify the Research Assistants in the study procedures, to assure inter-rater reliability among RAs, and initially to refine the order of the study procedures for maximum efficiency. We will ask up to 20 volunteers to complete the pilot testing each year as needed to recertify staff or train newly hired staff in the study procedures. Pilot study volunteers will not be potential study participants.

Monthly Phone Calls – A research assistant will call participants each month to check in with the particiant and to ask about any falls, hospitalizations or emergency room visits. If the participant has a fall at any time over the course of the year that he/she is participating in the study, he/she will be asked a few questions about the fall, such as where he/she was and what he/she was doing at the time of the fall. Health Care Service Utilization – Participants will be asked to provide his/her Medicare Unique Patient Identifier Number. In order to determine whether taking part in Tai Chi or Health and Wellness activities regularly for one year has any impact on needed health care services, such as doctor's visits, hospitalizations or emergency room visits, we will request permission to track the participant's Health Care Service Utilization encounters over the course of the year that he/she are taking part in his/her assigned activity group and for one year following the completion of his/her assigned activity group.

After the participants verbally consent to participate in the focus group, the focus group leader will use a discussion guide developed by the research team to explore how participants feel over these time periods, their motivation, social connections, sense of social support, satisfaction with the instructor, affect, and willingness to continue. For the drop-outs, the leader will also explore reasons for not participating. The discussion will be recorded and key themes will later be extracted using the qualitative procedure described below. These themes will be described in a publication and used to develop methods to promote adherence in future exercise interventions.

Through an iterative process, we will use the immersion/crystallization technique to analyze the transcripts for themes. After each group session, the leader will summarize their impressions of the discussion and its major themes. All of the investigators will review each of the transcripts independently and develop coding categories to describe important segments. We will not restrict categories to those targeted by the discussion guide; each reviewer will develop categories from the content of the transcripts. Second, we will hold a series of meetings to review each transcript together, discussing our different codes until we reach consensus. Finally, one investigator will review all coded segments, group them into themes, and identify quotations that illustrate the themes.

7.2 List procedures being performed as routine medical care (e.g. for diagnostic or treatment purposes):
None of the procedures described above are being performed as routine medical care.

7.3 List procedures being performed solely for the research:
All the procedures described in section 7.1 are being performed solely for the research.

7.4 Describe the methods used to protect participant privacy:
All study interviews will be conducted in a private space, either in the participant's apartment or a private area of the housing site.

8 STATISTICAL PLAN

8.1 Statistical methods:

Analysis for each Aim: Specific Aim 1: To determine the effects of the Tai Chi intervention on functional performance over a one-year period in poor, multiethnic, elderly residents of subsidized housing facilities. The primary functional outcome will be the Short Physical Performance Battery (SPPB) score. We will also examine the effects of Tai Chi on self-reported physical and mental health, gait and balance, falls, executive function, social engagement, overall activity level, and other patient-centered outcomes.

The effect of the Tai Chi intervention on functional performance as measured by SPPB will be estimated from a shared-baseline linear mixed model with fixed effects for age, follow-up time, age x time interaction, and treatment x time interaction and random effects of community, site within community, participant within site, community x treatment, community x time, community x treatment x time, site x time, and participant x time interactions. The shared baseline across treatment groups reflects homogeneity of the population with respect to treatment prior to random assignment and adjusts for effects of baseline level in a manner equivalent to ANCOVA. The random effects acknowledge the expected correlations among sites within a community, among participants within a site, and among repeated longitudinal assessments of each participant. This approach also naturally accommodates unequal enrollment across sites and loss to follow-up, even potentially informative loss to follow-up, if well predicted by the observed data on participants prior to drop-out. All participants will be included in the primary analysis according to their treatment assignment, following the intention-to-treat principle. Primary inference will be based on a two-tailed test at alpha = 0.023 of the fixed treatment x time interaction estimating Tai Chi-dependent improvement in rates of change in SPPB. An additional alpha = 0.002 is reserved for one interim analysis. The total two-tailed alpha = 0.025 for testing SPPB preserves an overall type I error rate of 0.05 for the functional and utilization primary aims.In addition to intention-to-treat analyses, we will perform secondary per-protocol analyses, defining participants in a tai chi group as 'per-protocol' if they attended ≥50% of tai chi classes averaged over the year-long intervention.

Secondary continuous outcomes will be analyzed using the same model. Counts of falls will be analyzed in a similar mixed effect negative binomial regression. Both nominal p-values and step-down Bonferroni-adjusted p-values will be calculated for analyses of secondary outcomes. Secondary analyses will consider effects of treatment dose based on attendance records. Given the possible influence of perceived treatment efficacy on adherence, which could bias the effect of adherence on Tai Chi efficacy, these analyses will be exploratory. Other secondary analyses will determine if Tai Chi is more effective or uniquely effective for specific subgroups of participants by including fixed effects for subgroup indicators and their interactions with treatment, time, and treatment x time.

Specific Aim 2: To determine the effects of the Tai Chi intervention on health care utilization and Medicare cost in poor, multiethnic, elderly residents of subsidized housing facilities. The primary outcome is health care utilization, which includes number of emergency department (ED) visits, hospitalizations, doctor visits, skilled nursing and nursing home admissions, and the total number of encounters. The secondary outcome is total Medicare spending. These will be measured using Medicare claims. The effect of the Tai Chi intervention on both outcomes will be estimated in generalized linear mixed models according to the nature of each outcome measure. For primary analysis, count data (e.g., number of ED visits, hospitalizations, etc.) will be modeled as over-dispersed Poisson or negative binomial distributed outcomes. For secondary outcomes, Medicare claims amounts will be winsorized at the 5th and 80th percentiles of each year's distribution of costs to avoid distortion of estimates by the highest (and lowest) cost patients. Cost data will be modeled as log-normal or gamma distributed. All models will include fixed effects of treatment group, time period (one year before, one year during, and one year after the intervention) and treatment x period interaction and random effects of community, site within community, and community x treatment interaction and their interactions with period to accommodate covariance among residents within a given facility or community. Models will include additional fixed effects of age, sex, race, primary language, income, education, BMI, and history of falls to adjust for known predictors of health care utilization and cost. Linear contrasts on the treatment x period terms will be used to test for Tai Chi-dependent change in annual per-person mean Medicare claim totals from the pre-intervention to the intervention or post-intervention period. Inference will be based on a two-tailed test at alpha = 0.023, reserving alpha = 0.002 for one interim analysis, as in the analysis for Aim 1. Persistence of such an effect will be tested in a similar linear contrast between the intervention and post-intervention periods. Secondary analyses will test the effects of adherence and differential effects among subgroups using similar approaches to those for Aim 1.

Interim analysis: One interim analysis for efficacy, futility, and sample size re-estimation is planned after all participants enrolled in wave 1 have completed their 12-month assessment (or dropped out). The study will be stopped for efficacy based on a two-sided Haybittle-Peto boundary at alpha = 0.002 for each co-primary outcome. A non-binding proposal to stop the study for futility will be based on a beta spending rule linear in information time, or beta = 0.10. The study will be stopped early for efficacy or futility only if both co-primary outcomes have demonstrated efficacy or futility. Observed drop-out and community-level, site-level, and participant-level variance components and their collective effect on the standard error of the treatment x time interaction term will be estimated. The benefit of increasing the number of sites or the number of participants per site will be considered based on the pre-specified minimum treatment effects of interest on SPPB and total health care utilization. Results of the efficacy and futility analysis will be shared only between an unblinded statistician and the DSMB. Estimates of the nuisance parameters and their effect on power for the pre-specified effect sizes will be shared with the study team given negligible risk of deducing the treatment effect and the importance of logistical constraints in planning any increase in sample size.

DURING THE CLOSED SESSION OF THE MOST RECENT DSMB MEETING ON OCTOBER 20, 2017, THE DSMB AND NIA PROJECT OFFICER REVIEWED THE STUDY REPORT, INCLUDING SAFETY DATA AND A PREPLANNED INTERIM ANALYSIS FOR THE PRIMARY

OUTCOME, SPPB - SHORT PHYSICAL PERFORMANCE BATTERY - USING 12 MONTH WAVE 1 DATA. RESULTS OF THE A PRIORI DEFINED INTERIM ANALYSIS INDICATED THAT THE PRESPECIFIED BOUNDARY FOR THE TRIAL CESSATION DUE TO FUTILITY WAS CROSSED. GIVEN THAT THE STOPPING RULE FOR FUTILITY WAS SATISFIED, THE DSMB RECOMMENDED DISCONTINUING THE MI-WISH TRIAL.

8.2 **Sample size determination** (include power calculations or provide justification for their absence, e.g., pilot/feasibility study)**:**

Sample Size Calculation and Justification: Power for the primary analysis of SPPB (Short Physical Performance Battery) can be estimated by extrapolating results from our preliminary study in similar housing facilities where the mean baseline SPPB score was 8 out of a total possible score of 12. In a mixed model ANCOVA of 3-month change in SPPB that included a site-level random effect of treatment, the standard error for the fixed effect of treatment was 0.268. Extrapolating from 3 months to 12 and from 2 sites to 16 (each study with 20 participants per site), the estimated standard error for a treatment effect on 12-month change in SPPB would be 0.268 x 12/3 x sqrt(2/16) = 0.379. Given that estimate, the current study would have 85% power to detect a 1.38 point difference in 12-month change in SPPB based on a two-tailed test at alpha = 0.023. Even with up to 20% loss to follow-up, the study will be well powered to detect treatment-dependent differences in 12-month change in SPPB of less than 2 points – a clinically meaningful difference.

Power for effects of Tai Chi on health care utilization can be estimated from data collected in the COLLAGE Project at Hebrew SeniorLife and Kendall Corporation. Based on 90-day retrospective self reports from 668 residents of 22 housing and low-income housing sites, the mean rate of physician visits, overnight hospitalizations, and ED visits was 2.2 total encounters per person with an over-dispersion coefficient of 1.9, combining excess variation due to both person-to-person and site-to-site variation in underlying service needs. Given these estimates, our study will have 80% power to detect a 27% reduction in total encounters over 90-days for a two-tailed test at alpha = 0.05. Extrapolating conservatively to a mean annual total encounter rate of 6 encounters / person-year, the study would have 80% power to detect a reduction of just one encounter per year, assuming no increase in over-dispersion for the full-year counts. Even if over-dispersion increases 50% due to non-independence of successive 90-day intervals, the study would still have 80% power to detect a 20% reduction in mean annual total encounter rate. Previous studies of Tai Chi have reported a 30% reduction in fall rates, as well as improvements in many of the chronic illnesses (COPD, CHF, depression) that precipitate emergency, hospital, and doctor's visits. While the minimum effects of Tai Chi on measures of health care utilization and cost that are detectable with high probability will be larger if we have under-estimated year-to-year or site-to-site variation, one goal of our interim analysis is to update our estimates of these nuisance parameters and re-calculate power.

Power for the secondary cost outcome can be estimated by a two-group t-test on year-to-year change in expenditures. Total Medicare expenditure data in 2011 from the Beacon Community Medicare Project, a national sample of communities of Medicare beneficiaries that is being evaluated by our Brandeis colleagues, had a person-level standard deviation (SD) after winsorizing at the 5th and 80th percentiles of $3,650. Year-over-year

correlations in physician visits, overnight hospitalizations, and ED visits, among the COLLAGE sample ranged from 0.32 to 0.51. Assuming a correlation of 0.40 between year-over-year expenditures, the effective SD for the year-to-year change would be $3,650 x (2 – 2 x 0.4) = $4,380 (we previously multiplied by 1 - 2 x 0. 2). From that estimate and an assumed intra-cluster correlation (ICC) of 0.05, we would have 80% power to detect a $2,352 reduction in total Medicare expenditures due to Tai Chi, based on a two-tailed test at alpha = 0.023 (to accommodate two interim analyses and two co-primary aims). This is a reasonable effect size given the positive effect of Tai Chi on health outcomes such as heart failure, COPD, falls, fractures, depression, and cognition. It represents a 26% reduction in total 2011 Medicare costs ($9,184) for people aged 65-90 with perceived health status of "fair" living in metropolitan statistical areas of the Northeast US (AHRQ Medical Expenditure Panel Survey (http://meps.ahrq.gov). The only previously reported reduction in costs due to Tai Chi was related to fall-related fractures, which averaged $1240/ person/year.

8.3 **Data management** (data collection and data entry)**:**

Data will be gathered at the housing facilities through self- and researcher-administered questionnaires, functional assessments (e.g., SPPB and Get-up-and-go tests), interactive computer programs (e.g., Trails and other cognitive tests), physiologic monitoring equipment (e.g., balance platform, gait mat, dynamometer, stadiometer), and downloaded computer files (e.g. Medicare claims). All primary study data will be recorded with computer tablets on electronic case report forms (CRF) or as digital files generated from laboratory equipment. Confidentiality will be maintained by recording subject data using a unique subject identifier. Identifiable data, such as contact information and medical record numbers, will be recorded and stored separately from the clinical study data. Any paper-based study material and any identifiable data will be kept separately in a locked file cabinet accessible by authorized study staff only. All electronic CRF data will be stored securely in an electronic data capture and management system. Raw electronic instrumentation data will be organized and saved on a private network file dedicated to the research project. All documents and electronic data will be archived for a minimum of three years, or as required by HSL IRB and federal regulations, after the completion of the clinical trial. The study will be registered at clinicaltrials.gov.

The Institute for Aging Research primarily employs the REDCap system to facilitate data managementoperations. REDCap is a full-featured clinical trials data management system (DMS) accessible to data entryand data analysis workstations using secure Web technologies. The REDCap product is developed and maintained by Vanderbilt University in cooperation with REDCap Consortium members including Hebrew SeniorLife. HSL hosts and maintains a dedicated instance of REDCap for use across our research enterprise.

Each research study is provided separate project workspace in which all of the study data are stored in a MySQL relational database on the private corporate network behind several firewalls and located physically within the HSL data center

9 FORESEEABLE RISKS, POTENTIAL BENEFITS, COMPENSATION AND COSTS TO PARTICIPANTS

9.1 **Potential medical risks of study procedures:**

There is a risk of feeling tired during the health interview, walking and balance or handgrip strength assessments. The participant will be given breaks and will be told he/she may

	also ask to take a break, or may stop at any time. There is a small risk of feeling dizzy when standing up from a chair during the assessment. If this occurs the participant may sit down again. A trained research assistant will be at the participant's side at all times during the assessments. The participant will be made aware that he/she can refuse to complete a specific assessment, or if he/she becomes uncomfortable during an assessment, he/she should let the research assistant know and he/she will be allowed to skip or stop the assessment. There is a risk of muscle fatigue or soreness from the Tai Chi exercises. This muscle soreness may last a few days. There is a small risk of a fall during the exercises. The Tai Chi groups will be limited to 20 persons and an experienced Tai Chi instructor will closely supervise each of the activities to minimize any risk of falling. Chairs are provided and participants will be encouraged to rest whenever needed.
9.2	**Psychosocial** (non-medical) **risks, discomforts, inconveniences:** None forseen
9.3	**Potential benefits to individual participant:** Individual participants may benefit from the proposed study by learning about and possibly improving their health and function with health promotion recommendations and Tai Chi exercises. Participants may also derive a sense of satisfaction and self-esteem from contributing to an increase in overall scientific knowledge of the benefits of Tai Chi exercise
9.4	**Potential benefits to study population, community, or society:** The proposed research is innovative, in our opinion, because: 1) it is based on a unique conceptual model derived from complex systems theory, 2) it engages a previously understudied, underserved, and expensive population in a unique academic-community partnership, and 3) it examines important physiologic and economic outcomes that have not been previously investigated, yet can lead to a better mechanistic understanding and downstream impact of our results.
9.5	**Describe provisions for medical care and available compensation in the event of injury, if any:** Any participant who develops adverse events during the conduct of study protocols will be given immediate medical care at their facility and, if indicated, emergency treatment according to the housing facility's emergency plan. The participant will be referred to their primary care physician for ongoing care. The Principal Investigator will be informed immediately of any adverse events that occur during the conduct of the study protocol. There is no compensation available in the event of an injury. Cost for care in the event of an injury may be billed to the participant's insurance company. We will try to have these costs paid for, but the participant may be responsible for some of them. For example, if the care is billed to the partcipant's insurer, he/she will be responsible for payment of any deductibles and co-payments required by the insurer.
9.6	**Remuneration for participants** (e.g. goods, services, gift cards, cash, etc.)**:** Participants will receive a check of $10 upon completion of the first assessment,, a second check of $10 when they have reached the 6 month timepoint of the intervention, and

another check of $10 when they have completed the third and final assessment. We will provide snacks after Tai Chi or educational sessions. Small tokens such as pens, pins, magnets, and water bottles with the study logo will also be given out to acknowledge progress and reward participation and adherence.

Participants in the focus group will receive a stipend of $15 per session so $45 for participating in three focus group sessions. Participants in the withdrawal group will receive a stipend of $15 for taking part in the individual interview. The stipend will arrive in the form of a check within 3-6 weeks following the completion of each session.

9.7 Describe any costs participants may incur during the study:
There will be no costs to participate in the study.

10 SAFETY ASSESSMENT AND STUDY MONITORING

10.1 Definitions of adverse event and serious adverse event for the study:
An adverse event (AE) is any untoward medical occurrence in a participant, whether or not is is causally related to the study. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom or disease temporally associated with the study. Adverse events will be recorded on the appropriate case report forms and source documents. The investigator and/or trained staff member will evaluate all adverse events as to their severity and relation to the test article. The severity of adverse events will be graded as follows:

Mild: Awareness of a sign or symptom but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient.

Moderate: Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities, but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning.

Severe: Events interrupt the participant's normal daily activities and generally require systemic drug therapy or other treatment, they usually are incapacitating.

Life Threatening: The participant was at immediate risk of death from the AE as it occurred.

Expectedness: ADs must be assessed as to whether they were expected to occur or unexpected, meaning not anticipated based on current knowledge found in the protocol. Categories are:

- Unexpected - nature or severity of the event is not consistent with information about the condition under study or intervention in the protocol or consent form.
- Expected - event is known to be associated with the intervention or the condition under study.

The Investigator will also assess the relationship of any adverse event to study, based upon available information, using the following guidelines:

- Definitely Related: The adverse event is clearly related to the investigational procedure - i.e. an event that follows a reasonable temporal sequence from

administration of the study intervention, follows a known or expected response pattern to the suspected intervention, that is confirmed by improvement or stopping and reappearance of the event on repeated exposure and that could not be reasonably explained by the known characteristics of the subject's clinical state.

- Possibly Related: An adverse event that follows a reasonable temporal sequence from administration of the study intervention follows a known or expected response pattern to the suspected intervention, but that could readily have been produced by a number of other factors.
- Not Related: The adverse event is clearly not related to the investigational agent/procedure - i.e. another cause of the event is most plausible; and/or a clinically plausible temporal sequence is inconsistent with the onset of the event and the study intervention and/or a causal relationship is considered biologically plausible.

A serious adverse event is any experience that results in any of the following outcomes:

• death,

• is life threatening,

• inpatient hospitalization or prolongation of hospitalization,

• a persistent or significant disability/incapacity.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the patient or participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

10.2 Adverse event (AE) reporting (method, distribution and time frame)**:**
Adverse events will be reported to the Hebrew SeniorLife Institutional Review Board (IRB) and the NIA according to established guidelines. All serious adverse events (SAEs) will be reported promptly to the Safety Monitoring Board and the IRB, in accordance with IRB requirements.

When SAE's occur that are unanticipated they will be reported to the NIA Program Administrator and to the DSMB Chair or designated DSMB member within 48 hours of the study's knowledge of the SAE. A death would be reported expeditiously, within 24 hours of the study's knowledge. A summary of all other SAE's will be reported to the NIA Program administrator and the DSMB quarterly, unless otherwise requested by the DSMB.

Any participant who develops adverse events during the conduct of study protocols will be given immediate medical care at their facility and, if indicated, emergency treatment according to the housing facility's emergency plan. The participant will be referred to their primary care physician for ongoing care. The Principal Investigator will be informed immediately of any adverse events that occur during the conduct of the study protocol.

10.3 Process for data and safety monitoring:

Safety monitoring procedures will be implemented and reviewed by a Data Safety Monitoring Board (DSMB), in accordance with NIA safety policies for human intervention studies. The criteria for discontinuing a participant's participation include the participant's request, as well as any Iife-threatening or potentially disabling event, including syncope, an injurious non-accidental fall, hemodynamic collapse, stroke, transient ischemic attack, dysrhythmia, renal insufficiency, angina, myocardial infarction, anaphylaxis, acute hemorrhage, or hospitalization for acute illness. These adverse events will be recorded and included in the database. If the participant recovers from a potentially serious event, he/she may re-enter the study if they are assessed safe to return. In this situation, we will ask the participant's primary MD to assess the participant's medical fitness to return to the study. To do this, we will send the attached letter to the participant's MD, with the participant's permission and request that the participant's MD sign off that it is medically safe for the participant to resume their participation in the study. If a determination about continued participation cannot be made according to these criteria, the adverse event report will be faxed to the chair of the Data Safety Monitoring Board who will make a decision with members of the Board.

A DSMB will be established for this project. This will consist of nationally recognized experts in geriatric medicine, biostatistics, senior housing, and clinical research. The chairperson will be an individual who is readily accessible for consultation in the local area. At the first meeting of the DSMB, members will review the study protocol and safety-monitoring plan.

Prior to the start of the study the DSMB will review the IRB approved protocol and procedure manual, with regard to participant safety, recruitment, randomization, intervention, data management, quality control, and the informed consent document. The Board will recommend any necessary changes of the protocol to the PIs and will review and approve revisions. The Board will identify relevant data parameters and the format of the information to be regularly reported.

The Board will then meet biannually to review standardized reports. They will review the progress of recruitment and retention of participants, compliance with the protocol, and operating procedures. If they raise concerns about safety issues, they may request additional data and propose specific analyses. They will make recommendations to the PI regarding recruitment, retention, compliance, and safety issues, and will send a written report to the Program Administrator following each meeting. The DSMB will be sent reports of research activity and summaries of safety monitoring information before each meeting.

10.4 If this is a multi-site study, indicate how modifications of study procedures or materials will be communicated across sites, as well as communication of adverse events, or other issues affecting the research:
This is not a multi-site study.

11 DATA HANDLING AND RECORD KEEPING (FOR BOTH PAPER AND ELECTRONIC DATA)

Confidentiality of Data:

a. Identifiers to be stored with data:
Age, sex, Medicare Unique Patient Identifier number, BMI, medical conditions, measures of physical and cognitive function, falls, gait speed.

b. If codes are to be assigned in the place of participant identifiers, storage location of key/links to codes:
All data collected for analysis will be de-identified and labeled with participant numbers, which are assigned to the participants once they have enrolled into the study. Any identifiable information collected on paper, such as screening information and the consent form, will be stored in locked drawers.

c. Study data storage location:
Data will be stored at Hebrew SeniorLife, IFAR, in a locked storage cabinet to which only the site Principal Investigator, Dr. Lipsitz and the study coordinator have the key. Nobody other than the PI and study staff designated by the PI will have access to these drawers

d. Data Security Measures:
All de-identified electronic files are stored on password-protected, encrypted computers at Hebrew SeniorLife with access limited to the PI and designated study staff. All data will be accessible only by a password-protected server using the participant number. A separate electronic file will contain the code linking the participant number to their identifiable information.

e. Individuals who will have access to identifiable data, or key/link to codes:
Only the PI and/or designated study staff will have access to identifiable data.

f. Timing of destruction of materials containing identifiers and keys/links to codes:
The current HSL Record Management, Retention, Disposition and Destruction Guidelines will be followed for this study. Current guidelines are for records to be retained for at least 3 years following completion of the study.

g. Method for destroying materials with identifiers and keys/links to codes:
Will follow HSL/IFAR standard protocol for research document disposal. Materials with identifiers are placed in the locked boxes. HSL subcontracts with Iron Mountain Secure Shredding which is AAA certified by the National Association for Information Destruction

11.1 List source of data (e.g., hospital records, clinical and office charts, checklists, pharmacy dispensing records, etc)**:**
Self report questionnaires, physical performance data, Falls record data, class attendance data, Medicare claims, will be recorded directly to a secure de-identifed data file.

11.2 Record retention (e.g. where and for how long after study completion; for guidance, please see HSL's Record Retention Policy)**:**
The current HSL Record Management, Retention, Disposition and Destruction Guidelines will be followed for this study. Current guidelines are for records to be retained for at least 3 years following completion of the study.

12 SENDING/RECEIVING SPECIMENS/DATA TO/FROM RESEARCH COLLABORATORS

12.1 Specimens/data to be sent and/or received:

Password protected and encrypted electronic data files will be sent/received for 1) Medicare claims from Dr. Cindy Thomas at Brandeis University to Dr. Lipsitz in IFAR using secure web-based data transfer software available at HSL and 2) password protected and encrypted electronic data files will be sent from Dr. Lipsitz in IFAR using secure web-based data transfer software to Dr. Eric Macklin at MGH. Dr. Macklin will guide and conduct statistical analyses.

12.2 Who will send and/or receive data:

Drs Cindy Thomas will send Medicare claims data to Dr. Lipsitz to connect with subject materials on file at HSL, and Dr. Eric Macklin will receive data files for statistical analysis.

12.3 How will specimens/data be transported:

Data will be transported via password protected and encrypted elctronic data files using secure web-based data transfer software.

12.4 Do you expect to use data or specimens collected as part of this research for other, future research projects? ☒ **Yes** ☐ **No**

If yes, be sure to include authorization for future use in the consent form.

13 DISSEMINATION OF RESULTS

13.1 Publication plan (if not addressed in a separate agreement):

This study will be registered at Clinical Trails.gov. Following its completion, we will publish our results in peer-reviewed medical research journals and prepare a detailed Training and Protocol Manual on how to implement the Tai Chi intervention in senior housing facilities. This will be made available for free on the National Council on Aging website for other institutions seeking to replicate our Intervention.

13.2 Plan to share individual and/or aggregate results with participants (e.g., results letter)**:**

Participants will receive newsletters about aggregate results at certain milestones, for example, once data collection is completed, or when results are published.

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15 ATTACHMENTS (RECRUITMENT & CONSENT MATERIALS, SURVEYS, INTERVIEW QUESTIONS, ETC)