DUHS INSTITUTIONAL REVIEW BOARD NOTIFICATION OF AMENDMENT APPROVAL

Protocol ID: Pro00110021
Reference ID: Pro00110021-AMD-4.0
Principal Investigator: Lee, Richard
Protocol Title: Evaluate the feasibility and acceptability of current Vivo prototype in sedentary older adults with prediabetes.
Sponsor/Funding Source(s): National Institutes of Health (NIH)
Federal Funding Agency ID: R44-AG076087-01
Date of Declared Concordance with federally funded grant, if applicable:

The Duke University Health System Institutional Review Board for Clinical Investigations has conducted the following activity on the study cited above:
Activity: Amendment **Review Type:** Expedited
Review Date: 08/26/2022
Issue Date: 08/26/2022
Expiration Date: 04/22/2024

DUHS IRB approval encompasses the following specific components of the study:
Protocol, version/date:
DUHS IRB Application version: 1.8
Consent form reference date: 08/26/2022
Investigator Brochure, version/date:
Pediatric Risk Category:
Other: Functional Assessment Form Vivo; Recruitment Email; Not a Candidate message; MyChart message to interested people; Updated module training for Liz (Chmelo) Kemp

The DUHS IRB has determined the specific components above to be in compliance with all applicable Health Insurance Portability and Accountability Act ("HIPAA") regulations.

This study expires at 12 AM on the Expiration Date cited above. At that time, all study activity must cease. If you wish to continue specific study activities directly related to subject safety, you must immediately contact the Executive Director of the DUHS IRB or if urgent, call the IRB's main number 919-668-5111, then follow paging instructions to reach the IRB Chair on call. Continuing review submissions (renewals) must be received by the DUHS IRB office 60 to 45 days prior to the Expiration Date.

No change to the protocol, consent form or other approved document may be implemented without first obtaining IRB approval for the change. Any proposed change must be submitted as an amendment. If necessary in a life-threatening situation, where time does not permit your prior consultation with the IRB, you may act contrary to the protocol if the action is in the best interest of the subject. You must notify the IRB of your action within five (5) working days of the event.

The Duke University Health System Institutional Review Board for Clinical Investigations (DUHS IRB), is duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human research protocols. The DUHS IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the DUHS IRB complies with 45CFR46, 21CFR50, 21CFR56, 21CFR312, 21CFR812, and 45CFR164.508-514. In addition, the DUHS IRB complies with the Guidelines of the International Conference on Harmonization to the extent required by the U. S. Food and Drug Administration.

DUHS Institutional Review Board
2424 Erwin Rd | Durham, NC | 919.668.5111
Federalwide Assurance No: FWA 00009025Suite 405 |

DUHS IRB Application (Version 1.8)

General Information

***Please enter the full title of your protocol:**

Evaluate the feasibility and acceptability of current Vivo prototype in sedentary older adults with prediabetes.

***Please enter the Short Title you would like to use to reference the study:**

Vivo SBIR
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

Add Study Organization(s):

List Study Organizations associated with this protocol:

Primary Dept?	Department Name
◉	**DUHS** - Center for Study of Aging
○	**DUHS** - Medicine - Geriatrics
○	**DUHS** - Medicine-Endocrinology and Metabolism

Assign key study personnel (KSP) access to the protocol

*** Please add a Principal Investigator for the study:**

(Note: Before this study application can be submitted, the PI MUST have completed CITI training)

Lee, Richard

3.1 If applicable, please select the Key Study personnel: (Note: Before this study application can be submitted, all Key Personnel MUST have completed CITI training)
*** Denotes roles that are not recognized in OnCore. Please select an appropriate role that is recognized in all clinical research applications (iRIS, OnCore, eREG, etc.)**

A) Additional Investigators, Primary Study Coordinator (CRC), and the Primary Regulatory Coordinator (PRC):

King, Alyssa
Primary Study Coordinator (CRC/CRNC/RPL)

B) All Other Key Personnel

Boucher, Nathan
Collaborator*

Hecker, Emily
Regulatory Coordinator
Parrish, Lori
Other*
Rincker, Jamie
Other*
Starr, Kathryn, Ph.D.
Sub-Investigator

***Please add a Study Contact:**

Hecker, Emily
Lee, Richard
Starr, Kathryn, Ph.D.

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g., The study contact(s) are typically the Principal Investigator, Study Coordinator, and Regulatory Coordinator.)

Oncore

Please select the Library for your Protocol:

This field is used in OnCore. Determines the Reference Lists, Forms, Protocol Annotations, Notifications, and Signoffs available for the protocol. Protocols that require reporting to the NCI (National Cancer Institute), must select the Oncology library.

- ○ Oncology
- ◉ Non-Oncology

Protocol Application Type

Select the type of protocol you are creating:

Please see additional criteria and information in the policy titled "Reliance on the IRB of Another Institution, Organization, or an Independent IRB" on the **IRB web site**.

- ◉ Regular Study Application - Most common. The IRB will determine if the study is eligible for expedited review or requires full board review upon submission.
- ○ Application for Exemption from IRB Review - Includes Exempt, Not Human Subject Research, & Not Research.
- ○ External IRB Application - Any study using an external IRB as the IRB-of-Record.
- ○ Trainee Research While Away from Duke - Research conducted by medical students overseen by the Office of Curriculum & other student/trainee research away from Duke.
- ○ Individual Patient Expanded Access, Including Emergency Use - Use of an investigational product under expanded access, including emergency use of an investigational drug or biologic or emergency use of an unapproved device.

Conflict of Interest

Are any key personnel an inventor of any of the drugs, devices or technologies used in this research?

○ Yes ◉ No

Do any key personnel have a conflict of interest management plan issued by DOSI-COI related to this research?

(•) Yes ( ) No

Please give the name(s) of the relevant personnel. Please ensure the relationship is disclosed in the consent form before submitting the protocol.

Kathryn Starr

Oversight Organization Selection

CRU (Clinical Research Unit) or Oversight Organization Selection:

Please select the CRU.

Medicine

The Clinical Research Unit that takes responsibility for this study.

- Please select **Medicine** as the CRU **only** if the PI is in one of these Divisions or Institutes: Endocrinology, Gastroenterology, General Internal Medicine, Geriatrics, Hematology, Infectious Diseases, Nephrology, Pulmonary, Rheumatology & Immunology, Center for Applied Genomics and Precision Medicine, Center for the Study of Aging and Human Development, Duke Molecular Physiology Institute.
- More information on CRUs can be found on the Duke Office of Clinical Research (DOCR) website, **http://docr.som.duke.edu**
- Questions concerning CRU selection should be directed to docr.help@dm.duke.edu.
- For questions about the Campus Oversight Organization, please visit **Campus Oversight Organization**.

List all Key Personnel on the study who are outside Duke:

- **Note:** You will also need to attach the documentation of Human Subjects Certification for each individual, if they have completed the certification somewhere other than Duke.
- **If outside key personnel will have access to Duke PHI, a data transfer agreement AND external site IRB approval (or IRB authorization agreement) will be needed.** See HRPP policy **Use of Research Data by Former Duke Students or Former Duke Faculty and Employees**
- In the panel below, "PHI" is Protected Health Information.

Entry 1

Name	Eric Levitan
Study Role	SBIR Grant PI at Vivo
Email Address	eric@teamvivo.com
Institution / Organization	Vivo
Will he/she have access to Duke P.H.I.?	(•) Yes ( ) No
Is he/she an unpaid volunteer at Duke on the study?	( ) Yes (•) No

Entry 2

Name	Liz (Chmelo) Kemp
Study Role	Research Director at Vivo
Email Address	liz@teamvivo.com
Institution / Organization	Vivo
Will he/she have access to Duke P.H.I.?	(•) Yes ( ) No
Is he/she an unpaid volunteer at Duke on the study?	( ) Yes (•) No

Indicate the Protocol source below:

The protocol source is the author of the protocol. If the protocol is a joint authorship between multiple sources, select the primary author.

An IRB fee may be assessed for all research that is supported by for-profit entities and requires full board review. For additional information, see the **IRB fees section of the IRB web site**

- (•) PI initiated
- ( ) Commercial / Industry (for-profit entity) initiated
- ( ) Federal Government initiated
- ( ) Cooperative Group Initiated
- ( ) Foundation (non-profit group) initiated
- ( ) Other

Sponsor and Funding Source

Add all funding sources for this study:

View Details	Sponsor Name	Sponsor Type	Contract Type:	Project Number	Award Number
⊟	National Institutes of Health (NIH)	Externally Peer-Reviewed	Subcontract		

Sponsor Name:	National Institutes of Health (NIH)
Sponsor Type:	Externally Peer-Reviewed
Sponsor Role:	Funding
Grant/Contract Number:	R44-AG076087-01
Project Period:	From:01/01/2022 to:12/31/2024
Is Institution the Primary Grant Holder:	No
if No, then who is the Primary Grantee?	Vivo
Contract Type:	Subcontract
Project Number:	
Award Number:	
Grant Title:	
PI Name: (If PI is not the same as identified on the study.)	

Explain Any Significant Discrepancy:	

Is this a federally funded study?

(•) Yes ( ) No

Does this study have any of the following?

- Industry sponsored protocol
- Industry funded Duke protocol
- Industry funded sub-contract from another institution
- Industry provided drug/device/biologic
- SBIR/STTR funded protocol

(•) Yes ( ) No

This study will require ORC review to ensure correct injury language is added to consent forms. Have you already received an email from ORC containing the appropriate language?

( ) Yes
(•) No
( ) Not Applicable

ORC Language Pending
You can continue completing the applicaton and submit it for review. You will need to incorporate the changes and upload the ORC or ORA email later via a Modification/Stipulation request. If you have any questions about this process, you can contact your ORC or ORA Agreement Manager.

As part of this study, will any samples or PHI be transferred to/from Duke to/from anyone other than the Sponsor, a Sponsor subcontractor, or a Funding Source?

( ) Yes (•) No

Is the Department of Defense (DOD) a funding source?

( ) Yes (•) No

For Federally funded studies:

Is your funding subject to, and does it comply with, the funding agency's policy for data sharing?

(•) Yes ( ) No

Check all that apply:

- [ ] NIH Genome Sharing - dbGaP
- [ ] NIH Genome Sharing - GWAS
- [ ] NIH Genome Sharing - NCI databases
- [ ] NIH Genome Sharing - other
- [ ] Non-NIH Genomic
- [x] General Data Sharing

Enter the Grant Number or Other Federal Agency Proposal or Application Number:

R44-AG076087-01

Note: The Federal Funding Agency ID Number is the Sponsor's grant number assigned to your project and available on your Notice of Award (example: R01HL012345).

If known, enter the SPS (Sponsored Projects System) number if applicable:

26622

In the Initial Submission Packet, attach the following:
(1) The entire grant, or an explanation of why a grant is not needed.
(2) NIH institutional Certificate form related to data sharing (if applicable).

Have you successfully synced your protocol to OnCore by clicking the 'Sync Data Over API' button at the top of this page?

Please verify that the protocol has been created in OnCore before submitting this application for PI Signoff.

- (●) Yes, I synced my protocol to OnCore and verified it was successfully sent by logging into OnCore.
- ( ) I may have forgotten! I'll click it again right now, just to be sure, and verify it was successfully sent by logging into OnCore.

Mobile Devices and Software

Does this study involve the use of a software or a mobile application?

(●) Yes ( ) No

Please describe the following:

- The developer of the mobile app and how the app will be obtained.
- What PHI will be collected via the app.
- Where the data will be stored and who will have access to it.

Vivo: Vivo, based in Atlanta, GA, is a technology platform that uses Zoom to support the premiere live and interactive online strength training program designed specifically for adults 55 and older. Vivo's corporate headquarters are at 4551 Stella Dr, Atlanta, GA 30327. Vivo makes use of the Microsoft 365 cloud platform to provide the infrastructure to manage a remotely distributed workforce. Vivo trainers and staff are currently across the country in Georgia, South Carolina, North Carolina, New Jersey and California, and have the ability to be anywhere across the globe.

Research Electronic Data Capture (REDCap) system (Vanderbilt/NIH)
All participant data will be archived in a REDCap database. REDCap offers a mobile app; however, the mobile app will not be used for this study.

List all software, including third party (non-Duke) and mobile apps, that will be utilized for ascertainment, recruitment, or conduct of the research/project: (eg, MaestroCare, DEDUCE):

MaestroCare will be used for ascertainment and recruitment
Zoom will be used for conduct of the research project (see above)
REDCap will be used for storage of participant data (see above)
Duke Box will be used for storage of study documents

Multi-site Research

Is this a multi-site study?

○ Yes ◉ No

Complete for each site if Duke is the Primary grant awardee or coordinating center:

Entry 1

Site Name:	
City:	
State/Province:	
Country:	
	Site Contact Information
Primary Contact Name:	
Primary Contact Phone:	
Primary Contact Email:	
	Site Details
Does the site have an IRB?	○ Yes ○ No
Site IRB approval expiration date:	
If date not provided, explanation of why:	
Has the site granted permission for the research to be conducted?	○ Yes ○ No
Does the site plan to rely on the DUHS IRB for review?	○ Yes ○ No
What is the status of the study at this site?	○ Open ○ Closed
Site approval letters or site personnel lists:	Attach site approval letters, site closure letterS (if applicable), or site personnel lists in the Initial Submission Packet.

Research Abstract

Please type your Research Abstract here:

The Research Abstract should summarize the main points of your study in one paragraph. The following guidelines may help you:

1. Purpose and objective (1-2 sentences)
2. Study activities and population group (2-4 sentences)
3. Data analysis and risk/safety issues (1-2 sentences)

Aim: Evaluate the acceptability, feasibility, and fidelity of current Vivo prototype in sedentary older adults with prediabetes

This will be a 12-week single arm feasibility study using the currently available Vivo prototype. After informed consent and baseline assessments, 24 individuals will be enrolled in cohorts of 5-6 people. Each cohort will meet virtually twice a week with their small group and certified trainer for 45 minutes.

Participants will be men and women, ≥60 years old, sedentary, with prediabetes and low function. All participants will complete a pre- and post-intervention virtual physical function assessment, 3-day food record, height, weight, waist circumference, and social support, self-efficacy, and psychosocial functioning questionnaires. At 12-weeks, semi-structured interviews will be conducted to assess acceptability, usability and satisfaction.

In this single-arm feasibility study with pre- and post assessment (baseline and 12 weeks) we will use descriptive statistics to summarize the distribution of the covariates and dependent variables, and student t-tests to compare pre- and post-outcomes. These analyses are designed to support the feasibility of executing the fully powered randomized trial in Phase II. Table 2 summarizes all outcome measures. Qualitative interviews will be used to explore concepts related to barriers, acceptability, and retention of the health behaviors.

Research Summary

State your primary study objectives

Evaluate the acceptability, feasibility, and fidelity of current Vivo prototype in sedentary older adults with prediabetes.

State your secondary study objectives

Access feasibility of intervention delivery.

Please select your research summary form:

Standard Research Summary Template

This is the regular (generic) research summary template which is required for all regular applications (unless your protocol fits under the other research summary templates in this category). Use of these instructions is helpful for ensuring that the research summary contains all necessary elements.

Standard Research Summary

Purpose of the Study

- Objectives & hypotheses to be tested

Evaluate the acceptability, feasibility, and fidelity of current Vivo prototype in sedentary older adults with prediabetes
1: Assess a) attendance, benefits and barriers/facilitators of participation; b) ease of use; and c) overall satisfaction.
2: Assess trainer fidelity.

Background & Significance

- Should support the scientific aims of the research

Most older adults experience a 30% loss in muscle mass between ages 50–70, resulting in increased risk of injury and even death, all of which can be prevented and managed with improved resistance training. Sarcopenia is the progressive loss of muscle mass and strength that is inevitable with aging; however, resistance training is the most effective strategy for improving both muscle mass and function and managing sarcopenia.1,2 With age, lean muscle mass naturally declines from about 50% of total body weight in
young adults to about 25% at 75–80 yrs.3 The progressive deterioration of muscle quantity and quality leads to slower movement, a decline in strength and power, and increased risk for falls.3 Every 11 seconds, an older adult is treated for a fall in the emergency room; every 19 minutes, an older adult dies from a fall.4

Because age-related muscle loss is reversible, a technology platform designed to support and guide users through resistance training represents a novel product despite the crowded digital fitness market. Decades of research have shown that resistance training is a feasible and effective modality to improve physical function, muscle quality (mass and strength), insulin sensitivity, cognitive function, quality of life and well-being, reduce the risk for falls, and prolong independent living and aging in place.5-7 Resistance training is highly effective in reversing age-related muscle loss in older adults with and without comorbidities. Studies of resistance training recommend that it is characterized by periodization and progression, i.e., 1) tailored to the individual, 2) regular periods of work that include multiple sets of multi-joint exercises for each major muscle group at intensities of 70-85% of 1 rep maximum, and 3) done at least twice a week.8 Despite the well-established benefits of resistance training, most older adults don't meet this exercise threshold: only 19.3% of adults aged 65-74, and <15% of older adults aged ≥75 report meeting the federal guideline of
performing moderate/high intensity muscle strengthening involving all major muscle groups on ≥2 days per week.9

Why don't older adults participate in strength training exercise? Older adults report not participating in resistance training due to lack of age appropriate programs, fear of a gym setting, poor access to a gym, joint and other kinds of pain, and lack of social support.10 These barriers have been compounded as a result of COVID-19, wherein older adults are encouraged to socially isolate, leading to even less physical activity.
Especially relevant today during the Covid pandemic, population-based studies show that socially isolated and lonely older adults have a 59% higher risk of physical and mental health decline.11 Vivo addresses these major barriers to carrying out strength training with the social support and ease of use factors leading to our product's popularity during the pandemic last year (The New York Times, December 14, 2020).12 Vivo trainers deliver strength training instruction and coaching through an interactive online training session incorporating social support and social engagement. Vivo is a monthly membership based online resistance training program where small groups (families, friends, couples) work with a trainer for 45 minutes 2-3 times/week on building strength, flexibility, balance, and cognitive skills. Typically, there is a maximum of 6 participants per group. Classes are structured and designed to measure progress and provide custom feedback to all users.

Other than the live classroom experience via Zoom the current Vivo prototype does not have interactive dashboard capability. Feedback about performance and resistance training outcomes are all recorded manually and discussed over Zoom with the trainer at each session. To date since the onset of the pandemic in March 2020, 92 people have participated in Vivo (age range 44-93). We conduct baseline and 8-week functional assessments on all participants. Even with the technological limitations we found excellent proof of concept in our small pilot study of 34 older adults (74% women; mean age 70.9 y; range 60-84y) after 8 weeks of participating in Vivo with a certified trainer (average of 12 hours of training per person). We observed:
• +25.8% improvement in upper body strength as measured by the 30 second arm curl test
• +25.9% improvement in lower body strength as measured by the 30 second chair stand test
• +28% improvement in endurance as measured by the 2-minute knee raise test

Design & Procedures

- Describe the study, providing detail regarding the study intervention (drug, device, physical procedures, manipulation of the subject or the subject's environment, etc.). Discuss justifications for placebo control, discontinuation or delay of standard therapies, and washout periods if applicable. Identify procedures, tests and interventions performed exclusively for research purposes or more

frequently than standard of care. Include alternative therapies, concurrent therapies discontinued per protocol, risk benefit ratio, and use of tissue/specimens. Discuss monitoring during washout periods if applicable. Include brief description of follow-up, if any.

This will be a 12-week single arm feasibility study using the currently available Vivo prototype to assess 1) adherence and retention, 2) acceptability and satisfaction with Vivo, 3) technology useability (i.e., Zoom, email), and 4) change in physical function in sedentary older adults with prediabetes and lower function.

Remote Consent: The study informational session is done one-on-one via a scheduled ZOOM meeting appointment with study staff. The secured REDCap platform will be used to obtain the participants' electronic consent (eConsent).

After informed consent and baseline assessments, 30 individuals will be enrolled in cohorts of 5-6 people.

Physical Function, Activity, and Diet Outcomes (baseline and week 12)	
Physical measurements	Height, weight, and waist circumference
30-second chair stands to quantify lower body strength	Number of full stands that can be completed in 30 seconds with arms folded across chest
Short Physical Performance Battery to quantify balance, lower extremity strength	Balance (side-by-side, semi-tandem, tandem), strength (time to complete 5 chair stands).
Gait speed tests	Number of seconds required to walk 4 meters
2-minute step test to measure aerobic endurance	Number of full steps completed in 2 minutes, raising each knee to a point midway between the patella (kneecap) and iliac crest (top hip bone)
8-ft Up and Go to assess agility/dynamic balance	Number of seconds required to get up from a seated position, walk 8 feet (2.44 m), turn, and return to seated position
30-second arm curl to quantify upper body strength	Number of arm curls completed in 30 seconds
Social Support and Self-efficacy	
Social Support	Perceived social support: "The people I spend most of my time with now encourage me in physical fitness activities" using a rating scale 1: strongly disagree and 5: strongly agree Social Support within Vivo: "I have received support and encouragement from other [Vivo] participants to continue participating in this program?" 5-point scale of agreement
Self-efficacy	Five item question to determine beliefs in capability when faced with potential barriers, "Over the next three months, I am confident I can attend Vivo when … (I am tired, in a bad mood, feel I don't have time, am on vacation, it's raining or snowing) with a 7-point scale of agreement[40]
Psychosocial Functioning	

Quality of Life; Mood; Depression; Stress, and satisfaction with life	Short Form Health Survey 36 (SF-36),Profile of mood state (POMS), Center for Epidemiologic Studies Depression Scale (CES-D), Perceived Stress Scale (PSS), Satisfaction with Life (SWL)

Each participant will receive a welcome kit that includes resistance bands to use during class along with written instructions about the assessments, and a tape measure.

Each cohort will meet virtually twice a week with their small group and certified trainer for 45 minutes.

All participants will complete a pre- and post-intervention virtual physical function assessment, 3-day food record, height, weight, waist circumference, and social support, self-efficacy, and psychosocial functioning questionnaires.
At 12-weeks, semi-structured interviews will be conducted to assess acceptability, usability and satisfaction.

Selection of Subjects

- List inclusion/exclusion criteria and how subjects will be identified.

Inclusion Criteria
• Age ≥ 60 years;
• Diagnosis of Pre-diabetes within prior 12 months: fasting glucose between 100 to 126 OR HbA1c between 5.7 and 6.4%
• Ambulatory and community-dwelling
• Sedentary: less than 150 minutes of moderate physical activity OR less than 60 minutes of vigorous physical activity per week
• Have not engaged in resistance training for at least 6 months prior to enrollment
• Low functioning (defined as able to do at least 1 chair stand without using hand in 30 second but unable to meet the moderate function criteria for age and gender)
• Access to WiFi in defined exercise space
• Willing to maintain weight and current diet throughout the study

Exclusion Criteria
• Inability to complete physical function assessment or inability to do a chair stand without using hands.
• Use of antidiabetic medications
• Use of testosterone supplement or replacement
• Clinical disorder precluding/interfering with participation or assessments
o Unstable angina, arrhythmia, uncontrolled hypertension
o End Stage Renal Disease on Hemodialysis
o Lower extremity amputation or paralysis
o Neurological conditions causing functional or pronounced cognitive impairments
o Active malignancy except for non-melanomatous skin cancers
• Unable to provide consent
• Weight instability (defined as gain or loss of ≥10% body mass over the last 6 months)

Subject Recruitment and Compensation

- Describe recruitment procedures, including who will introduce the study to potential subjects. Describe how you will ensure that subject selection is equitable and all relevant demographic groups have access to study participation (per 45 CFR 46.111(a) (3)). Include information about approximately how many DUHS subjects will be recruited. If subjects are to be compensated, provide specific prorated amounts to be provided for expenses such as travel and/or lost wages, and/or for inducement to participate.

Participants will be recruited from outpatient Geriatrics, Endocrinology and Primary Care clinics serving Duke Health using Duke Office of Clinical Research, Research Innovation Center, Maestro Care recruitment tool, and from the Duke Health and Exercise Research Registry.

We will use the Duke Office of Clinical Research, Research Innovation Center, Maestro Care recruitment tool to identify potentially eligible patients in Duke Health geriatric medicine, endocrinology and primary care clinics. Using the Maestro Care electronic medical record, we will identify and invite older patients with prediabetes to be a part of our study. For any subject for which the study team and associates

do not have an established prior relationship, the patient's research contact preference will be noted and no contact will be made with those individuals with an opt-out status. Finally, we will check against the "banner" in MaestroCare to verify whether or not the patient has opted out for being contacted.

Clinicians in the geriatric medicine and primary care clinics may also refer potential subjects.

In addition, we will use the Duke Health and Exercise Research Registry.
The Duke Health and Exercise Research Registry was developed in April 2019 and is a registry of persons interested in exercise-related research studies. There are 4035 persons registered with a signed consent, contact information, and health information available for screening. Of these 4035, there are 600+ individuals who are ≥60 years; there are an additional 716 individuals with missing age, that would be included on the study invitation list, which would include over 1000 person's total.

We will recruit 30 sedentary adult men and women ages ≥60 including ~30% non-white participants.

Participants will receive $30 after the initial assessment and another $50 after the endpoint assessment and semi-structured interview.

Consent Process

- Complete the consent section in the iRIS Submission Form.

Subject's Capacity to Give Legally Effective Consent

- If subjects who do not have the capacity to give legally effective consent are included, describe how diminished capacity will be assessed. Will a periodic reassessment occur? If so, when? Will the subject be consented if the decisional capacity improves?

Only subjects able to give legally effective consent will be enrolled.

Study Interventions

- If not already presented in #4 above, describe study-related treatment or use of an investigational drug or biologic (with dosages), or device, or use of another form of intervention (i.e., either physical procedures or manipulation of the subject or the subject's environment) for research purposes.

Risk/Benefit Assessment

- Include a thorough description of how risks and discomforts will be minimized (per 45 CFR 46.111(a) (1 and 2)). Consider physical, psychological, legal, economic and social risks as applicable. If vulnerable populations are to be included (such as children, pregnant women, prisoners or cognitively impaired adults), what special precautions will be used to minimize risks to these subjects? Also identify what available alternatives the person has if he/she chooses not to participate in the study. Describe the possible benefits to the subject. What is the importance of the knowledge expected to result from the research?

There is minimal risk to the participants. Exercise testing and training is used extensively for research and clinical purposes with minimal risk to participants. the Vivo program is led by certified trainers and carefully designed to ensure maximum safety. Participants will be instructed to only do the activities they feel comfortable doing and will asked to provide their rate of perceived exertion multiple times throughout the

exercise class to allow for close monitoring. The minimal risk to human participants in this study is greatly outweighed by potential health benefits that may accrue participants and by the importance of the scientific knowledge that may reasonable be expected to result from this work.

Costs to the Subject

- Describe and justify any costs that the subject will incur as a result of participation; ordinarily, subjects should not be expected to pay for research without receiving direct benefit.

There will be no additional costs to the subjects.

Data Analysis & Statistical Considerations

- Describe endpoints and power calculations. Provide a detailed description of how study data will be analyzed, including statistical methods used, and how ineligible subjects will be handled and which subjects will be included for analysis. Include planned sample size justification. Provide estimated time to target accrual and accrual rate. Describe interim analysis including plans to stop accrual during monitoring. Phase I studies, include dose escalation schema and criteria for dose escalation with definition of MTD and DLT.

A) Qualitative - To explore concepts related to a complex process (barriers, acceptability, and retention of a health behavior) the team will employ a qualitative analytical approach. Drs. Boucher and Starr will use applied thematic analysis, organizing the data in response to the a priori questions contained in the semi-structured interviews and interview guides.46 Audio recordings will be transcribed verbatim following a transcription protocol.47 Boucher and Starr will use NVivo 12 software to develop and apply structural (a priori) codes to segment participants' narratives into conceptual categories (e.g., all text describing a similar concept, such as psychosocial factors).48 Next, analysts will identify and apply content-driven (emergent) codes to the text for each of the conceptual categories (e.g., potential themes related to psychosocial factors). Inter-coder reliability assessments will be conducted on approximately 25% of transcripts during both structural and content coding. Discrepancies in coding will be resolved through analyst discussions; transcripts will be re-coded, and the codebook revised accordingly. Once coding is complete, we will examine code frequencies across transcripts to identify salient factors for each interview, followed by comparing and contrasting factors between interviews. The team will complete analytical memos describing the factors influencing success in adherence, usefulness and impact of Vivo on function and QOL, together with illustrative quotes for each.

B) Quantitative - In this single-arm feasibility study with pre- and post-assessment (baseline and 12 weeks) we will use descriptive statistics to summarize the distribution of the covariates and dependent variables, and student t-tests to compare pre- and post-outcomes. These analyses are designed to support the feasibility of executing the fully powered randomized trial in Phase II.
Primary outcome will be number of full stands that can be completed in 30 seconds with arms folded across chest. The 30-second has excellent test-retest reliability (r = 89, 95% CI = 0.79-0.93) and criterion validity compared to weight adjusted leg press (r = 0.77, 95% CI = 0.64-0.85). Additional outcomes include Balance component of the SPPB; 2-minute step test for aerobic endurance; 8-ft Timed Up and Go; 3-day food records; Waist Circumference; Perceived social support and Self-efficacy;
Quality of Life Short Form Health Survey 36 (SF-36); Profile of mood state (POMS); Center for Epidemiologic Studies Depression
Scale (CES-D); Perceived Stress Scale (PSS); Satisfaction with Life scale (SWL).

Data & Safety Monitoring

- Summarize safety concerns, and describe the methods to monitor research subjects and their data to ensure their safety, including who will monitor the data, and the frequency of such monitoring. If a data monitoring committee will be used, describe its operation, including stopping rules and frequency of review, and if it is independent of the sponsor (per 45 CFR 46.111(a) (6)).

The study is carefully designed for safety. Our study staff is carefully trained and has the expertise to safely conduct physical function measures. Furthermore, the study physician, Dr. Richard Lee, will always

be "on page"; he will be available as needed for consultation regarding medical concerns related to study participation. Information provided to the participants at the beginning of the study will include a listing of warning signs with instructions should injury or other health problems occur. Participants will be provided contact information for Dr. Starr and all study team members and encouraged to communicate with them about any concerns regarding the assessment measures, Vivo strength training session, or any other aspects of the study. All reported events will be recorded in the adverse event log (including the subject's name, date, and event description) and the PIs, study physician, co-investigators, and study staff will be notified. All health occurrences will be recorded and regularly reviewed by the study staff and reported to Duke IRB according to IRB guidelines.

Privacy, Data Storage & Confidentiality

- Complete the Privacy and Confidentiality section of the iRIS submission form.

Describe Role of External Personnel:

Both at Vivo, Eric Levitan is MPI of the SBIR grant and Liz Kemp is Director of Research.

We will share functional, interview, and survey data with Vivo to correlate with information regarding exercise participation at Vivo (the study intervention), per data sharing agreement in research contract. Additionally, we will share name, phone number and email address to allow them to schedule the participants to participate in the 12-week virtual strength training program that Vivo will be implementing.

Eric Levitan and Liz Kemp will not have access to PHI until a fully executed agreement is in place.

Study Scope

Does this study have a cancer focus? Cancer focus includes studies that enroll >50% oncology or malignant hematology patients; or, preventing, detecting, and diagnosing cancer or understanding the impact of cancer on patients and their caretakers.

○ Yes ◉ No

Are you using a drug, biologic, food, or dietary supplement in this study?

○ Yes ◉ No

Are you using a medical device, an algorithm (whether computer based or not), an in vitro diagnostic test, or using samples to look for biomarkers in this study?

○ Yes ◉ No

Does this study employ magnetic resonance, including imaging (MRI), spectroscopy (MRS), angiography (MRA) or elastography (MRE) beyond the standard of care?

○ Yes ◉ No

Does this study specify or require the performance of diagnostic procedures using ionizing radiation (x-rays, DEXA, CT scans, nuclear medicine scans, etc.) that are beyond the standard of care?

○ Yes ◉ No

Does this study specify or require the performance of therapeutic procedures using ionizing radiation

(accelerator, brachytherapy or systemic radionuclide therapy) that are beyond the standard of care?

○ Yes ◉ No

Does this study specify or require the use of a laser system for diagnosis or therapy that is beyond the standard of care (excludes the use of lasers as a standard surgical instrument)?

○ Yes ◉ No

Will the participant be subjected to increased or decreased ambient pressure?

○ Yes ◉ No

Do you plan to recruit subjects from Duke Regional Hospital (DRH)?

○ Yes ◉ No

Do you plan to recruit subjects from Duke Raleigh Hospital (DRAH)?

○ Yes ◉ No

Are you using the Duke logo in any advertisements?

○ Yes ◉ No

Is this study retrospective, prospective, or both?

"Retrospective" means that data or samples already in existence (collected prior to the study submission) will be used.
"Prospective" means there will be data or samples collected in this study for research purposes.

○ Retrospective
◉ Prospective
○ Retrospective and Prospective

If the study is both retrospective and prospective: Is this a review solely of information collected for non-research purposes (i.e. a review of medical records)?

○ Yes ○ No

Does this protocol include any research using botulinum toxin, including the FDA-approved clinical product (Botox)?

○ Yes ◉ No

Does this protocol involve the administration of any of the following materials to humans?

•Any viral vector or plasmid
•Any cells that have been modified by a viral vector
•Any other genetically-modified cells
•Any genetically-modified virus, bacterium, or other agent
•Any other recombinant or synthetic nucleic acid

○ Yes ◉ No

Subject Population Groups and Enrollment

Population Groups (Select targeted population groups only):

- [x] Adults
- [ ] Minors who are Wards of State
- [ ] Minors
- [ ] Duke Patients
- [ ] Pregnant Women
- [ ] Fetuses
- [ ] Prisoners
- [ ] Adults incapable of giving consent
- [ ] Adults with diminished capacity
- [ ] Handicapped subjects
- [ ] Students
- [ ] Employees
- [ ] Healthy Controls
- [ ] Deceased subjects
- [ ] Blanket Protocol

Please select any population groups excluded from participation in this study:

- [x] Pregnant women

Will you administer a pregnancy test to eligible female subjects prior to the start of study activities?

- ( ) Yes
- (•) No

Please explain:

Subject age criterion > 60 years

Maximum number of subjects to be consented at Duke:

Enter a single number. If you anticipate consenting a range of subjects, enter the **upper** limit of the range. The number should represent the maximum number of subjects for the life of the study.

34

Maximum number of subjects to be consented at all sites:

Enter a single number. If you anticipate consenting a range of subjects, enter the **upper** limit of the range. The number should represent the maximum number of subjects for the life of the study.

34

Subject Procedures and Costs

Biobank - Does this study involve the collection, use, tracking, banking (storage) or distribution of human biological specimens?

Human biological specimens include blood or its components, healthy or diseased tissue, bodily fluids, DNA /RNA or human stem cells.

- ( ) Yes
- (•) No

Procedures

Check all that apply:

- [ ] Genetic Testing
- [ ] Gene Transfer
- [ ] DNA Banking
- [ ] Testing for Reportable Infectious Diseases
- [ ] Human Cell Banking
- [ ] *Use of Human Embryonic Stem Cells
- [ ] *Use of Human-induced Pluripotent Stem Cells
- [ ] *Use of Other Cells Derived from Human Embryos
- [ ] *Use of Human/Animal Chimeric Cells
- [ ] *Specialized Cell Populations for Cell Therapy
- [ ] Use of Human Tissue
- [ ] Use of Bodily Fluids
- [ ] Use of Blood (or its components)
- [x] Not Applicable

Will blood be drawn in this study for research purposes?

○ Yes ◉ No

Will the Operating Room be used in this study?

Include only research time, not clinical care time.

○ Yes ◉ No

Will there be extra costs to subjects or insurance as a result of the research (e.g. tests, hospitalization)?

○ Yes ◉ No

Will there be Subject Compensation?

◉ Yes ○ No

Compensation for Travel / Lost Income (in USD):

80

Other Subject Compensation:

participants will receive $30 after the initial assessment and another $50 after the endpoint assessment and semi-structured interview.

Subject Recruitment Materials

For each document to be reviewed, use the table below to provide the following information:

Attach a copy of each advertisement that you will be using with this study in the Initial Submission Packet. If any Ad will have multiple wording variations, attach a copy of each version of the Ad.
All materials that will be used to advertise the study in order to recruit subjects must be approved by the IRB.

Types of subject recruitment materials include, but are not limited to, the following:

Direct Advertising
Posters
Billboards
Flyers
Brochures

Media Advertising
Newspaper Ads
Magazine Ads
Radio Ads
TV commericals / Video
Internet website
Social Media

Other Types of Advertising
Newsletter
Email
Postcards / Letters

(Note: Doctor-to-Doctor letters do not require IRB approval)

Document name	Material category	Location material displayed	Has this material previously been approved by the IRB?
MyChart Invitation_Pro00110021_Starr_PI_Clean Copy_5-31-22	○ Billboard / Flyer / Poster ○ Brochure ○ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ◉ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. MaestroCare MyChart invitation to be sent to potential participants	○ Yes ◉ No
		Please be specific.	

Telephone Script for Pre-Screen - Vivo Phase 1_6.24.22	○ Billboard / Flyer / Poster ○ Brochure ○ Internet website / Email ○ Letter / Postcard ◉ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. To be used to introduce the study to potential participants over the phone	○ Yes ◉ No
Feasibility and Acceptability of Vivo Phone Screen_6.22.22	○ Billboard / Flyer / Poster ○ Brochure ○ Internet website / Email ○ Letter / Postcard ◉ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. To be used with the telephone script to assess eligibility of potential participants	○ Yes ◉ No
	○ Billboard / Flyer / Poster	Please be specific. For example, "Duke" would not be an appropriate location.	

Vivo Prediabetes Consent Presentation	○ Brochure ○ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ◉ Other	"Duke Hospital Television" would be an appropriate response. Power Point presentation to be used in conjunction with e-consent to explain the study details to potential participants	○ Yes ◉ No
Vivo_Pro00110021_MyChart_message_to_interested_people_8.19.2022	○ Billboard / Flyer / Poster ○ Brochure ◉ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. MyChart message to people who express interest in the study.	○ Yes ◉ No
	○ Billboard / Flyer / Poster ○ Brochure ◉ Internet website / Email ○ Letter / Postcard	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an	

Vivo_Pro00110021_Not_a_Candidate_8.19.2022	○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	appropriate response. Message to be used in Maestro Care to respond to interested individuals who do not qualify.	○ Yes ◉ No
Vivo_Pro00110021_Recruitment_email_8.19.2022	○ Billboard / Flyer / Poster ○ Brochure ◉ Internet website / Email ○ Letter / Postcard ○ Phonescript ○ Radio ○ Television / Video ○ Newsletter / Newspaper / Magazine ○ Other	Please be specific. For example, "Duke" would not be an appropriate location. "Duke Hospital Television" would be an appropriate response. Recruitment email to send to potential candidates who do not open the MyChart invitation.	○ Yes ◉ No

Consent Process

Attach draft consent forms in the Initial Review Submission Packet.

Consent forms must be MS Word documents and follow the specific format outlined by the IRB. **Click here** to download a copy of the consent form template.

Note: Please do not edit the section of the footer that contains the Protocol ID, Continuing Review and Reference Date fields. Those fields will be used to stamp the final consent form when it is approved by the IRB. If you want to add an internal version date, please put it in the header.

Who will conduct the consent process with prospective participants?

Give the person's role in this study (PI, Study Coordinator, etc.):

Study PI and/or Research Coordinator

Who will provide consent or permission?

(Select all that apply):

- [x] Participant
- [ ] Parent(s) or Legal Guardian(s)
- [ ] Legally Authorized Representative (LAR)

How much time will the prospective participant (or legally authorized representative) have between being approached about participating in the study and needing to decide whether or not to participate?

If you are not giving the person overnight to consider whether or not to participate, please justify.

At the virtual consent visit, the study team member will explain the study and be present to answer any questions participants may have. Participants will then be provided as much time as necessary to review the consent form. If requested, the screening visit can be rescheduled to provide potential participants additional time to review the consent form before signing electronically using Redcap.

Where will the consent process occur?

Participants will be consented virtually via Zoom or Webex and will sign the consent form electronically using Redcap.

What steps will be taken in that location to protect the privacy of the prospective participant?

A Zoom room will be created for each participant for the consent process with access limited to study staff and potential participant, using secure Zoom features.

How much time will be allocated for conducting the initial consent discussion, including presenting the information in the consent document and answering questions, with each prospective participant?

Subjects will be given as much time as needed to review the consent form and to have all study related questions answered prior to the subject signing consent.

What arrangements will be in place for answering participant questions before and after the consent is signed?

Staff who are delegated to the consenting process will be knowledgeable as to study activities and general questions. If questions are unable to be answered by the staff member, the Principal Investigator is available by phone to answer any additional questions. The study doctor is also available by phone or page to answer any questions brought up by the subject both before and after the consent process

Describe the steps taken to minimize the possibility of coercion or undue influence.

It will be made clear that participation in the research study is completely voluntary. Their decision not to participate will not affect their care in Duke University Health System. They can stop participation any time.

What provisions will be in place to obtain consent from participants who do not read, are blind or who do not read/understand English?

Subjects who are unable to read/understand English will be excluded from this study.

Do you plan to obtain written consent for the conduct of research?

(●) Yes ( ) No

Protected Health Information (PHI)

Indicate how you intend to use potential subjects' Protected Health Information (PHI):

( ) I will review, but not record, PHI prior to consent.
(●) I will record PHI prior to consent.
( ) I do not intend to use PHI prior to consent.
( ) I will record PHI without consent. (decedent research, database repository, chart review)

Request for Waiver or Alteration of Consent and/or HIPAA Authorization

Will the population include deceased individuals?

( ) Yes (●) No

This waiver request applies to the following research activity or activities:

☑ Scheduling of research activities in MaestroCare and/or the recording of PHI via telephone for screening purposes prior to obtaining written consent for the research. Scheduling of research activities in MaestroCare and/or the recording of PHI via telephone for screening purposes prior to obtaining written consent for the research.
☑ Ascertainment (identification, selection) and/or recruitment of potential subjects while recording identifiable private information, such as protected health information (PHI), prior to obtaining the subject's consent.
☐ Conduct of the research project without obtaining verbal or written consent and authorization.

Note: Answer the questions below as they pertain solely to PHI collected prior to consent.

Provide the following information:

List the elements of informed consent and/or HIPAA authorization for which waiver or alteration is requested:

- Provide the rationale for each.

We request waiver of all elements of informed consent and HIPAA to identify and ascertain eligibility for potential subjects, and to record PHI via telephone for screening purposes prior to obtaining written consent for the research.

List the specific protected health information (PHI) to be collected and its source(s):

- (Note: PHI = health information + identifiers)

For identification and ascertainment, we will record the following PHI: name, MRN, medical diagnoses (e.g. prediabetes, diabetes), medications, laboratories (e.g. HbA1c), phone number, email address. This information will be obtained from the Maestro Care recruitment report.

For potential candidates who are contacted by phone for screening purposes, we will record the following PHI, obtained directly from the individual: date of phone screen, name, phone number, mailing address, email address, demographics (sex, date of birth, age, height, weight), medical and exercise history, current symptoms, internet access, and availability of transportation. Details are included in the attached document "Feasiblity_and_Acceptability_of_Vivo_Phone_Screen_6.22.22".

Criteria for Waiver: The DUHS IRB may waive the requirement for informed consent and authorization if all of the following criteria are met:

- Please respond to each item in the space below using protocol-specific language to provide justification:

a) The research or clinical investigation involves no more than minimal risk to subjects:

Reviewing PHI prior to consenting involves minimal risk to the subjects. There is a possible risk of loss of confidentiality. Every effort will be made to protect the confidential information.

b) The waiver or alteration will not adversely affect the rights and welfare of the subjects. Include a description of any measures to be taken to ensure that the rights and welfare of subjects will be protected:

This waiver will not adversely affect the rights and welfare of subjects because all the information collected will be safely secured in a locked cabinet or password protected database accessible only to study staff, and all PHI data of subjects not qualifying for the study or choosing not to participate will be destroyed at the end of the recruitment period.
PHI will not be released to anyone outside of the research study without the written consent of the participant.

c) Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

N/A, if subject chooses not to participate and subsequently consent to the study, all PHI data of the potential subject will be destroyed at the end of the recruitment period.

d) If this research activity relates to research involving deception, explain how subjects will be provided with additional pertinent information after study participation and what information will be provided. Otherwise indicate "not applicable":

N/A

e) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements (e1. and e2.)

Demonstrate that the use or disclosure of PHI involves no more than minimal risk to the privacy of subjects by describing the plans requested below:

**e1) An adequate plan to protect the identifiers from improper use and disclosure.
Describe the plan (how protection will be accomplished) and indicate where the PHI will be stored and who will have access:**

PHI will be stored in a folder in Duke Box accessible only to study staff.

e2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Describe the plan (how and when identifiers will be destroyed and by whom). If there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, provide the reason to retain identifiers:

For individuals who decline or do not qualify for the study based on information provided before informed consent is obtained, all personally-identifiable PHI in the screening log will be shredded/destroyed and the individual's names and contact information will be removed from our subject database. PHI for individuals who do not qualify or who do not consent to participate will be destroyed at the end of the recruitment period. For individuals who do qualify for the study, we will obtain written consent to use their PHI.

e3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity except (i) as required by law, (ii) for authorized oversight of the research study, or (iii) for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule. By electronically signing this submission, the PI provides this written assurance:

By electronically signing this submission, the PI provides this written assurance

f) The research could not practicably be conducted or carried out without the waiver or alteration:

- Explain why informed consent/authorization can not be obtained from subjects.

In order to help in recruitment for this study and to lessen burden on potential study participants, the ability to record PHI for screening purposes prior to obtaining written consent for the research is being requested. Without the waiver, study team would need to require participants (many of which are unlikely to be local), to consent leading to inefficient study conduct and unnecessary burden for potential research participants.

g) The research could not practicably be conducted or carried out without access to and use of the protected health information:

The research could not be practicably conducted without access to and use of the PHI because eligibility criteria include the presence or absence of certain medical conditions identified in the medical history and on laboratory data.

h) For research using biospecimens or identifiable information, the research could not practicably be carried out without access to and use of the protected health information:

The research could not be practicably conducted without access to and use of the PHI because eligibility criteria include the presence or absence of certain medical conditions identified in the medical history and on laboratory data.

Waiver of Documentation of Consent and HIPAA Authorization for Scheduling in MaestroCare and/or the recording of PHI via telephone for screening purposes:

These research activities prior to obtaining written consent for the study presents no more than minimal risk of harm to subjects:

- (●) True
- ( ) False

These are procedures for which written consent is normally not required outside of the research context:

- (●) True
- ( ) False

An IRB-approved phone script will be used to obtain verbal consent from subjects for scheduling and/or screening prior to obtaining written consent for the study:

- (●) True
- ( ) False

Privacy and Confidentiality

Explain how you will ensure that the subject's privacy will be protected:

Consider privacy interests regarding time and place where subjects provide information, the nature of the information they provide, and the type of experience they will be asked to participate in during the research.

Consent and personal conversations will occur in a Zoom room with access limited to study participant and study team, using secure features.

Describe how research data will be stored and secured to ensure confidentiality:

How will the research records and data be protected against inappropriate use or disclosure, or malicious or accidental loss or destruction? Records and data include, for example, informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheets, screening logs or telephone eligibility sheets, web based information gathering tools, audio/video/photo recordings of subjects, labeled specimens, data about subjects, and subject identifiers such as social security number.

At each level of data management and for each subject contact, strict adherence to Duke and NIH polices will be observed regarding HIPAA, IRB, and other Duke patient quality controls. These procedures will

protect the identity of all patients and providers as pertains to any reports generated from this study. Study records will be kept confidential as required by law. For records disclosed outside of Duke, a unique code number will be assigned. The key to the code will be kept in a password-protected file on a Duke secure network. Information collected about participants for this research study will be kept in a research study record separate from their medical record. Any significant findings developed during the course of this research, which may bear upon the subject's condition or willingness to continue participation in the study, will be provided to them and their primary physician. The study results will be retained in research records indefinitely after the study is completed. All specimens collected will be labeled with the unique identifying code number and cannot be traced back to the subject's identity except by the study staff with access to the code key. All data values electronic and hand entered data will be captured and managed using RedCap (Research Electronic Data Capture). The database will have internal validation and will be checked for data integrity and quality. All computer files will be password protected and the database will be de-identified. Identifying information will be viewed and managed only by the trained study staff. Files containing names and addresses will have a separate password, will be accessible only to personnel who need to contact the subjects, and will be stored separately. All entered data will be reviewed for missing responses, accuracy of entry, and inconsistencies.

Application Questions Complete

Please click Save & Continue to proceed to the Initial Submission Packet.

The Initial Submission Packet is a short form filled out after the protocol application has been completed. This is an area to attach protocol-related documents, consent forms, and review the application.