NCT05568511

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position:_____

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the title of this research study (this "Research Study")?

Home-based digital exercise training program to improve physical function of older sepsis survivors - HEAL Sepsis Trial

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Principal Investigator:	Stephen Anton, Ph.D.	352-273-7514
Other research staff:	Study Coordinator	352-273-9212

4. Who is paying for this Research Study?

The sponsor of this study is the National Institute of Health.

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research? How long will you be involved?

The purpose of the study is to test the safety and feasibility of implementing a 12-week physical activity using an app-based exercise intervention program. We would like to test if following the exercise intervention remotely will improve physical function in sepsis survivors. Participation in the study could potentially take up to 15 weeks including an initial screening visit at the home/hospital, a home/hospital visit, baseline and 12- week follow-up visits via Zoom. Additionally, we will do follow-up weekly calls with you and might make additional visits to your home in case of arising issues that cannot be solved via phone/Zoom call.

b) What is involved with your participation, and what are the procedures to be followed in the research?

There will be two in-person visits including the screening visit at home (or at the hospital) and a home/hospital visit. If you are discharged outside our team members' shift hours, you might be asked to return for a short physical function assessment, if you are willing. Baseline and 12-week follow-up visits will be conducted via Zoom. Participation in the exercise group will train 30 minutes each time, 5 times a week. You will record daily activities using the health diary feature on the Blue Marble Health Platform - Health in Motion app, whether you are in the exercise or control group. The visits will vary in length and include a review of your medical history, sign the Medical Records Release Authorization, answer questionnaires, and assessment of your physical functions in-person and via Zoom. If you are female between the ages of 55 – 62 years old with undetermined childbearing status, you will be asked to complete an in-person urine pregnancy test at the second visit. We will also send you a monthly urine pregnancy test to complete at home. We will call you once a week to check up on you. Your pregnancy status will also be reassessed during the weekly calls. You will be asked to complete the health diary during the entire course of the study.

c) What are the likely risks or discomforts to you?

Potential risks are those associated with a remotely delivered exercise program, short physical performance test, online supervision physical function test including walking test, 30 Second Sit to Stand Test, and 4 Stage Balance test, potential loss of confidentiality related to the study questionnaires, completing the cognitive test, completing the urine pregnancy test, and using the Blue Marble Health Platform - Health in Motion app, Zoom call and tablet.

d) What are the likely benefits to you or to others from the research?

Benefits may include information about your health and assessments of your physical function status. If you are in the exercise group, you will receive remotely delivered exercise training at home. You will be offered to keep the TheraBand upon your completion of the study to stay engaged in exercise and track your activity levels.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

If you do not wish to be in this study, please tell a study team member and do not sign this form. The Health in Motion app is publicly available for download and purchase through the app store on your Apple or Android device (smartphone or tablet). You may begin an exercise program on your own after consulting with your physician.

Additional and more detailed information is provided within the remainder of this Informed Consent form. Please read before deciding if you wish to participate in this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

No procedures in this study will be part of your normal clinical care. Your normal clinical care will not be affected by this study.

7. What will be done only because you are in this Research Study?

You are being contacted for this study because you were initially deemed potentially eligible by your clinical care team as a sepsis survivor and you indicated you were interested in hearing more about the study.

For this study, you will be asked to complete a total of two in-person study visits and two remote visits. First, we ask that you complete an in-person screening visit at the hospital, before discharge. Alternatively, you may schedule this screening visit with the study team within 3 days after being discharged home, depending on your preference. For the second in-person visit, we ask that you schedule this visit with us after your discharge. This visit should occur at our research facilities, or at your home. The details of what this visit involves are listed below. The screening visit and second in-person visit may be combined into one in-person visit. You will be asked to record your daily activities such as your heart rate and walking steps for the entire course of the study. Finally, you will be asked to complete 2 assessment visits remotely (a baseline visit and 12-week follow-up visit) conducted by the UF or University of Alabama at Birmingham (UAB).

If you wish to participate, your first screening visit will be to determine your eligibility for the study. This visit may be combined with the next in-person visit if you would prefer one longer visit as opposed to two separate visits. Details regarding the tests to be conducted

during this screening visit and other study visits (if you are eligible) are described below. The screening visit will take place at the UF Health Gainesville hospital, or at your home.
Screening Visit (In-person at the hospital): At this visit, you will be asked to do the following:

- Consent to the study
- Medical history review and medication inventory
- Provide demographic and contact information
- Complete a questionnaire to assess your mood
- Perform short tests of mobility function, such as a test of your preferred walking speed, balance ability, and ability to rise from or sit down in a chair
- Schedule your second home/hospital visit
- Answer questions about your pre-hospitalization status, including questions from the Zubrod/ECOG questionnaire.

If you score ≥ 16 on the mood questionnaire, we will inform your clinical care team to help provide you resources and appropriate treatment. You are encouraged to consult with your primary care doctor about the result.

If you qualify to participate in this study after the above screening, you will be invited to attend the baseline visit. If you prefer, we can coordinate the home visit through your designated emergency contact.

Home/hospital Visit (In-person): At this visit, you will be asked to do the following:

- Medical record release authorization
- Urine pregnancy test (only applicable if you are female between 55 – 62 years old with undetermined childbearing status).
- Receive TheraBand
- Receive tablet and guidance on how to set up the internet and Bluetooth connection
- Receive pre-addressed iPad return package
- Receive instruction on how to navigate and complete exercise/physical assessment/ health diary on the Blue Marble Health Platform - Health in Motion app
- Receive Zoom training

Information regarding the Medical Records Release Authorization: The study team will ask you to sign the Medical Records Release Authorization. We would like to have this form signed by you if we need to request your health records if you are hospitalized or any health problems worsen and the study team has to report details of these events to regulatory authorities (Institutional Review Board, the study sponsor, etc.) to ensure your safety during participation in this research study. This form will be signed only once – during the second in-person home/hospital visit. Health information collected using this release will be used only for any health events that occur during your participation in this research.

Additional information regarding the urine pregnancy test: if you are a female participant between 55 – 62 years old, we will send you a urine pregnancy test every month to complete at home. We will also reassess your pregnancy status during the weekly calls. If you reported that you could potentially be pregnant, we will send you the test via mail promptly to confirm your pregnancy status.

Once you complete your baseline visit, you will be randomly assigned to one of two study groups. You will be randomly assigned (like computer-generated flip of a coin) into the exercise or control group. No member of the study team has control over which group you will be assigned to. The study statistician has already predetermined a randomization list for the study to ensure the random order is followed. If you are randomized into the control group, you will be asked to record your daily activities using the health diary feature on the Blue Marble Health Platform - Health in Motion app, complete questionnaires and perform physical assessment test during the assessment visits. If you are randomized into the exercise group, you will be asked to do everything as the control group and follow the exercise intervention, which involves exercising for 30 minutes each session, 5 sessions per week for 12 weeks.

The exercise intervention will be delivered entirely remotely by the Blue Marble Health Platform – Health in Motion app. The app has over 100 avatar-guided strengthening, balance and aerobic exercises, along with 23 standardized assessments and a personal health diary. You will receive daily reminders (5 days/week) on your phone for the first two weeks via text message or phone call to perform training sessions. After the first two weeks, you will receive a weekly reminder call. The training app with an avatar demonstrating and guiding the exercise will register the progress and the intensity will be adjusted according to your self-reported exertion score during each session. A request to assess your exertion level will pop up in the application at the beginning, middle, and end of each session. The exercise routine will be manually adjusted by the study staff so that the repetition number and intensity maintain continuous progress during the intervention. Each session will take 30 minutes, including a 5 minutes warm-up, 20 minutes of aerobic and resistance/bodyweight exercises, and 5 minutes of cool down. The progression of resistance exercises will include the addition of TheraBand, an increase in the number of repetitions/workloads, or a reduction of support such as a countertop for balance.

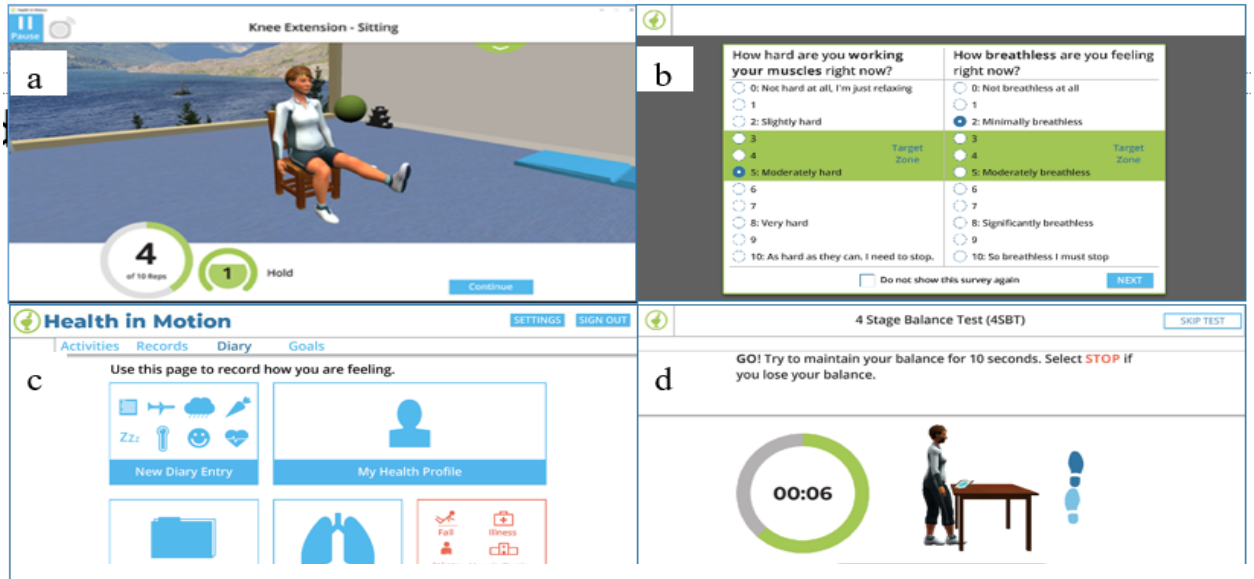

Figure 1. (a) Screenshot of an in-app avatar guided exercise, b) self-reported exertion & breathlessness measures, c) health Diary Menu, d) guided assessment test.

Additionally, the physical function assessment at baseline and 12-week follow-up visits will be guided via the Blue marble Health Platform – Health in Motion app. The assessment includes a walking test, 30-second sit to stand test, and a 4-stage balance test. The 4-stage balance test assesses your ability to stand on one leg, stand with one foot in front of another, stand with the heel of one foot touching the big toe of another foot, and stand with 2 feet side by side. The app also shows you how to perform the test safely with the assistance of another person, sturdy furniture, and a chair placed behind you just in case you lose your balance. Between the baseline and 12-week remote visits, you will be contacted regularly by the study team and asked to provide updates about your health and exercising program.

Remote Assessment Visits (baseline and 12-week Follow-up visit): At this visit, you will be asked to do the following:

- Update your medical history and medication inventory
- A memory test
- A questionnaire about your quality of life and health status
- Complete the Blue Marble Health Platform - Health in Motion app-guided physical function assessment, including the walking test, 30 second sit to stand test, and 4 stage balancing test.
- Ask you about changes in your health status and update medication changes

If any identifiable information is collected as part of this research, it is possible that your research information, with all personally identifiable information removed, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. What identifiable health information will be collected about you and how will it be used?

The UF and UAB Research Team will collect:

- Name
- Social Security Number for compensation purposes
- Contact, emergency contact, and demographic information
- Date of Birth
- Information about your health, and medical history
- Information about the medication that you are taking
- Information about your physical abilities
- Information about your mood status
- Information about your quality of life
- Information about your cognitive abilities

The Research Team may collect this information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are

not part of this research (other doctors, hospitals or clinics). Other professionals at the University of Florida or Shands Hospital who provide study-related care, and the University of Florida Institutional Review Board (IRB), may also collect your health information.
The Research Team listed in question 3 above will use or share your health information as described below to carry out this research study.

9. With whom will this health information be shared?

This health information may be shared with:

- the study sponsor (listed in Question 4 of this form)
- United States governmental agencies which are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- The IRB that reviewed this Research Study and ensures your rights as a Study Subject are protected.
- The UAB research team that is responsible for assisting with remote study visits.

Otherwise, your identifiable health information will not be shared without your permission unless required by law or a court order. Once your health information is shared with those listed above, it is possible that they could share it without your permission because it would no longer be protected by the federal privacy law.

10. How long will you be in this Research Study?

You will be in this study for up to 15 weeks. The initial screening visit will be at the hospital; we will then have a second in-person home/hospital visit within 2 weeks. You will be required to complete two remote assessment visits (baseline and 12-week follow-up visits) via Zoom and receive daily reminders to exercise (only in the exercise group) during the first two weeks, weekly checkup calls, and record your daily activities via the Blue Marble Health Platform - Health in Motion app.

This Authorization to use and share your health information expires at the end of the study, unless you revoke it (take it back) sooner.

11. How many people are expected to take part in this Research Study?

Our study team will identify and screen potential sepsis survivors through UF Health Gainesville site. Participants who are interested in the study will be screened in person at the UF Health hospital, or at their home. Many of the participants will not meet all of the study enrollment criteria and will not be eligible to participate in the study. We plan to enroll 40 participants from UF Health Gainesville site that meet all eligibility criteria. We expect to enroll 250 people in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

12. What are the possible discomforts and risks from taking part in this Research Study?

Risk associated with exercise intervention

The primary risk associated with exercise training is muscle soreness. There are other risks that relate to falls and fractures, worsen your arthritis and other joint conditions, post-exercise low blood pressure, and cardiovascular events. There is a risk that you may trip, stumble, or fall during the exercise sessions and experience shortness of breath, dizziness, chest pain or discomfort, heartburn, lightheadedness, or feeling about to faint.

To minimize this risk, the exercise levels will be tailored to your capabilities to gradually improve your physical function without overstraining your physical ability. The Blue Marble Health Platform - Health in Motion app guides will guide you through the exercise and encourages you to perform the exercise in a safe environment. The app also demonstrates how to do the exercise safely and encourages you to stand nearby sturdy furniture or countertop in case of losing balance. You are instructed to stop the exercise immediately if you experience chest pain, shortness of breath, leg cramps, or pale appearance during the exercise intervention. Additionally, the app has an exercise symptom rating scale that includes breathlessness, pain/exertion/dizziness that can be added to your exercise routine before/at midpoint/ and after you complete the exercise. Also, if you exit the exercise routine before it is completed, the app will ask you why you did that and request you to fill out the exercise symptom scale again.

The study team will enable the Record Health Event feature of the Blue Marble Health Platform - Health in Motion app to monitor your safety. This feature enables you to record if you have a fall, illness, or injury. It will ask for the date/time of the fall or illness; if you went to the hospital, cause of the fall, and a text box to describe the event in detail.

Our study team will see the reports and follow up with you to ensure your safety. We will provide you with the NAME/ADDRESS/ and EMERGENCY CONTACT in case you fall while performing the exercise. We recommended you call 911 if you fall and needed assistance. Research staff will call you weekly to monitor your health status and adverse events. We may have additional home visits in case of arising issues that cannot be solved by phone/Zoom.

Risk associated with Short Physical Performance Battery test

The Short Physical Performance Battery test may be associated with the risk of falling or the development of chest discomfort due to coronary ischemia or dyspnea due to heart failure or lung disease. Rarely, falling during the SPPB test may result in a fracture.

Research staff members who collect data will be trained on proper administration of the Short Physical Performance Battery test prior to administering the test to you.

To minimize these risks, research staff are trained in the conduct of all physical performance tests and certified by Dr. Mankowski or his designee before they work with you. Study staff are instructed not to perform these tests if they feel that testing is unsafe for you or if you are concerned about safety. If safety concerns are identified by either the study staff or you during the testing procedures, testing is halted and you are not allowed to complete the test. In either case, you will be assessed to determine the need for medical intervention and the cause for concern will be evaluated. All study staff are trained in activating the emergency response system at The University of Florida facility.

Risk associated with the supervised online physical function test include walking test, 30 Second Sit to Stand Test, 4 Stage Balance Test

All of these tests may put you at risk of falling. You are encouraged to perform all tests safely, with the assistance of another person, using an assistive device, or using a sturdy support surface. For each follow-up test, the Blue Marble Health Platform - Health in Motion app guides you through the test and encourages you to perform the test in a safe environment.

To mitigate falls, the Blue Marble Health Platform - Health in Motion app describes and demonstrates each physical assessment including the walking test, stand as many times as you can in 30 seconds test and the 4-stage balance test. The app shows you how to perform the test safely with the assistance of another person, sturdy furniture, and a chair placed behind you just in case you lose your balance. If you feel that the test is unsafe to perform, you may skip the test and document your reason for skipping using the Blue Marble Health Platform - Health in Motion Health Diary feature. For the baseline and 12-week follow-up remote visits, if you demonstrate a higher risk of falls from the questionnaires, a study staff member or in-home support person will guard you to ensure you are safe to perform the test. The study staff will guide you on ways to perform the follow-up tests independently and safely in your home.

During the screening visit, we will provide you with the NAME/ADDRESS/ and EMERGENCY CONTACT should you fall while performing the test. The study coordinator present on Zoom will call 911 if you fall and are unable to call, otherwise, the study coordinator will ask you to call 911 and we will remain on the Zoom call until the first responders arrive.

Risk associated with questionnaires administration

Participation includes a risk of loss of confidentiality of personal health information. A number of methods are employed to maintain your confidentiality. First, questionnaire data are collected in secure spaces where the interview cannot be overheard. Second, only study investigators and key research staff have access to the study database. Third, you are assigned a unique study identifier. Individual names will ultimately be removed from the study database and only the unique study identifier will be used to distinguish participants in the database. Fourth, collected data are maintained in locked computer

files and file cabinets to which only study investigators have access. Collected data will be used only for research purposes. Published data will not contain any individual identifiers. Finally, all research staff members have to retake refresher course certification exams.

To minimize this risk, questionnaire data are collected in secure spaces where the interview cannot be overheard. You can decline to answer questions that are uncomfortable or concerning. All research staff members complete annual HIPAA for Researchers training as required by UF. Collected data will be maintained in locked computer files and file cabinets to which only study investigators have access. Only study investigators and key research staff (i.e. data manager and study programmers) have access to the study forms or database. You will be assigned a unique study identifier; individual names will be removed from the study database and only the unique study identifier used to distinguish participants in the database. Collected data will be used only for research purposes, and publications will not contain any individual identifiers.

Risks associated with Cognitive Tests.

There is a risk that you will find memory and concentration tests stressful and might feel tired or sad because it may be difficult to remember things that they are asked to remember. You may skip any question you do not wish to answer. Research staff will explain what to do and answer questions that you might have during cognitive testing.

To minimize this risk, questionnaire data are collected in secure spaces where the interview cannot be overheard. You can decline to answer questions that are uncomfortable or concerning. All research staff members complete annual HIPAA for Researchers training as required by UF. Collected data will be maintained in locked computer files and file cabinets to which only study investigators have access. Only study investigators and key research staff (i.e. data manager and study programmers) have access to the study forms or database. You will be assigned a unique study identifier; individual names will be removed from the study database and only the unique study identifier used to distinguish participants in the database. Collected data will be used only for research purposes, and publications will not contain any individual identifiers.

Risk associated with the potential loss of confidentiality using the Blue marble Health Platform - Health in Motion app, Zoom call, and tablet.

Participation includes a risk of loss of confidentiality of your health and your personal information when using the Blue Marble Health Platform - Health in Motion app, Zoom call, and tablet.

To minimize this risk, you will be assigned a unique study identifier associated with all of your accounts on the Blue Marble Health Platform - Health in Motion app and Zoom. The tablet that will be given to you will only have the active Blue Marble Health Platform - Health in Motion app and the Zoom app. You will be instructed to use the tablet only to complete study-specific tasks. Your accounts and collected data will be de-identified and associated only with your study-specific ID number. We will not collect or store any identifiable information about you, such as your name or date of birth, on either the Blue

Marble Health Platform - Health in Motion app, Zoom account and tablet. The data from these devices will be saved internally on our secure departmental drive. All research staff members complete annual HIPAA for Researchers training as required by UF.

Risk associated with the urine pregnancy test

The pregnancy test may provide a false-positive or false-negative result. To minimize this risk, you are encouraged to take an additional urine pregnancy test to confirm the result.

This Research Study may also include risks that are unknown at this time.

Please note, participating in more than one research study or project may further increase the risks to you. If you are already enrolled in a research study, please inform one of the Research Team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

During the study, the Research Team will notify you of new information that may become available and might affect your decision to remain in the study.

The University of Florida is required by law to protect your health information. Your health information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices, as required by University policy. However, there is a slight risk that information about you could be released inappropriately or accidentally. Depending on the type of information, a release could upset or embarrass you, or possibly affect your ability to get insurance or a job.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the Research Team members listed in question 3 in this form.

13a. What are the potential benefits to you for taking part in this Research Study?

Importantly, the proposed project should have tangible benefits for you. These benefits include information about your health and assessments of your physical function status. You are encouraged to communicate the results from the study to your primary care providers. Moreover, participation in exercise groups will receive remotely delivered exercise training at your home. We offer the Theraband for you to keep at the end of the study. We expect that these benefits will improve your quality of life.

13b. How could others possibly benefit from this Research Study?

The information gained from your participation in this study may provide doctors with new information for recommending exercise treatments to sepsis survivors. The study may also provide scientists and physicians with new knowledge about how home-based digital exercise training programs can improve the physical function of older sepsis survivors.

13c. How could the Research Team members benefit from this Research Study?

In general, presenting research results helps the career of a researcher. Therefore, the Research Team listed in question 3 of this form may benefit if the results of this Research Study are presented at scientific meetings or in scientific journals.

13d. Will you be allowed to see the research information collected about you for this Research Study?

You may not be allowed to see the research information collected about you for this Research Study, including the research information in your medical record, until after the study is completed. When this Research Study is over, you will be allowed to see any research information collected and placed in your medical record.

14. What other choices do you have if you do not want to be in this study?

If you do not want to be in this study do not sign this form. If you have already signed this form, please notify the Principal Investigator listed in question 3 above. If you do not want to be in this study, the alternative choice is simply not to participate.

You may also refuse to authorize the use of your health information, but if you refuse, you may not be allowed to be in this research study or receive any research-related treatment that is only available in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

15a. Can you withdraw from this study?

You may withdraw your consent and stop participating in this Research Study at any time. If you do withdraw your consent, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you decide to withdraw your consent to participate in this Research Study for any reason, please contact the Research Team listed in question 3 of this form. They will tell you how to safely stop your participation.

You can also change your mind and take back this Authorization at any time by sending a written notice to the Research Team listed in question 3 of this form to let them know your decision. If you take back this Authorization, the Research Team may only use and disclose your health information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team. However, if you take back this Authorization, you may not be able to continue in this study. Please discuss this with a member of the Research Team listed in question #3.

15b. Can the Principal Investigator withdraw you from this Research Study?

You may be withdrawn from this Research Study without your consent for the following reasons:

- If the Principal Investigator or study physician decide that your participation in the study could be harmful to you

- If you develop a medical condition or need treatment not allowed in the study
- If you do not follow study instructions
- If the study is cancelled
- Unexpected circumstances

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

16. If you choose to take part in this Research Study, will it cost you anything?

No, there will be no additional costs to you or your health plan as a result of your participation in this study. The sponsor will pay for all health care costs related to your participation, including all required study items, services and procedures described in this consent form. However, if you feel you have received a bill related to this study, please contact the Principal Investigator.

If you receive any healthcare at UF Health that is not related to this study, this care will be billed as usual.

17. Will you be paid for taking part in this Research Study?

Yes, you will be compensated up to $310 in the form of gift cards. A gift card of $10 will be given to you if you have to return for the screening visit within 3 days after discharge. You will receive $50 at the completion of baseline visit, 4 weeks, and 8 weeks of the study. You will receive $150 upon your completion of the 12-week follow-up visits. Successfully return the iPad will activate your 12-week follow-up visit compensation. You will not be compensated for the Screening Visit if it is completed before your discharge. Additionally, you will be offered to keep the Theraband once you completed the study.

If you are paid more than $199 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to nonresident aliens must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Research Participant Payment (RPP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (RPP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment, contact the study coordinator.

18. What if you are injured while in this Research Study?

If you are injured as a direct result of your participation in this study, only the Professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact Dr. Stephen Anton (352-273-7514) if you experience an injury or have questions about any discomforts that you experience while participating in this Research Study.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this Research Study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

_____ _____

Signature of Person Obtaining Consent and Authorization Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described above. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Participant Date