Title of the study: Daily Weight Feedback for Wheelchair Users to Promote Weight Loss

NCT number: 03264248

Date: June 5th, 2018

[reviewer notes¬]

Provide a short title for this study (200 characters or less)**:**

Daily weight feedback for wheelchair users to promote weight loss

T1.0

Select the type of application:
New Research Study

T2.0

Is the proposed research study limited to the inclusion of deceased individuals?
* No

T2.1

Are any research activities being conducted at the VA Pittsburgh Healthcare System or with VA funds?

* No

[reviewer notes¬]

T3.0 **What is the anticipated risk to the research participants?**

Minimal Risk

T3.1 **Why do you feel that all aspects of this research study, including screening and follow-up, involve no more than minimal risk to the research subjects?**

This study is a standard behavioral weight loss study focusing on diet, physical activity, and behavioral strategies to effectively make lifestyle changes. It will also include using a new scale (E-scale) which has minimal risk as it will continuously record the weight of the bed which will allow for capturing the weight of the person when they are in bed.

T4.0

Does the proposed study qualify for 'exempt' IRB review or for a determination of either 'not research' or 'no human subject' involvement?

* No

T5.0

Does the proposed research study qualify for 'expedited' IRB review status?

* Yes

[reviewer notes¬]

CS1.0 What is the reason for this submission?

New Research Protocol Submission

CS1.1

Has this research study been approved previously by the University of Pittsburgh IRB?

* No

CS1.1.1

Has this research study (or a substantially similar research study) been previously disapproved by the University of Pittsburgh IRB or, to your knowledge, by any other IRB?

* No

[reviewer notes¬]

CS2.0

Title of Research Study:

Daily weight feedback for wheelchair users to promote weight loss

CS2.0.1

Requested approval letter wording:

CS2.1 Research Protocol Abstract:

The goals of the proposed study are to test the usability, feasibility and preliminary efficacy of the E-Scale with wheelchair users. Up to fifteen overweight or obese wheelchair users will be enrolled in a 13 week study that includes standard behavioral treatment (SBT) for weight loss that focuses on diet, physical activity, and behavioral strategies (e.g., goal setting, self-monitoring) to support lifestyle changes specifically for people with mobility impairments. The subjects will also be provided the E-scale to track their weight daily. The primary outcomes will be usefulness (subjective feedback from a survey about the program/E-scale), feasibility (accuracy and repeatable measurements from the E-scale) and efficacy (improvements in weight and other measures of health) of the weight loss program coupled with the E-scale at the end of 13 weeks. The results could inform the refinement of this technology to increase its applicability for wheelchair users to independently monitor their weight in their own homes while attempting to lose weight.

CS2.2

Select the category that best describes your research:
Hybrid - includes aspects of BOTH types of research (check this option if your research is mainly social/behavioral but also involves specimen collection or blood draws to look at biological measures)

[reviewer notes¬]

CS3.0 Name of the Principal Investigator:

Jonathan Pearlman

Note: Adjunct faculty of the University, including lecturers and instructors, are not permitted to serve as a PI or Faculty Mentor but may serve as co-investigators. Refer to Chapter 4 on the HRPO website for more information.

CS3.1 Affiliation of Principal Investigator:

UPitt faculty member

If you chose any of the **Pitt options**, please indicate the specific campus:
Main Campus - Pittsburgh

If you chose the UPitt faculty member option, provide the PI's **University Faculty Title**:
Associate Professor

CS3.2 Address of Principal Investigator:

6425 Penn Ave Suite 400
Pittsburgh, PA 15206

CS3.3 Recorded Primary Affiliation of the Principal Investigator:

U of Pgh | School of Health and Rehabilitation Sciences | Rehabilitation Science and Technology

CS3.4 Identify the School, Department, Division or Center which is responsible for oversight of this research study:

U of Pgh | School of Health and Rehabilitation Sciences

CS3.5 Telephone Number of Principal Investigator:

412-822-3685

CS3.6 Recorded Current E-mail Address of Principal Investigator to which all notifications will be sent:

jlp46@pitt.edu

CS3.7 Fax Number:

412-822-3699

CS3.8 Does this study include any personnel from Carnegie Mellon University, and/or use any CMU resources or facilities (e.g., Scientific Imaging and Brain Research Center (SIBR)?

* No

CS3.9 **Is this your first submission, as PI, to the Pitt IRB?**

* No

[reviewer notes¬]

CS4.0

List of Co-Investigators:

Last	First	Organization
Duvall	Jonathan	U of Pgh | School of Health and Rehabilitation Sciences | Rehabilitation Science and Technology
Gold	Elizabeth	Other
Karg	Patricia	U of Pgh | School of Health and Rehabilitation Sciences

[reviewer notes¬]

CS5.0 **Name of Primary Research Coordinator:**

Patricia Karg

CS5.1

Address of Primary Research Coordinator:

6425 Penn Ave
Suite 401
Pittsburgh, PA 15206

CS5.2

Telephone Number of Primary Research Coordinator:

412-624-6207

CS6.0

Name of Secondary Research Coordinator:

CS6.1 **Address of Secondary Research Coordinator:**

CS6.2 **Telephone Number of Secondary Research Coordinator:**

CS6.3 **Key Personnel/Support Staff (Only list those individuals who require access to OSIRIS):**

Last First Organization
There are no items to display

[reviewer notes¬]

CS7.0 **Will this research study use any Clinical and Translational Research Center (CTRC) resources?**

No

[reviewer notes¬]

CS8.0 Select the entity responsible for scientific review.

External Scientific Review Completed – The **scientific merit of this research protocol has been confirmed** by an external scientific review committee as a condition of funding.

[reviewer notes¬]

CS9.0 Does this research study involve the administration of an investigational drug or an FDA-approved drug that will be used for research purposes?

* No

CS10.0 Is this research study being conducted under a University of Pittsburgh-based, sponsor-investigator IND or IDE application?

* No

If YES, you are required to submit the IND or IDE application and all subsequent FDA correspondence through the Office for Investigator-Sponsored IND and IDE Support (O3IS). Refer to applicable University policies posted on the O3IS website (www.O3IS.pitt.edu).

[reviewer notes¬]

CS11.0

Use the 'Add' button to upload one or more of the following:

- **the sponsor protocol (including investigator initiated studies) and/or other brochures**
- **the multi-center protocol and consent form template, *if applicable***

Name Modified Date

Is this research study supported in whole or in part by industry? This includes the provision of products (drugs or devices).

* No

Is this a multi-centered study?

* No

[reviewer notes¬]

CS12.0

Does your research protocol involve the evaluation or use of procedures that emit ionizing radiation?

* No

CS13.0 Does this research study involve the deliberate transfer of recombinant or synthetic nucleic acid molecules into human subjects?

* No

Upload Appendix M of NIH Guidelines:
Name Modified Date

CS14.0 Are you using UPMC facilities and/or UPMC patients during the conduct of your research study?

* No

If Yes, upload completed Research Fiscal Review Form:
Name Modified Date

[reviewer notes¬]

CS15.0

Indicate the sites where research activities will be performed and/or private information will be obtained.

Choose all sites that apply and/or use **Other** to include sites not listed:

Sites:
University of Pittsburgh

University of Pittsburgh
Campus:
Main Campus - Pittsburgh

List university owned off-campus research sites if applicable:
Bakery Square

If you selected **School**, **International** or **Other**, list the sites:

***For research being conducted at non Pitt or UPMC sites, upload a site permission letter granting the researcher permission to conduct their research at each external site:**
Name Modified Date

CS15.1 Have you, Jonathan Pearlman , verified that all members of the

research team have the appropriate expertise, credentials, and if applicable, hospital privileges to perform those research procedures that are their responsibility as outlined in the IRB protocol?

* Yes

CS15.2

Describe the availability of resources and the adequacy of the facilities to conduct this study:

* Our facilities at the Human Engineering Research Laboratories has all of the capabilities needed to conduct this study. We have the equipment needed to conduct the baseline and final measurements (scale, body-fat monitor, and tape measure). We have a locked file room and protected servers for consent and other confidential information. There is a private room for conducting screening and consent procedures. The study has been fully funded by a grant from the Paralyzed Veterans of America foundation.

[reviewer notes¬]

CS16.0 Special Research Subject Populations:

Categories
None

[reviewer notes¬]

CS17.0 Does your research involve the experimental use of any type of human stem cell?

* No

[reviewer notes¬]

NIH Definition of a Clinical Trial

A research study[1] in which one or more human subjects[2] are prospectively assigned[3] to one or more interventions[4] (which may include placebo or other control) to evaluate the effects of those interventions on health related biomedical or behavioral outcomes.[5]

[1] See Common Rule definition of research at 45 CFR 46.102(d) .

[2] See Common Rule definition of human subject at 45 CFR 46.102(f) .

[3] The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

[4] An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g.,

telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

[5] Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

CS18.0 * **Based on the above information, does this study meet the NIH definition of a clinical trial?**

(•) **Yes** ( ) No

If Yes, click Save and then Click Here For Study Team's CITI Training Records . Please ensure all personnel's training is up to date

	Section: Section 1 - Objective, Aims, Background and Significance

[reviewer notes¬]

1.1 Objective: What is the overall purpose of this research study? (Limit response to 1-2 sentences.)

To determine the usefulness, feasibility and efficacy of the E-scale system coupled with a standardized behavioral treatment weight-loss intervention for overweight or obese wheelchair users.

1.2 Specific Aims: List the goals of the proposed study (e.g., describe the relevant hypotheses or the specific problems or issues that will be addressed by the study).

Aim 1. To investigate the usefulness and feasibility of the E-scale system and efficacy of the E-scale coupled with a weight-loss intervention to assist overweight or obese wheelchair users with losing weight.

Hypothesis 1a: The E-scale will be useful based on self-reported feedback from wheelchair users by more than 50% stating that the E-scale is easy to use, their preferred weight monitoring system, them feeling that they would use the E-scale if it was available for them to purchase.

Hypothesis 2b: The E-scale will be feasible by providing accurate (+/- 2 lbs. from a calibrated scale measurement) and repeatable (<3lbs difference from day-to-day) weight measurements and by the wheelchair users continuing to use the scale more than 70% of the days of the study.

Hypothesis 2c: The E-scale coupled with the weight loss intervention will demonstrate efficacy by wheelchair users having significant improvements in weight, abdominal girth, body fat percentage and score on the Self-Rated Abilities for Health Practices Scale (SRAHP).

1.3 Background: Briefly describe previous findings or observations that provide the background leading to this proposal.

Wheelchair users have about twice the prevalence of obesity than the general population. There is also very little or no technology to which they have access to measure their weight frequently in their homes. Research however, has shown that monitoring your body weight frequently (i.e. daily) yields significantly better weight loss and weight maintenance results. This research has never included wheelchair users because they have not had access to technology to be able to measure their weight daily. The E-scale was developed as a weight monitoring technology for wheelchair users and has been tested for precision and accuracy in the laboratory.

1.4 Significance: Why is it important that this research be conducted? What gaps in existing information or knowledge is this research intended to fill?

This research will tell whether wheelchair users find the E-scale to be useful and feasible as a way to monitor their weight in their homes. It will also show whether wheelchair users, like the general population, have better weight loss outcomes if they monitor their weight daily. This could lead to refinement of the E-scale and a push for more available technology for wheelchair users to monitor their weight at home which could in turn lead to a decrease in the prevalence of obesity among wheelchair users.

[reviewer notes¬]

2.1 Does this research study involve the *use* or evaluation of a drug, biological, or nutritional (e.g., herbal or dietary) supplement?

* No

[reviewer notes¬]

2.2 Will this research *use* or evaluate the safety and/or effectiveness of one or more devices?

* Yes

2.2.1 Does this research study involve an evaluation of the safety and/or effectiveness of one or more devices not currently approved by the FDA for general marketing?

* Yes

If **YES**, describe your **plan to prevent unauthorized use of the investigational device**: The E-scale is a non-invasive device which measures the weight of each of the four legs of a bed. As such there would be no benefit or harm from unauthorized use.

2.2.1.1 List each of the unapproved devices being evaluated in this research study.

Specify for each listed device the corresponding Investigational Device Exemption (IDE) number or provide a justification for why you feel that this device and its use, as proposed in this research study constitute a non-significant risk (i.e., to include potential failure of the device) to the research subjects:

	Unapproved device	IDE #	Non-significant risk justification
View	E-scale		The E-scale is a set of weight sensors for each leg of a bed. This device does not have potential for serious risk to the health, safety, or welfare of a subject since (1) The device is not an implant; (2) The device is not used in supporting or sustaining human life; or (3) The device is not of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health. It has also been used in the home without any adverse events in IRB # PRO14080007

[reviewer notes¬]

2.2.2 Does this research study involve the use or evaluation of the safety and/or effectiveness of one or more devices approved by the FDA for general marketing?

* No

[reviewer notes¬]

2.3 **Summarize the general classification (e.g., descriptive, experimental) and methodological design (e.g., observational, cross-sectional, longitudinal, randomized, open-label single-blind, double-blind, placebo-controlled, active treatment controlled, parallel arm, cross-over arm) of the proposed research study, as applicable.**

This study will be experimental. It will be a 13 week longitudinal efficacy study.

2.3.1 **Does this research study involve a placebo-controlled arm?**

* No

[reviewer notes¬]

2.4 **Will any research subjects be withdrawn from known effective therapy for the purpose of participating in this research study?**

* No

[reviewer notes¬]

2.5 **Will screening procedures (i.e., procedures to determine research subject eligibility) be performed specifically for the purpose of this research study?**

* Yes

2.5.1 **List the screening procedures that will be performed for the purpose of this research study. Do NOT include the inclusion/exclusion criteria in this section as they will be addressed in section 3; questions 3.13 and 3.14.**

A self-report questionnaire will be administered when the person first contacts us and prior to informed consent, this includes most of the screening for inclusion and exclusion criteria. When the person comes into the laboratory, and after consent, weight and height measurements will be taken, and the Center for Epidemiologic Studies Depression Scale (CES-D) and the Eating Disorder Diagnosis Scale (EDDS) will be administered. We will also ask as part of our first contact that the potential subjects obtain a doctor's note approving their participation in the study and record their diet for 3 days. The note and food record can be provided anytime up until they start the intervention. If they do not complete these two tasks they will be excluded.

[reviewer notes¬]

2.6 **Provide a detailed description of all research activities (e.g., all drugs or devices; psychosocial interventions or measures) that will be performed for the purpose of this research study.**

This description of activities should be complete and of sufficient detail to permit an assessment of associated risks.

At a minimum the description should include:

- **all research activities**
- **personnel (by role) performing the procedures**
- **location of procedures**
- **duration of procedures**
- **timeline of study procedures**

Potential subjects will be screened over the phone or in person with a list of questions that may exclude them from the study. If it is determined that they are likely to be eligible, they will be asked to contact their doctor for a letter approving their participation in a weight loss program and scheduled to come to the lab where they will be consented into the study. They will also be asked to record their diet for 3 days to determine if they are willing to comply with this key component of the study. When they come into the lab, informed consent will be performed first. After the consent process is complete, subjects will be given the Center for Epidemiologic Studies Depression Scale (CES-D) and the Eating Disorder Diagnosis Scale (EDDS) to determine if they would be considered to have a current eating disorder or are currently depressed. Next the subject's weight and height will be measured in the lab by having the subjects drive onto a calibrated roll-on scale to get the weight of their chair with them in it. Then they will transfer out of their wheelchair (with assistance of the research team or trained member of our lab if requested) onto a mat table where they will be asked to lay flat on their back so that their height can be measured with a tape measure. While they are on the mat table, a member of the research team will take their chair back to the roll-on scale to weigh the chair. The subject's weight will be determined by subtracting the weight of the chair from the weight of the subject in the chair. The subject's Body Mass Index (BMI) will then be calculated. They will then transfer (or be assisted) back to their chair.

After the subjects' have been determined to be eligible, they will have their abdominal girth measured with a tape measure and their body-fat percentage will be measured with a hand-held BIA inductance measuring tool. They will also be given a demographics questionnaire and the Self-Rated Abilities for Health Practices questionnaire to answer. The LoseIt! (diet and activity journal) and E-scale apps will be installed on their phones/android devices or they will be provided with an android device with the apps already installed to use during the study. De-identified login and passwords will be provided to the subjects to use during all of the study procedures so no identifiable data will ever be collected by these apps. Some training on use of the E-scale and LoseIt! apps will be provided to the subjects as well as the first lesson of the 13-week curriculum. Over the next few days, the study team will go to all of the subject's homes to install the E-scale under their beds.

During the next 12 weeks, subjects will be asked to weigh themselves every day with the E-scale app and record their diet, exercise and weight every day with the LoseIt! app. The data that is reported in the LoseIt! app by the subjects will be monitored by the study team using the ascendapp for LoseIt!, which allows a "coach" to monitor all of the data submitted by a client. The weight loss curriculum involves weekly lessons for the participants to learn and practice things like counting calories and fat, reorganizing their kitchens, doing more cardio work around the house, etc. This curriculum was adapted from the Diabetes Prevention Program Group Lifestyle Balance (DPP GLB) curriculum at Pitt specifically for people with mobility impairments. The study team will send periodic emails with comments to the participants encouraging their progress and adherence to the protocol and lesson materials for that week. Every week at a pre-defined time, a group chat room will be conducted with all of the subject's and the research team invited to attend to go over the lesson for that week and to have a group discussion for the participants to share successes and difficulties with the group. The chat room will be hosted using Adobe Connect with the audio and video capabilities disabled. The link to the chat room for each week will be emailed to the subjects along with the lesson materials. The curriculum disbursement, progress emails, and chat rooms will be led by a dietitian/nutritionist with experience in leading group weight loss programs.

During the last week of the study (week 13). The subjects will be asked to come back to the lab in-person where their weight will again be measured using the roll-on scale. Their

abdominal girth and body-fat percentage will also be measured again. The SRAHP will be administered to the subjects again and they will also be given the final questionnaire, System Usability Scale (SUS), which will evaluate how they felt about the E-scale and some aspects of entire study. Any android devices that were loaned to the subjects during the study will be collected and the apps on their personal devices will be deleted if they wish. Over the next few days, the study team will visit all of the subject's homes to remove the E-scales or the participants can bring them with them to the lab.

If a participant indicates during the study that the E-scale they are using is malfunctioning, an investigator may talk to the participant on the phone and/or schedule a time to travel to the subjects home to troubleshoot and/or replace the E-scale with one that is working properly.

2.6.1

Will blood samples be obtained as part of this research study?

* No

*If submitting a protocol for expedited review, it should be clear that the planned blood draws are within the parameters described here: http://www.hhs.gov/ohrp/policy/expedited98.html (see Expedited Research Category #2)

If **Yes**, address the frequency, volume per withdrawal, the total volume per visit, and the qualifications of the individual performing the procedure:

Study Flow Chart:

Name	Modified Date
Flowchart	4/17/2017 10:46 AM

[reviewer notes¬]

2.7 **Will follow-up procedures be performed specifically for research purposes? Follow-up procedures may include phone calls, interviews, biomedical tests or other monitoring procedures.**

* No

[reviewer notes¬]

2.8 **Does this research study involve the use of any questionnaires, interview or survey instruments?**

* Yes

Upload a copy of all materials except for the SCID or KSADS which are on file at the IRB. The use of all instruments must be addressed in question 2.6 and/or question 2.7 (except for an exempt submission where they should be addressed on the appropriate uploaded exempt form).

Name	Modified Date
EDDS	6/24/2017 2:48 PM
Screening tool	7/17/2017 4:35 PM
Final Survey	1/29/2018 9:45 AM
CES-D	6/24/2017 2:47 PM
Demographics	6/24/2017 2:50 PM
SRAHP	6/24/2017 2:50 PM

Previously the name and publisher for commercially available materials were listed in the textbox below but effective 9/1/2015, all materials (except for the SCID and KSADS) must be uploaded using the Add button above.

[reviewer notes¬]

2.9

If subjects are also patients, will any clinical procedures that are being used for their conventional medical care also be used for research purposes?

* n/a

If **Yes,** describe the clinical procedures (and, if applicable, their frequency) that will be used for research purposes:

2.10 The blood sample question was moved to 2.6.1.

[reviewer notes¬]

2.11 **What is the total duration of the subject's participation in this research study across all visits, including follow-up surveillance?**

* 13 weeks

[reviewer notes¬]

2.12 **Does this research study involve any type of planned deception?**
If Yes, you are required to request an alteration of the informed consent process (question 4.7)

* No

[reviewer notes¬]

2.13 **Does this research study involve the use of UPMC/Pitt protected health information that will be de-identified by an IRB approved "honest broker" system?**

* No

[reviewer notes¬]

2.14

Will protected health information from a UPMC/Pitt HIPAA covered entity be accessed for research purposes or will research data be placed in the UPMC/Pitt medical record?

* No

2.14.1 **Will protected health information from a non-UPMC/Pitt HIPAA covered entity be obtained for research purposes or will research data be placed in the non-UPMC/Pitt medical record?**

* No

[reviewer notes¬]

2.15 **Does this research study involve the long-term storage (banking) of biological specimens?**

* No

[reviewer notes¬]

2.16 **Will research participants be asked to provide information about their family members or acquaintances?**

* No

[reviewer notes¬]

2.17 **What are the main outcome variables that will be evaluated in this study?**

Subjective feedback from the survey about the usefulness and participants' satisfaction with portions of the program and E-scale.

Accuracy and repeatability of the E-scale measurements

Weight change, abdominal girth change, body-fat percentage change and Self-Rated Abilities for Health Practices (SRAHP) change

2.18 **Describe the statistical approaches that will be used to analyze the study data.**

* Addressed below:

Since there is only one group, most outcome variables will be analyzed using summary statistics. Baseline and final measurements will also be analyzed using paired t-tests.

[reviewer notes¬]

2.19

Will this research be conducted in (a) a foreign country and/or (b) at a site (e.g., Navajo Nation) where the cultural background of the subject population differs

substantially from that of Pittsburgh and its surrounding communities?

* No

Note that copies of training records, licenses, certificates should be maintained in the study regulatory binder and are subject to audit by the Research Conduct and Compliance Office (RCCO).

In addition, individuals planning to conduct human subject research outside the United States must complete an optional module on the CITI training website: International Studies. Click here to access the instruction sheet for accessing optional CITI modules.

[reviewer notes¬]

2.21

Will this research study be conducted within a nursing home located in Pennsylvania?

* No

[reviewer notes¬]

Section 3 - Human Subjects

3.1 What is the age range of the subject population?

18-80

3.2 What is their gender?

* Both males and females

Provide a justification if single gender selected:

3.3 Will any racial or ethnic subgroups be explicitly excluded from participation?

* No

If **Yes**, identify subgroups and provide a justification:

3.4 For studies conducted in the U.S., do you expect that all subjects will be able to comprehend English?

* Yes

[reviewer notes¬]

3.5 Participation of Children: Will children less than 18 years of age be studied?

* No

If **No**, provide a justification for excluding children:
Since we are investigating weight changes or weight loss, we do not want to include children who may be growing.

[reviewer notes¬]

3.6 Does this research study involve prisoners, or is it anticipated that the research study may involve prisoners?

* No

[reviewer notes¬]

3.7 Will pregnant women be knowingly and purposely included in this research study?

* No

[reviewer notes¬]

3.8 **Does this research study involve neonates of uncertain viability or nonviable neonates?**

* No

[reviewer notes¬]

3.9 **Fetal Tissues: Does this research involve the use of fetal tissues or organs?**

* No

[reviewer notes¬]
--->

3.10

What is the total number of subjects to be studied at this site, including subjects to be screened for eligibility?

Note: The number below is calculated by summing the data entered in question 3.11. Any additions or changes to the values entered in 3.11 will be reflected in 3.10.

* 20

3.11

Identify each of the disease or condition specific subgroups (include healthy volunteers, if applicable) that will be studied.

Click on the "Add" button and specify for each subgroup:

1) how many subjects will undergo research related procedures at this site; and

2) if applicable, how many subjects will be required to undergo screening procedures (e.g., blood work, EKG, x-rays, etc.) to establish eligibility. Do Not include subjects who will undergo preliminary telephone screening.

*

	Subgroup	Number to undergo research procedures	Number to undergo screening procedures
View	All subjects	15	20

3.12 **Provide a statistical justification for the total number of subjects to be enrolled into this research study at the multicenter sites or this site.**

* Described below:

Since this is an efficacy and exploratory study no sample size calculation was needed or conducted. Similar weight loss studies include 10-20 people in each group session or cohort.

[reviewer notes¬]

3.13 Inclusion Criteria: List the specific criteria for <u>inclusion</u> of potential subjects.

• Use Wheelchair as primary means of mobility
• Uses a bed with 4 legs
• BMI ≥27 and ≤40.0
• age 18-80
• Has daily access to Internet to access LoseIt website and/or app and weekly chat meeting (Adobe Connect)
• Currently owns or willing to use an android device
• Provides physician's clearance to participate in a weight loss intervention
• Speaks English

3.14 Exclusion Criteria: List the specific criteria for <u>exclusion</u> of potential subjects from participation.

• Presence of an unstable condition requiring physician-supervised diet and exercise (e.g., diabetes, recent myocardial infarction)
• Presence of condition precluding engagement in exercise at moderate intensity (e.g., asthma, congestive heart failure, etc.)
• Pregnancy or intention to become pregnant during study
• Currently being treated for any psychological issues or problems, taking any psychotropic medications, or receiving treatment with psychotropic medications within the previous 6 months
• Reported alcohol intake > 4 drinks/day
• Reported participation in a formal weight loss program, loss of ≥5% weight in the past 6 months, or current use of weight loss medication.
• History of bariatric surgery (lap-band, gastric bypass, etc.)
• Planned extended vacations, absences, or relocation during study
• A score ≥20 on the Center for Epidemiologic Studies Depression Scale (CES-D)
• A classification of Anorexia Nervosa, Bulimia Nervosa or Binge Eating Disorder on the Eating Disorder Diagnosis Scale (EDDS)
• Unwilling to provide a diary of 3 days diet prior to beginning the intervention

3.15

Will HIV serostatus be evaluated specifically for the purpose of participation in this research study?

* No

If **Yes**, provide a justification:

	Section: Section 4 - Recruitment and Informed Consent Procedures

[reviewer notes¬]

4.1 Select all recruitment methods to be used to identify potential subjects:
Advertisements
Research Registry
Pitt + Me
Other Strategies: Described below

Advertisements

Upload the advertisements for review:

Name	Modified Date
PRO16110460 Pearlman.pdf	10/10/2017 10:29 AM
Flyer	4/18/2017 3:45 PM

Research Registry

List the IRB approval number and title for each registry source:
Human Engineering Research Laboratories (Pitt IRB #PRO12080311)
Department of Physical Medicine and Rehabilitation (Pitt IRB #PRO12030122)

4.2

Provide a detailed description of your recruitment methods, including identifying and initiating contact with participants:

We will distribute and post flyers at locations where wheelchair users meet (i.e., doctors offices, support groups, adaptive sporting events, etc.). We will also send flyers to wheelchair users in two wheelchair research registries and through the CTSI registry. We will also utilize social media to spread the word about the study and the Pitt+me registry. This would include posts with our flyer, a link to the Pitt+me study page, etc.

Note: Questions jump from 4.2 to 4.6 as questions 4.3-4.5 have been removed and the information is now captured in 4.1

[reviewer notes¬]

4.6 **Are you requesting a waiver to document informed consent for any or all participants, for any or all procedures? (e.g., a verbal or computerized consent script will be used, but the subjects will not be required to sign a written informed**

consent document. ***This is not a waiver to obtain consent.***

* Yes

4.6.1

Identify the specific research procedures and/or the specific subject populations for which you are requesting a waiver of the requirement to obtain a signed consent form.

Addressed below:

If not all, identify the specific procedures and/or subject populations for which you are requesting a waiver:
The only activities that will be conducted before obtaining written consent is a phone or in-person screening to determine that the potential participant meets most of the eligibility criteria prior to having them travel to our lab.

4.6.2

Indicate which of the following regulatory criteria is applicable to your request for a waiver of the requirement to obtain a signed consent form.

45 CFR 46.117(c)(2)

45 CFR 46.117(c)(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

45 CFR 46.117(c)(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

4.6.2.1

Address why the specific research procedures for which you are requesting a waiver of the requirement to obtain a signed consent form present no more than minimal risk of harm to the research subjects:

We will go through a series of questions over the phone that determine if a person meets some of the criteria. The least personal and invasive questions that are similar to everyday conversations will be asked, followed by questions similar to those asked when making a clinical appointment. Questions will be discontinued and no information will be maintained if the person is ineligible for any criteria.

4.6.2.2

Justify why the research listed in 4.6.1 involves no procedures for which written informed consent is normally required outside of the research context:

The screening will only involve questions that occur during normal conversation and making a clinical appointment, and no identifiable information will be recording with the screening unless they complete the screening and are willing to participate.

4.6.3

Address the procedures that will be used and the information that will be provided (i.e., script) in obtaining and documenting the subjects' verbal informed consent for study participation:

When a potential subject responds to the ads, a member of the research team will go through the attached phone or in person screening script. The participant will be asked if it

is okay that we go through a series of questions to determine if they are eligible for the study, and instructed that they may discontinue and choose not to answer at any time. As soon as an answer to a screening question makes them ineligible, no information about them will be saved and the screening discontinued. If they meet the screening eligibility requirements, they will be invited to come to the lab and their screening answers will be kept on the secured server in our department.

Upload Scripts:

Name	Modified Date
Screening.docx	6/24/2017 3:07 PM

[reviewer notes¬]

4.7 **Are you requesting a waiver to obtain informed consent or an alteration of the informed consent process for any of the following?**

* No

4.7.1 **If Yes, select the reason(s) for your request:**

There are no items to display

General Requirements: The Federal Policy **[45 CFR 46.116 (d)]** specifies in order for a waiver of consent to be approved, the request must meet four criteria. For each request, you will be asked to provide a justification addressing how each of these criterion is met.

[reviewer notes¬]

4.8 **Are you requesting an exception to the requirement to obtain informed consent for research involving the evaluation of an 'emergency' procedure?**

Note: This exception allows research on life-threatening conditions for which available

treatments are unproven or unsatisfactory and where it is not possible to obtain informed consent.

* No

[reviewer notes¬]

4.9

Upload all consent documents for watermarking:

Draft Consent Forms for editing:

Name	Modified Date
ICF	10/19/2017 3:33 PM

Approved Consent Form(s):

Name	Modified Date
ICF	12/13/2017 11:35 AM

[reviewer notes¬]

4.10 **Will all potential adult subjects be capable of providing direct consent for study participation?**

*
Yes

[reviewer notes¬]

4.11

At what point will you obtain the informed consent of potential research subjects or their authorized representative?

After performing certain of the screening procedures, but prior to performing any of the research interventions/interactions

4.11.1

Address why you feel that it is acceptable to defer obtaining written informed consent until after the screening procedures have been performed.

The questionnaire portion of the screening procedures will be done over the phone or in person prior to the subject coming to the lab so that the subjects will not have to make a trip to the lab location if they will not be eligible. Once the subject is at the lab in person, informed consent will be obtained before their weight and height are measured and they are asked to complete the Center for Epidemiologic Studies Depression Scale (CES-D) and the Eating Disorder Diagnosis Scale (EDDS).

4.11.2

Taking into account the nature of the study and subject population, indicate how the research team will ensure that subjects have sufficient time to decide whether to participate in this study. In addition, describe the steps that will be taken to

minimize the possibility of coercion or undue influence.

The study will be described to the potential subjects over the phone or in person prior to them coming to the lab. Once they come to the lab, informed consent will be obtained where they will be given time to decide if they want to proceed with the study.

[reviewer notes¬]

4.12 Describe the process that you will employ to ensure the subjects are fully informed about this research study.

* Addressed below:

This description must include the following elements:

- who from the research team will be involved in the consent process (both the discussion and documentation);
- person who will provide consent or permission;
- information communicated; and
- any waiting period between informing the prospective participant about the study and obtaining consent

In addition, address the following if applicable based on your subject population:

- process for child assent and parental permission
  - continued participation if a child subject turns 18 during participation
- process for obtaining proxy consent and assent for decisionally impaired subjects
  - continued participation if subject regains capacity to consent

All members of the research team will be involved with discussing and obtaining informed consent at the beginning of the subject's initial visit. The information about the study will be described during the screening and again when the potential subject comes into the lab, and all questions answered. This will give the subjects adequate time to decide to participate or not. The subjects will provide their own consent.

4.13

Are you requesting an exception to either IRB policy related to the informed consent process?

- For studies involving a drug, device or surgical procedures, a *licensed physician who is a listed investigator* is required to obtain the written informed consent unless an exception to this policy has been approved by the IRB
- For all other studies, a *listed* investigator is required to obtain consent (Note: In order to request an exception to this policy, the study must be minimal risk)

* No

If **Yes**, provide a justification and describe the qualifications of the individual who will obtain consent:

4.14 Will you inform research subjects about the outcome of this research study following its completion?

* No

If **Yes**, describe the process to inform subjects of the results:

[reviewer notes¬]

5.1

Describe potential risks (physical, psychological, social, legal, economic or other) associated with screening procedures, research interventions/interactions, and follow-up/monitoring procedures performed specifically for this study:

*

View	**Research Activity:**	Consent, measurements and questionnaires
	Common Risks:	*No Value Entered*
	Infrequent Risks:	breach of privacy and confidentiality
	Other Risks:	*No Value Entered*
View	**Research Activity:**	Installation and removal of escale
	Common Risks:	*No Value Entered*
	Infrequent Risks:	damage to bed or surrounding areas
	Other Risks:	*No Value Entered*
View	**Research Activity:**	Transfers for weighing
	Common Risks:	*No Value Entered*
	Infrequent Risks:	Falling during transfers
	Other Risks:	*No Value Entered*
View	**Research Activity:**	Using apps and adobe connect
	Common Risks:	*No Value Entered*
	Infrequent Risks:	breach of privacy and confidentiality
	Other Risks:	*No Value Entered*
View	**Research Activity:**	Using E-scale
	Common Risks:	*No Value Entered*
	Infrequent Risks:	Breach of privacy with motion being detected. Height of the bed is increased by approximately 1/2 inch which could make transfers more difficult.
	Other Risks:	*No Value Entered*

5.1.1 **Describe the steps that will be taken to prevent or to minimize the severity of the potential risks:**

Consent, measurements and questionnaires: During all activities of consent, measurements and questionnaires we will provide the subjects will a private location to answer the questions. Subject codes will be used on all data collection forms. All identifiable information will be stored in a locked file room separate from the research data. The only linkage code will be stored on a password protected department server.

Installation and removal of E-scale: The study team will visit the participants' homes to install and remove the E-scale. It is possible that during this time, damage could be caused

to the participant's bed or surrounding areas. The investigator is liable for any damage that occur as a result of participation in the study and damage will be reimbursed accordingly. During the first visit, the investigator will assess the condition of the bed and items placed near the bedside. After such verification, it is to the discretion of the investigator if he wishes to continue with installation of E-Scale or disqualify the participant due to concerns with the bed. IRB # PRO14080007 is a past study using these scales with no adverse events.

Use of E-scale: During the use of the E-scale, the bed height will be raised by approximately 1/2 in when the sensors are under the bed legs. This may make transfers to and from bed more difficult for the wheelchair users. We will describe this risk during the consent process so they are aware and can withdraw from the study if they feel it will be an issue. The E-scale also collects the weight from the bed legs continuously and as such changes in weight distribution may make it possible to detect when the person is in or out of bed and if they are moving. We will also make the participants aware of this risk during the consent process.

Transfers for weighing: During the process of measuring the participant's height and weight, we will have them transfer to a mat table independently or with assistance. During the transfers, we will have a spotter for all transfers and will provide someone who has been trained to assist with transfers help if needed.

Using apps and adobe connect: During the study we will have the participants using the LoseIt! app, the E-scale app and adobe connect. LoseIt! and E-scale apps will be installed on their android device or one will be provided to them to use during the study. Non-personal logins for these devices will be provided to them so that no identifiable information is ever communicated with these apps. Adobe connect will be used to conduct weekly chat sessions with no audio or video being used. We will email the participants a link to join the chat room and ask them to join using their first names only.

5.2 **What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study?**

* **Not Applicable**

5.3 All the risk questions (screening, intervention/interaction, follow-up) have been merged into one question (5.1).

[reviewer notes¬]

5.4 **Do any of the research procedures pose a physical or clinically significant psychological risk to women who are or may be pregnant or to a fetus?**

* No

[reviewer notes¬]

5.5 **Do any of the research procedures pose a potential risk of causing genetic mutations that could lead to birth defects?**

* No

[reviewer notes¬]

5.6 **Are there any alternative procedures or courses of treatment which may be of**

benefit to the subject if they choose not to participate in this study?

* No

If **Yes**, describe in detail:

[reviewer notes¬]

5.7

Describe the specific endpoints (e.g., adverse reactions/events, failure to demonstrate effectiveness, disease progression) or other circumstances (e.g., subject's failure to follow study procedures) that will result in discontinuing a subject's participation?

* Describe below:

If the subject is admitted to the hospital for more than 5 days we will remove them from the study. Also if the subject has not participated in any study procedures for 2 weeks they will be removed from the study.

[reviewer notes¬]

5.8

Will any individuals <u>other</u> than the investigators/research staff involved in the conduct of this research study and authorized representatives of the University Research Conduct and Compliance Office (RCCO) be permitted access to research data/documents (including medical record information) associated with the conduct of this research study?

* Yes

5.8.1

Identify the 'external' persons or entity who may have access to research data/documents and the purpose of this access:

The sponsoring agency (The Paralyzed Veterans of America) may access the research data and documents.

5.8.2

Will these 'external' persons or entity have access to identifiable research data/documents?

*

No; the research data/documents will be coded and subject identifiers removed prior to access by the external persons

If **Yes**, describe how they will protect the confidentiality of the research data:

5.9

Has or will a Federal Certificate of Confidentiality be obtained for this research study?

* No

5.10

Question has been moved to 5.17

5.11

Question has been moved to 5.16

[reviewer notes¬]

5.12 **Does participation in this research study offer the potential for direct benefit to the research subjects?**

Yes - Describe the direct benefit that subjects may receive as a result of study participation. Indicate if all, or only certain, of the subjects may derive this potential benefit.

Describe the benefit:
All subjects may lose weight, which could benefit their overall health

5.13 **Describe the data and safety monitoring plan associated with this study. If the research study involves multiple sites, the plan must address both a local and central review process.**

A data safety and monitoring plan will be implemented to ensure that there are no changes in the benefit/risk ratio during the study and that confidentiality of research data is maintained. All investigators, study personnel, and the clinical coordinators involved in the study will meet quarterly to discuss the study (e.g., study goals, progress, modifications, documentation, recruitment, retention, data analysis, and confidentiality) and address any issues or concerns at this time. The PI holds weekly lab meeting, in which progress is reviewed and issues addressed. Any instances of adverse effects will be reported immediately using the standard forms and/or procedures set forth by the Institutional Review Board. In addition, clinical coordinators will periodically review study documentation and/or consent forms to ensure that subject's confidentiality is maintained. A summary report of all data and safety monitoring activities will be included in the annual IRB renewal application.

[reviewer notes¬]

Section 5 - Potential Risks and Benefits of Study Participation

5.14

What precautions will be used to ensure subject privacy is respected? (e.g. the research intervention will be conducted in a private room; the collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research, so that no unneeded sensitive information is being collected, drapes or other barriers will be used for subjects who are required to disrobe)

During consent and collection of questionnaires and measurements, the subjects will be provided a private space. The collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research, so that no unneeded sensitive information is being collected.

5.15

What precautions will be used to maintain the confidentiality of the research data during collection, transmission and storage? It is important that you indicate the data security measures for all data types.

Go to the A-Z Guidance, download the Data Security Assessment Form, complete, and upload using the Add button below. Depending on the data type, you may need to consult with your data manager to address some of the sections. Email irb@pitt.edu if you have any questions.

* **Upload Data Security Form:**

Name	Modified Date
Data Security Assessment form	10/10/2017 11:04 AM

Address what precautions will be used to maintain the confidentiality of the research data collected in paper format if applicable:
Records will be coded by assigning a case number unique to this study. The linkage code will be stored electronically and not with other paper based files. All electronic data will be stored on the University of Pittsburgh network. Paper based records will be kept in a locked file room within the Human Engineering Research Laboratories. Access to both the electronic and paper based files is restricted to the Principal Investigator and the associated research staff working on the project.

5.15.1

Does your research study require a data security review? Answer Yes if any of the following conditions are met:

- Identifiable or *coded data will be collected, stored, or transmitted using any of the following technologies: mobile app, web-based site or survey, wearable device, text messaging, electronic audio, photographic, or video recording or conferencing **and/or**
- The IRB requested a data security review during their review of the study

* Yes

*__Coded__: Identifying information (such as name) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a code (number, letter, symbol, or any combination) and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens

5.16

If the subject withdraws from the study, describe what, if anything, will happen to the subject's research data or biological specimens.

If the subject withdraws from the study, any existing data will be rendered anonymous and included in results. We will ask the participant to answer the final questionnaire if they are willing to. Because this is a usefulness, feasibility and efficacy trial, even partial data could provide us with useful results.

5.17

Following the required data retention period, describe the procedures utilized to protect subject confidentiality. (e.g., destruction of research records; removal of identifiers; destruction of linkage code information; secured long-term retention)

Following the data retention period, the linkage code file will be deleted. Data will be retained for a longer term using the security measures already outlined in section 5.15.

	Section: Section 6 - Costs and Payments

[reviewer notes¬]

6.1

Will research subjects or their insurance providers be charged for any of the procedures (e.g., screening procedures, research procedures, follow-up procedures) performed for the purpose of this research study?
*
No

[reviewer notes¬]

6.2 **Will subjects be compensated in any way for their participation in this research study?**

* Yes

6.2.1

Describe the amount of payment or other remuneration offered for complete participation in this research study.
200 dollars

6.2.2 **Describe the amount and term of payment or other remuneration that will be provided for partial completion of this research study.**
20 dollars for enrolling (passing the phone screening and coming to the lab to be consented) and being determined ineligible or withdrawing after enrolling
75 dollars for participating for 4 weeks
125 dollars for participating 8 weeks
200 dollars for completing all requirements of the study

	Section: Section 7 - Qualifications and Source(s) of Support

[reviewer notes¬]

7.1

Summarize the qualifications and expertise of the principal investigator and listed co-investigators to perform the procedures outlined in this research study.

Jon Pearlman, PhD is associate professor in the Department of Rehabilitation Science & Technology at the University of Pittsburgh. Dr. Pearlman earned his BS and MS in mechanical engineering at the UC Berkeley and Cornell University, respectively. Dr. Pearlman completed his PhD work Rehabilitation Science and Technology at the University of Pittsburgh in 2007, with an emphasis on assistive technology design and transfer to developing countries. Dr. Pearlman's research interests are in the areas of participatory action design, assistive technology transfer methods, and new product development.

Jonathan Duvall, MS is a graduate student researcher in the Rehabilitation Science and Technology Department at the University of Pittsburgh. He received a BS in Mechanical Engineering and an MS in Rehabilitation Science and Technology from the University of Pittsburgh. This study is a large portion of his dissertation work and he has been approved by his committee to conduct this work.

Patricia Karg received a BS degree in Mechanical Engineering from Lehigh University, and an MS degree in Biomedical Engineering from the University of Virginia. She has broad experience performing clinical research in the area of assistive technology. She performs clinical and laboratory evaluations of technology, maintains data and regulatory records.

Beth Casey Gold, MS,RDN,LDN is a Registered Dietitian with extensive experience leading online behavioral weight management groups. Beth earned her BS in Nutrition at Penn State and her MS in Nutrition and Food Sciences at the University of Vermont where she published on the effectiveness of a structured online behavioral weight loss program compared to a commercially available program.

[reviewer notes¬]

7.2 **Indicate all sources of support for this research study.**

*

Selections
Foundation: Upload a copy of the research plan that was submitted to the agency

If **Federal** support, provide the sponsor information:

Federal sponsor	Grant Title	Grant number	Awardee institution	Federal grant application

For projects not supported by a federal grant, upload the research plan that was submitted for funding:

Name	Modified Date
PVA project narrative	4/20/2017 1:02 PM

If **Industry** support, provide the sponsor information and level of support:

If **Foundation** support, provide the sponsor information:
Paralyzed Veterans of America

If **Other** support, provide the support information and level of support:

[reviewer notes¬]

7.3 **Is this study funded in part or whole by a PHS Agency?**

* No

Does any investigator* involved in this study (select all that apply):

	Name
☐	**A.** Have equity in a **publicly-traded entity** that either sponsors** this research or owns the technology being evaluated or developed that exceeds a **5% ownership interest** or a current value of **$10,000**?
☐	**B.** Have equity in a **non-publicly-traded entity** that either sponsors this research or owns the technology being evaluated or developed?
☐	**C.** Receive salary, consulting fees, honoraria, royalties or other remuneration from an entity that either sponsors this research or owns the technology being evaluated or developed that is expected to exceed **$10,000** during the past or next 12 months?
☑	**D. Have rights as either the author or inventor of intellectual property being evaluated or developed in this research that is the subject of an issued patent or has been optioned or licensed to an entity?**
☐	**E.** Have an officer or management position**** with a **Licensed Start-up Company** overseen by the COI Committee that either sponsors this research or owns the technology being evaluated or developed?
☐	**F.** Receive compensation of any amount when the value of the compensation would be affected by the outcome of this research, such as compensation that is explicitly greater for a favorable outcome than for an unfavorable outcome or compensation in the form of an equity interest in the entity that either sponsors this research or owns the technology being evaluated or developed?
☐	**None** of the above options apply and there are no other financial conflicts of interest in the conduct of this research.

*__Investigator__ means the PI, co-investigators, and any other member of the study team, regardless of title, who participates in the design, conduct, or reporting of this research, as well as his/her spouse, registered domestic partner, dependents, or other members of his/her household. **The PI is responsible for ensuring that s/he and all other relevant members of the study team review the above questions describing Significant Financial Interests.**

****through the provision of funds, drugs, devices, or other support for this research

*****Such as serving on the Board of Directors or Board of Managers or a position that carries a fiduciary responsibility to the company (e.g., CEO, CFO, CTO, or CMO).

7.3.1 **Provide the name of the investigator(s) and describe the nature of the Significant Financial Interest(s):**

Jonathan Pearlman and Jonathan Duvall both are listed as inventors for the E-scale. A PCT

has been filed by the University of Pittsburgh and the technology has been licensed to a start-up company called Nexaware. Neither inventors have equity in the company. Neither Jonathan Pearlman or Jonathan Duvall have received more than $5,000 in royalties.

*

Name Modified Date

[reviewer notes¬]

Supporting Documentation Section

References and Other Attachments

Additional documents:

Name	Modified Date	Version
3-day diary of diet	6/24/2017 3:29 PM	0.01
Script for Physician	6/27/2017 4:32 PM	0.02
System Usability Scale	11/30/2017 4:38 PM	0.01

Please use the Add button to the left to upload additional documents if needed.

[reviewer notes¬]

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

"Applicable clinical trials" are required **by federal law** to be registered in ClinicalTrials.gov.

Applicable Clinical Trials (ACTs) are studies that meet the following criteria:

- The study is an interventional study AND
- The study intervention is a drug, biologic, medical device, radiation or genetic AND
- The Study is not Phase 0 or 1 AND
- The study has at least one site in the United States or is conducted under an investigational new drug application or investigational device exemption

NIH Policy

Effective January 18, 2017, revised NIH Policy requires that all clinical trials funded in whole or in part by the NIH be registered and results information posted on ClinicalTrials.gov.

As defined by the NIH, a clinical trial is:

> *A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health related biomedical or behavioral outcomes.*

The NIH Policy extends beyond the Food and Drug Administration Amendment Act (FDAAA 801) requirements in that it requires registration and results reporting of:

- clinical trials of behavioral, surgical and other types of health and medical interventions
- phase 1 studies of drugs and biological products
- small feasibility studies of device products

Failure to submit all required registration and results information requested on ClinicalTrials.gov can jeopardize University grant funding, the future funding of the grantee and subject the University of Pittsburgh to future monetary penalties.

In addition, to promote transparency of the clinical trials process, the International Committee of Medical Journal Editors (ICMJE) has established a policy requiring the entry of clinical trials in a public registry, such as ClinicalTrials.gov, prior to subject enrollment as a condition of consideration for publication of the trial results.

* **Based on the above information, will this study be registered in ClinicalTrials.gov?**
Yes

Who will serve as the Responsible Party? UPMC/Pitt Investigator or IND/IDE Pitt Sponsor

Why are you registering your study? (Check all that apply)

It is strongly encouraged by the NIH

If you are not yet registered and need to establish an account for the PI or other research staff that may need to access the record, please send an email to the University of Pittsburgh PRS administrator at ctgov@pitt.edu with the following information for each individual:

- Full name
- Telephone number
- Pitt or UPMC email address

If you have any questions or concerns, please email us at ctgov@pitt.edu.

To find out additional information about how to register your study go to:
https://www.clinicaltrials.gov/ct2/manage-recs/how-register