Coverpage

Title: Advancement of Clinical Referral to Physical Activity for Cardiometabolic Disease Prevention

Brief Title: The Clinical Referral to Activity Study

NCT: NCT04743856

Date Created/Modified: November 3, 2025

Basic Study Information

1. * **Title of study:**
Advancement of Clinical Referral to Physical Activity for Cardiometabolic Disease Prevention

2. * **Short title:**
Clinical Referral to Physical Activity:The Clinical Referral to Activity Study

3. * **Brief description:**
The main aim of this effort is to develop and evaluate the efficacy and feasibility of a patient-centered, individually-focused physical activity intervention designed for integration into clinical care. The proposed intervention will be aligned with efforts by the US Centers for Disease Control to increase population physical activity levels and the American College of Sports Medicine (ACSM) to increase physical activity prescription in primary care.

In the first year of the project we will be updating existing ActiveGOALS intervention materials (UPITT IRB STUDY19080212), developing maintenance phase materials, and modifying the materials to fully integrate a body-worn activity monitor into the program. We will also be working with the UPITT CRAB to ensure that recruitment materials are inclusive.

In year 2, We will recruit adult patients (aged 40-70; n=54) of the UPMC General Internal Medicine-Oakland (GIMO) practice not meeting the US aerobic activity goal of 150 minutes/ week of at least moderate intensity physical activity who can safely increase physical activity without supervision and have who also have at least one of the following common cardiometabolic risk factors for which improving physical activity levels can be beneficial (high blood pressure:> 129 mm hg SP or >89 mm hg DP or medication use, high fasting glucose:>100 mg/dl or high HbA1c: ≥42 mmols/mol or medication use, overweight/ obesity: BMI ≥25 kg/m2). As low physical activity levels have been associated with numerous poor cardiometabolic health outcomes, the primary intervention goal will be achievement of the US physical activity goal. Intervention materials will be developed using a patient/provider centered approach and delivered weekly over 3 months via the existing GOALS online platform with participants self-tracking behavior (using a commercial wrist worn activity monitor). An additional 9 months of "maintenance" support will be provided via the GOALS platform and email/phone contact from a coach. Using an online approach will reduce staff and participant burden and will allow for wider dissemination of the program. A prospective randomized, active control design will be used to determine changes in the primary outcomes of objectively measured step counts, % of individuals meeting the moderate-vigorous physical activity goal. Active

control participants will be given a commercial wrist worn activity monitor and information on the CDC activity recommendations.

4. * **What kind of study is this?**
Single-site study

5. * **Will an external IRB act as the IRB of record for this study?**
○ Yes ● **No**

6. * **Local principal investigator:**
Bonny Rockette-Wagner

* **Is this your first submission, as PI, to the Pitt IRB?**
○ Yes ● **No**

7. * **Does the local principal investigator have a financial interest related to this research?**
○ Yes ● **No**

8. **Attach the protocol:**
   - Sponsor/Multicenter/Investigator-initiated protocol
   - Coordinating Center supplement
   - Emergency Use Consent/ Protocol/ FDA Form 3926
   - Exempt Application form

Document Category Date Modified Document History

There are no items to display

View: Pitt SF: Funding Sources (not integrated with Grants)

Funding Sources

1. * **Indicate all sources of support:**
   External funding

2. * **Identify each organization supplying funding for the study:**

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments	Pitt Awardee	Grant Recipient
National Institutes of Health			Grant Application		

Study Scope

Check all that apply

1. * Will this study actively recruit any of the following populations?

- [ ] Adults with impaired decision-making capacity
- [ ] Children (under the applicable law of the jurisdiction in which the research will be conducted (<18 years for PA))
- [ ] Children who are Wards of the State
- [ ] Employees of the University of Pittsburgh/UPMC
- [ ] Medical Students of University of Pittsburgh as primary research group
- [ ] Nursing School Students of University of Pittsburgh as primary research group
- [ ] Students of the University of Pittsburgh
- [ ] Neonates of uncertain viability
- [ ] Non-viable neonates
- [ ] Non-English speakers
- [ ] Nursing home patients in the state of Pennsylvania
- [ ] Pregnant women
- [ ] Prisoners
- [x] N/A

2. * Will any Waivers be requested?

- [ ] Waiver/Alteration of Consent
- [x] Waiver to Document Consent
- [ ] Waiver/Alteration of HIPAA
- [ ] Exception from consent for emergency research
- [ ] N/A

3. * Will this study involve any of the following?

- [ ] Specimens
- [ ] Honest Broker to provide data/specimens
- [x] Return of Results to Subjects or Others
- [ ] Fetal tissue
- [ ] N/A

4. * Will Protected Health Information be collected?

- [ ] Pitt medical records
- [x] UPMC medical records
- [x] Other Institutions' medical records
- [ ] N/A

5. * Other Requests?

- [ ] Deception (if not Exempt, also requires Waiver/Alteration of Consent)

- [ ] Emergency Use / Single Patient Expanded Access (using FDA Form 3926)
- [ ] Placebo Arm
- [ ] Withdraw from usual care
- [x] N/A

6. * **Determining Scientific Review:**
Received External funding where scientific merit was established as a condition of funding

7. * **Has this study (or substantially similar study) been previously disapproved by the Pitt IRB or, to your knowledge, by any other IRB?**
○ Yes ● **No**

Review the HRPO policy, if participating in research at the VA Pittsburgh Healthcare System or using funding from the VA

8. * **Does the study use an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to prevent, diagnose, cure, treat, or mitigate a disease or condition?**
○ Yes ● **No**

9. * **Does the study evaluate the safety or effectiveness of a device (includes in-vitro laboratory assays)?**
○ Yes ● **No**

10. * **Is this application being submitted to convert an approved study from OSIRIS to PittPRO?** (Tip Sheet)
○ Yes ● **No**

11. * **Does your research protocol involve the evaluation or use of procedures that emit ionizing radiation and, after reviewing this** HUSC guidance**, does your research protocol require HUSC review? (If yes, upload the** HUSC form **in the Local Supporting Documents section). If you are unsure of review requirement, select yes.**
○ Yes ● **No**

Research Sites

1. **Choose all sites that apply:**
   University of Pittsburgh
   UPMC

   * **Select the University of Pittsburgh sites where research will be conducted:**
   Main Campus – Pittsburgh

   List university owned off-campus research sites if applicable:
   NA

   * **Select the UPMC sites where research will be conducted:**
   Montefiore
   Presbyterian

2. **Describe the availability of resources and the adequacy of the facilities to conduct this study:**
   We worked with R3 to recruit patients from UPMC- we will not be conducting any research at a UPMC facility. The UPITT Center for Health Equity (CRAB) will also be helping us to develop strategies for minority recruitment and retention- they will not actively participate in recruitment. If needed we will employ community-based recruitment strategies and recruit through Pitt+ME.

   The resources provided by the funding from the National Institutes of Health (specifically NHLBI) are adequate to conduct this study. Appropriate facilities are available to provide the necessary privacy for participants
   and confidentiality for study data. Private space within the department of Epidemiology will be used for clinical assessments.

   Data management will occur through standard procedures of The Clinical and Translational Science Institute (CTSI) Data Center. The CTSI data center provides an exceptional infrastructure for collecting, editing, and storing study data. Data management will follow Data Center policy and procedures. Additional data will be collected and stored through the Redcap. All phone interviews will be conducted from telephones located in private rooms within the University of Pittsburgh Department of Epidemiology.

   The CRHC is a nationally recognized program in health services and clinical research at the University of Pittsburgh. The CRHC 1) provides a forum where ideas can be transformed into projects, 2) assembles multidisciplinary research teams capable of conducting high quality studies in health services research, 3) promotes a broad-based research agenda, 4) encourages collaborative relationships among departments and schools, and 5) trains future leaders and investigators in health services research. The primary goal of the Center for Research on Health Care (CRHC) is to promote and conduct high-quality health services research. The 62 core CRHC faculty members have primary appointments in 18 centers, departments, and schools. In 2009, CRHC core faculty served as principal investigators or co-principal investigators on 108 grants and received research funds exceeding $45 million. It has space for staff and space that can be used for

participant evaluations. The CRHC Data Center (DC) offers wide-ranging data management and analysis services. The DC's mission is to provide the University of Pittsburgh's clinical and health services researchers with consistent, high quality information technology, data management, and statistical services. The DC operates as a team, providing expertise in all phases of research, thus ensuring efficient use of resources. Over the past 5 years, the DC has worked on over 300 research projects, providing data management and statistical support for numerous grants, such as R01, R21, R34, P30, U01, and K awards. With extensive experience, the DC is able to provide research faculty with experts in data management, data entry, programming, and statistical analyses.

UPMC General Internal Medicine Oakland (GIMO) is a well-organized primary care office with an advanced electronic medical record system that allows for virtually paperless operation. The physical space consists of 32 exam rooms. Each room has computer access, including the EpicCare electronic medical record. I have already been working with GIMO and we have added a two-questionnaire activity screener to patient intake forms. This data is now stored in the EHR (as a result of my K12 work).

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Recruitment Methods

* **Will you be recruiting individuals for participation in this study?**
● **Yes** ○ No

1. * **Describe who will be recruiting individuals for participation for this study:**
Primary care patients (n=54) will be recruited primarily from UPMC General Internal Medicine-Oakland (GIMO). Additional patients may be recruited through community-based recruitment efforts and Pitt+Me.

A trained student worker under direct supervision of the study PI will be hired in the last quarter of year 1. This student worker will assist the PI with recruitment efforts. Recruitment may also be conducted by the study PI.

2. * **Select all methods to be used for recruitment:**
Directly approaching potential subjects (in-person)
Email/Listserv/Electronic Mailing List
Flyers/Posters or Brochures
Letters sent to potential participants
Pitt+Me

3. * **Provide details on your recruitment methods:**
Recruitment: Recruitment will take place in year 2 (expected 12 months). Participants will be primarily recruited through UPMC GIMO primary care physician referrals. GIMO has 59 physicians who saw over 21,000 unique adult patients between 7/15 and 7/17. A two question physical activity screener,[71] used by UPMC GIMO at routine care visits, will identify participants with low physical activity (<150 minutes of moderate-vigorous physical activity/week). Referring physicians will determine diagnosis of high blood pressure, high fasting glucose or HbA1c and overweight/obesity (using standard clinical guidelines). Eligible patients will be referred using the practice's standard electronic referral approaches. Referring physicians must note whether moderate physical activity is medically appropriate for patients they refer. Only those with a doctor's approval will be eligible to enroll. This process has been used successful in previous studies. If needed eligible GIMO patients may also be identified through R3 and contacted via email or US mail and community-based strategies including PITT+ME, newsletters/ fliers, (as needed). Also, if needed recruitment events may be held at GIMO in which study staff are available onsite to provide study materials, perform screenings, and answer questions regarding the study. Paper doctor referral forms are also available. These will be sent to individuals eligible based on phone screen who need them after they are phone screened to finish confirming eligibility. A basic study information sheet will be sent to individuals with the physicians referral form. Participants first referred by their physician will be contacted for a phone screen and sent a basic study information sheet (modified for them) at that time if they would like on.

Participants will need to provide verification for diagnosis of a cardiometabolic risk

factor. In the even that their doctor cannot provide verification and no EHR record is available, eligibility will be verified through an in-person screening that would involve height and weight measurement, blood pressure measurement, and onsite HbA1C measurement.

4. * **Describe all compensation/incentives offered to participants and timing of these offers:**
Study participants (n=54) will be reimbursed $30 for completing each assessment visit (including in-person visit, blood draw at Quest, and wearing/returning the research activity monitor). They will also be reimbursed of up to $9 for parking- for each visit. These visits will take place at baseline, 6 and 12 months. Participants will also receive an incentive gift, valued at $15, for completing their 6-month follow-up visit within their 2-week window. Participants completing their 12-month follow-up visit will receive an incentive of being able to keep the activity monitor provided to them as part of the intervention (valued at $100-150) and will receive an incentive gift, valued at $15, for completing their 12-month follow-up visit within their 2-week window.

5. **Recruitment materials:** (attach all material to be seen or heard by subjects, including advertisements and scripts)

Study Aims

1. * **Describe the purpose, specific aims, or objectives and state the hypotheses to be tested:**
The majority of US adults report lower than recommended physical activity (PA) levels.[1] Clinical guidelines from the American Heart Association (AHA), the American Diabetes Association (ADA), and the US Preventive Services Task Force (USPSTF) endorse physical activity for treating common cardiometabolic health conditions including obesity, dyslipidemia, and hypertension. [2-5] Although, clinical advice has been shown to positively affect lifestyle behaviors,[6,7]referral to physical activity by health professionals is relatively new and not part of standard care.[8-11]

Aim: To evaluate an intervention program for physical activity improvement in adult primary care patients with cardiometabolic risk factors. Primary care patients will be recruited (n=54) and randomized to receive a body worn physical activity monitor (PAT) alone or a PAT and ActiveGOALS (v2). The ActiveGOALS core program (uses paper and online tracking; IRB STUDY19080212) is currently being evaluated for use in the general adult clinical population (randomized control trial with 3 month end-point). This new effort will determine success of an updated (v2) core program with integrated use of a body worn monitor as a behavior change tool plus a 9 month maintenance program. Outcomes will be assessed at baseline, 6, and 12 months.
a. We hypothesize that participants randomized to ActiveGOALSv2 + PAT will have significantly larger (a) changes in step counts/day and % meeting moderate-vigorous physical activity goal of 150 minutes/week (to 12 months) compared to the active PAT control group. Primary outcomes will include changes in step/day and meeting the activity goal from validated research-grade PATs. Secondary outcomes will include changes in body weight, blood pressure, glycemic control, and cholesterol from study collected clinical outcomes and health questionnaires.
b. EHR data will also be used to assess program success, including program reach (comparing patients enrolling/not enrolling) and examining relationships between changes in EHR-recorded cardiometabolic outcomes and primary PA outcomes from PATs. Finally, pre-enrollment factors will be examined in relation to program success, toward better future identification of patients who may benefit from referral to programs for PA improvement. Results of this aim will be used toward developing a technology enabled referral system to an appropriate lifestyle intervention strategy with program evaluation methods that use EHR data

2. * **Describe the relevant prior experience and gaps in current knowledge including preliminary data. Provide for the scientific or scholarly background for, rationale for, and significance of the research based on existing literature and how it will add to existing knowledge:**
Advice from clinicians can significantly influence lifestyle behaviors. Following the American College of Sports Medicine, the American Heart Association (AHA) has recently issued a statement endorsing clinical physical activity prescription

programs. [15,18,38] In their statement the AHA outlines advantages of clinical PA advice and referral, including improved patient outcomes and lower healthcare costs.[38] Clinically administered advice on physical activity has also been shown to increase patient satisfaction with clinical care.[6,7] However, the concept of treating low physical activity levels through clinical practice is relatively new and often not part of standard care.[8-11]

This proposal will build on existing efforts to advance physical activity referral within routine clinical care. The inclusion of important stakeholders,[23-26] effective use of existing clinical resources,[27,28] and better integration of technology, including electronic health record (EHR) systems and body worn/ remote monitoring,[25,27-31] may increase the success of clinical physical activity referral programs, respectively. Clinical referral to physical activity is a multifaceted is-sue in which input from a number of different stakeholder groups is likely needed to ensure program success. [38-40] Evidence from surveys of health professionals suggest that existing clinical programs for physical activity advice and referral do not adequately consider the needs of clinical teams;[23-26,41] physical activity prescription programs usually put the burden on the clinician to prescribe and follow-up on patients and on patients to determine how they will reach the prescribed goal. [18,40] While referral to outside community-based programs are typically programs for weight-loss and physical activity (DPP-based), that may provide status updates on weight, but not on physical activity changes.[42] In relation to this, while self-monitoring of lifestyle behaviors has been shown to be an effective tool in behavior change, participants also find it to be difficult and it is not often maintained.[43-46] Most people currently own a PAT-enabled device and 20% of the population may be tracking their physical activity at any given time.[47] With increased interest in PATs, fully integrating them into intervention may help relieve tracking burden on participants and increase pro-gram participation and recruitment.[45] Additionally, integration of data from PATs into clinical EHR systems has been identified as a valuable way of communicating patient physical activity levels, but there is currently no standardized system for doing so.[38,48] We will further existing work by fully integrating PATs into an online lifestyle intervention and by outlining specific procedures for integrating PATs into a local Epic-based EHR. The design process will include important stakeholders, with metrics of stakeholder engagement collected.

We will consider aspects of program development beyond basic physical activity prescription. Most clinical programs for physical activity prescription consist of advice to increase physical activity with a one-time activity prescription, but no problem-solving support or regular contact.[18,49] In a recent meta-analyses, only 3 of the referenced clinical physical activity programs included theory-driven behavioral interventions and of those only one had more than 3 sessions.[49-52] Due to the newness of theory-driven physical activity interventions initiated through clinical practice, it is not surprising that existing pro-grams lack long-term contact and behavior maintenance sessions. This is unfortunate, as evidence is clear regarding the need for long-term contact[53-56] and year-long programs have emerged as the standard of care for lifestyle intervention[.57] Through this work, we will strive to develop programs that are tailored to account for patient and provider needs and are as effective as existing year-long community-based programs.

Finally, we will examine how to best leverage existing clinical data within the EHR in evaluating program success. The ability to use EHR data to determine program

success has the potential to reduce both cost and participant burden and increase feasibility while enabling us to determine long-term program success (possibly years after participation). This goal is consistent with the growing interest in using real world evidence for understanding health and improving care.[58-60]EHR data has been shown to be a useful, cost-effective tool for evaluating physical activity programs and other clinical therapeutic treatments.[38,61-63] Toward this end, we will examine issues of data availability and consider methods for dealing with missing data. We will also examine program participants' changes in physical activity levels and important cardiometabolic outcomes in the EHR and identify patient characteristics (in the EHR) that predict changes in physical activity levels. These results will help guide efforts to utilize EHR data in program evaluation and toward identifying a patient phenotype for referral to physical activity intervention.

Innovation.

• ActiveGOALSv1 is one of the first primary prevention program for physical activity referral designed specifically for use in clinical care with input from patients and clinical health professionals. The proposed K01 research will further innovate ActiveGOALS by incorporating feedback from participants and their clinicians. The new version will also be unique among clinical programs given its year-long duration and behavioral supports. Most clinically focused programs for physical activity improvement are single contact prescription programs (with follow-up at the next annual visit) without gradual goal setting, barrier recognition, or problem solving.

• This proposal departs from previous physical activity prescription efforts by integrating advances in remote mon-itoring/online delivery. The standardized intervention materials with weekly feedback from physical activity coaches, replaces individualized physical activity prescription; improving convenience for patients, lowering burden for clinicians, and increasing real-world feasibility. ActiveGOALSv2 will go beyond any other programs we are aware of by incorporating feedback we have gotten from patients, health specialists, and health systems to fully integrate commercial PATs into the program.

• When combined with a program to make PAT data accessible to health practitioners through the EHR, ActiveGOALS will enable real-time review of patient progress so health teams can provide support to patients' behavior change when it is most helpful and/or convenient (not only at the next office visit). We will use human-centered design practices to develop a novel, inter-disciplinary process de-sign model for making PAT data available to clinical teams in real-time through the EHR. We will include a diverse group of stakeholders in this decision-making process. As the primary end-users, health professionals will be included as advisory team members and through their participation in interviews related to barriers and facilitators of using electronically available PAT data; toward improving clinical care.

• I bring a novel skill set to this research. The additional training received through this K01 will uniquely position me to lead future efforts leveraging available technologies and clinical resources toward developing feasible programs for physical activity referral. I have an in-depth knowledge of body-worn PATs and a strong foundation in public health research. Through my K12, I acquired knowledge of Patient-Centered Outcomes Research. K01 funding will enable me to receive the training an experience that would enable me to utilize quantitative methods when involving stakeholders, to gain expertise in the use of EHR data in assessing clinically-integrated interventions, and to learn how to best utilize PAT output to

encourage behavior change. Process development strategies and pilot intervention data acquired during the K01 will be essential to being able to move forward in my own unique career trajectory.

Study Design

1. **Total number of subjects to be enrolled at this site (enter -1 for chart reviews, banking, registries):**
   54 to undergo research procedures; 200 to undergo screening

2. **Describe and explain the study design:**
   Fifty-four participants will be randomized to one of two groups: physical activity tracker (PAT)+ActiveGOALSv2 or the active control: PAT only.

3. **Describe the primary and secondary study endpoints:**
   1. Average Step Counts per day
   2. % of participants achieving the 150 minute/week aerobic activity goal

   Secondary: changes in body weight, waist circumference, blood pressure, glycemic control (fasting blood glucose and hba1c), and cholesterol (ldl, hdl, triglycerides) from study collected clinical outcomes. Quality of life and PROMIS score from health questionnaire.

4. **Provide a description of the following study timelines:**

   Duration of an individual subject's active participation:
   12-15 months
   Duration anticipated to enroll all subjects:
   12 month enrollment period
   Estimated date for the investigator to complete this study (complete primary analyses):
   12/31/2022

5. **List the inclusion criteria:**
   We will recruit participants aged 40-70 years of age with low physical activity (PA) levels (<150 minutes/week) who also have at least one of the following common cardiometabolic risk factors for which improving physical activity levels can be beneficial (high blood pressure:> 129 mm hg SP or >89 mm hg DP or medication use, high fasting glucose:>100 mg/dl or high HbA1c: ≥42 mmols/mol or medication use, overweight/ obesity: BMI ≥25 kg/m2).
   Eligible participants must be able to access the intervention via the internet, be able to read English at a 6th grade level, and should not have participated in a physical activity intervention program with behavior tracking and goal setting in the past year. They also must have been identified by their referring primary care provider (PCP) as able to increase their physical activity without supervision or provide a physician's permission to do so.

6. **List the exclusion criteria:**
   Participants told by a physician that they have diabetes (other than previous

gestational diabetes) or who have received a diagnosis of cardiovascular disease, regardless of when, (such as coronary artery disease, stroke, arrhythmia, congenital heart defect, cardiomyopathy, abdominal aortic aneurism, or previous myocardial infarction) will not be eligible.

Women currently reporting being pregnant or planning a pregnancy in <12 months and individuals who are non-ambulatory or planning a procedure that will cause them to be non-ambulatory in <12 months will not be eligible. Women who become pregnant during the study will be required to get an updated referral form from their primary care provider (PCP) stating that they are able to increase their physical activity without supervision .

7. **Will children or any gender, racial or ethnic subgroups be explicitly excluded from participation?**

● **Yes** ○ No

* **Identify the subgroups and provide a justification:**

Children are excluded. The physical activity requirements of 150 minutes of physical activity pertain only to adults. The intervention is designed for adults- materials specific to children would have to be designed for children.

8. **Describe the power analysis used and cite your method of statistical analysis. If a power analysis is not possible, thoroughly justify the sample size required for the study, including appropriate literature citation (alternatively provide page reference in attached protocol):**

For our Aim 1a primary outcomes, we hypothesize that participants randomized to ActiveGOALSv2 + PAT will have significantly larger (a) increases in step counts/day and % meeting moderate-vigorous physical activity goal of 150 minutes/week (to 12 months) compared to the active PAT control group. Descriptive analyses and graphic displays will be used to identify outliers, missing data, and pattern of attrition. To ensure rigor, the primary analytic strategy will be a linear or generalized mixed-effect models approach in which treatment group, time, and time by group interaction are treated as fixed effects, and subject is treated as a random effect to account for individual subject variability (two sided hypothesis test; .05 level). Mixed models are applicable to longitudinal datasets that contain missing observations, (assuming data is missing at random). Regression modeling will be conducted to adjust for important covariates. We will perform similar analyses to examine changes in secondary outcomes. Descriptive statistics on patient experience, beliefs/attitudes related to maintenance of physical activity changes, and program cost will also be reported.

Power and sample size: For a 2 sided test with alpha level set at .05, and assuming 20% attrition at 12 months, we plan to recruit 54 participants to identify clinically relevant mean difference between randomized groups at 12-months of 2000 steps/day (with a power of .80), and 35% meeting MVPA goal (with a power of .80), given reference mean (sd) values were calculated from baseline waist worn accelerometer data from the current K12 of: 5250 (2200) steps/ day and we assume 5% meeting goal at baseline in the control group.

For Aim 1b, descriptive statistics will be used to describe the total eligible population, those referred, and those referred who participated in the study; in order to determine program reach. Exploratory Analysis of Important Pre-Existing Factors: Factor analysis will be used to identify importance of factors related to physical activity levels/ activity goal achievement over the 12 month follow-up (Mplus) from participant EHR data collected prior to intervention start. Factor structures of how individual factors contribute to activity outcomes will be explored at each time point. The best factor structure will be determined with Eigenvalues and fit indices (RMSEA, CFI, and TLI). Factor structures at the 2 time points will be compared at three levels to establish measurement invariance: 1) Configural equivalence, number of factors/ pattern of factor-indicator relationships are identical over time; 2) Metric equivalence, factor loadings are equal over time; and 3) Scalar equivalence, means and values are equivalent over time. Finally, we will use descriptive statistics to report presence/absence of data on physical activity levels, cardiometabolic, and patient-centered outcomes in the EHR. We will apply the same regression approaches utilized in Aim 1a to determine differences between randomized groups for EHR reported outcomes.

Research Activities

1. * **Provide a detailed description of all research activities (including screening and follow-up procedures) 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.**
Development: Patient-partners will be recruited in the first 2 months of the study. They will be engaged by working with the PaTH Network's stakeholder engagement infrastructure and will participate in the monthly meetings held by the intervention team. Feedback received on intervention design and delivery, as well as, the need for any addition patient-centered outcomes, will be incorporated into the study design.

   We will work with the UPITT Community Research Advisory Board (CRAB) during months 1-4 to develop recruitment materials. Modification of existing ActiveGOALS materials will take place in months 1-8 (including updated coaching materials). This will also include full-integration of a PAT device. In months 8-12 we will develop the 9 monthly maintenance sessions. Staff hiring and training will take place in months 8-12; this will include at least 1 student worker to help with recruitment and retention and 1 graduate student coach with a background in exercise medicine or physical activity and health. All development will be completed by the end of year 1 of funding.

   Screening: Phone screenings and EHR records will be used to verify eligibility status. During the phone screen participants will be asked to verify their activity status and given a short disability screener to ensure their ability to safely participate. If eligibility for cardiometabolic risk cannot be confirmed via EHR or by a physician potential participants will be able to complete screening in-person, which will involve height and weight measurement, blood pressure reading, and onsite Hba1c testing (if needed) by trained clinic staff. Less invasive screening procedures will be performed first and the in-person screening will end once eligibility in confirmed- regardless of whether all procedures were completed. Height and weight will be taken first, followed by blood pressure, and then Hba1c.

   Weight: Weight will be measured twice without shoes on using a portable scale placed on a hard, flat surface. The subject will be asked to stand in the middle of the scale without touching any surface with eyes straight ahead. The subject will be asked to step down from the scale between measures. If the measures are more than 0.5 pounds apart, a third measure will be taken.

   Height: Height will be measured twice without shoes. The subject will be asked to stand erect under the stadiometer with eyes straight ahead. Subjects will be asked to step down between measures. If the measures are more than one-half inch apart, a third measure will be taken.

   Blood Pressure: Blood pressure will be measured with a validated automated cuff in the right arm with the patient seated comfortably with the right arm resting on a

table. Participants will be asked to rest quietly with feet flat on the floor for five minutes. The cuffed arm will be raised for 5 seconds after each inflation and a wait of 30 seconds will occur between each blood pressure reading. Blood pressure will be repeated twice with the average computed. If it is not possible to measure blood pressure in the right arm, the left arm should be utilized and noted in the patient record.

Hba1c: Hba1c will be assessed using a point of service hba1c monitor. Participants will be seated for the finger stick.Hand warmers may be used prior to the finger stick to ensure good blood flow. A sterile lancet will be used to prick the 3rd or 4th finger tip of the non-dominant hand- after the site has been prepped with a 70% isopropyl alcohol swab and is thoroughly dry. The first drop of blood will not be used, if needed the finger will be gently squeezed to obtain a second drop of free-flowing blood. A fresh finger stick will be applied and inserted into the monitor. Results will be available within 5-10 minutes.

Intervention Delivery:ActiveGOALS uses online self-directed once a week sessions with brief remote personalized e-coaching support. Social-cognitive behavior change theory and related strategies, including barrier recognition and problem-solving are included. There are 13 (20-25 minute) structured educational lessons with interactive workbook pages delivered via the GOALS online platform. After the 13 week “core intervention”, participants will continue to have access to resources on ActiveGOALSv2 for 9 more months and will receive once a month contact including a semi-personalized email from their coach and a link to online materials on a specific behavior maintenance topic (10 minutes in length). Printable workbook pages, resources, and tracking tools will also be available. The topics for the maintenance materials will be determined from output of satisfaction/ experience questionnaires administered to current ActiveGOALSv1 participants (PCOR K12 funded project) and already developed proven maintenance materials from DPP and DPP GOALS.

Brief weekly motivational feedback from a coach (with a physical activity and health or exercise science background) will be provided during the 13 week “core” intervention program via the ActiveGOALSv2 platform. Coaches will also access study administered participant PAT accounts. The coach will set goals in the PAT program to match weekly study goals and will utilize other program features (like reminders and push messaging) according to protocol developed in yr 1 of funding).

The primary behavior tracking tool will be a wrist worn PAT. However, participants will also be provided with paper and online tracking tools for physical activity to track/ report their step counts and activity minutes. I am currently working with Fitbit® monitors in other clinical patient population studies which we plan to use in this study. Currently, Fitbit devices are the most commonly used brand in the US and have been shown to validly and reliably record step counts.[69,70] As done in other studies, we will set-up PAT accounts for participants.

Outcome Assessment: All outcome measures will be collected at all time points (baseline, 6 and 12 months post-intervention) for all participants. After being consented, physical activity levels, clinical, and questionnaire measures will be

collected. Clinic visits should take 30-45 minutes to complete. Blood draws will be performed at a Quest™ lab.

Primary outcomes: Average step counts/day and time spent in moderate-vigorous (MV) physical activity will be collected from validated research grade body-worn PATs; ActiGraph wGT3X+ accelerometer (ActiGraph LLC; Pensaco-la, FL) worn on the waist during waking hours for the 7 days after a clinic visit. These accelerometers have been validated for assessing time spent in physical activity intensities and step counts in laboratory[76-81] and field settings[80,82-84] and are used to validate commercial monitors.[69,70] Data recorded in 1 second epochs will be output as activity counts [85,86] and converted to step counts and time spent in MV physical activity using accepted cut-points.[78,86]

Participants will be given a monitor and instructions (verbal, paper, and online video). Monitors will be returned by mail. Monitor on/off times will be reported via diary. To reduce reactivity, the first day of monitor data will not be used. Four or more days with at least 10 hours of wear/ day will be required for a record to be valid. Participants with incomplete data will be given the opportunity to “rewear” the monitor for a given visit (we expect <8% to require monitor rewear for any given visit; based on previous studies).

Secondary outcomes: Secondary analyses may not be fully powered (at $p<0.05$), but the findings will inform the design of an R01, fully-powered to examine the effect of ActiveGOALSv2 on cardiometabolic outcomes. Height (w/ stadiometer), weight (w/ electronic scale), waist circumference, and blood pressure (w/ automatic cuff) will be taken using validated instruments/techniques employed in previous GLB studies.

Weight: Weight will be measured twice without shoes on using a portable scale placed on a hard, flat surface. The subject will be asked to stand in the middle of the scale without touching any surface with eyes straight ahead. The subject will be asked to step down from the scale between measures. If the measures are more than 0.5 pounds apart, a third measure will be taken.

Height: Height will be measured twice without shoes. The subject will be asked to stand erect under the stadiometer with eyes straight ahead. Subjects will be asked to step down between measures. If the measures are more than one-half inch apart, a third measure will be taken.

Blood Pressure: Blood pressure will be measured with a validated automated cuff in the right arm with the patient seated comfortably with the right arm resting on a table. Participants will be asked to rest quietly with feet flat on the floor for five minutes. The cuffed arm will be raised for 5 seconds after each inflation and a wait of 30 seconds will occur between each blood pressure reading. Blood pressure will be repeated twice with the average computed. If it is not possible to measure blood pressure in the right arm, the left arm should be utilized and noted in the patient record.

Waist Circumference: The participant should be wearing loose clothing and standing

with feet together. Waist is measured using a cloth tape around the abdomen, with midpoints marked horizontally between highest point of the iliac crest and lowest part of the costal margin in the mid-axillary line. Both sides of the waist should be marked. The subject will be asked to have arms at side and to breathe in, out and hold, and then the measurement is taken. Waist measurement is recorded to the nearest quarter inch. The measure will be repeated twice. If waist measures differ by more than one-half inch, a third measurement will be recorded.

In-person clinic visits will be conducted at an on-campus clinic by trained clinic personnel, who will be blinded to randomization arm (to ensure rigor). Participants will be given instructions for the fasting blood draw (8-12 hours). Previously validated questionnaires will be administered (via computer) related to medical history/ medications, demographics/ education, healthy lifestyle habits, self-efficacy/confidence, quality of life (using PROMIS 29 and EQVAX from EQ5D), cost, patient experience; all previously used in the current K12 funded ActiveGOALSv1 study. Additional output from ActiGraph monitors (average minutes/day spent in MV physical activity, light, and sedentary) may be examined, as will data collected from PAT devices and the ActiveGOALSv2 platform. Blood samples (glucose, insulin, LDL and HDL cholesterol, triglycerides) will be drawn and processed at a Quest™ labs. Participants will be encouraged to fast for their appointment and get go to the Quest™ labs near UPITT, but can go to a Quest™ location convenient to them (25+ locations around Pittsburgh), within 10 days after the visit. To control for dietary change, participants will be asked if they attempted weight-loss through dietary change during intervention, questions on sugary beverage, water, vegetable, and protein intake will also be asked

The time commitment for accessing this version of the GOALS program will vary, but will generally not exceed 1 hour each week.

Accessing GOALS. Most participants will choose to access the GOALS website from home; others may do so from work, at a friend or family member’s home, and/or from a public location, such as a library. The GOALS platform is PC- and Mac-compatible only; it does not run on any mobile devices.

Support. Coaches will be available through secure messaging within the GOALS online platform; replies are sent within two business days. Participant progress will be reviewed by the coach at least weekly. Notes will be sent to the participant either in reply to a message or in response to an issue the coach has noted (e.g. failure to log in, tracking problems, etc.). Participants who do not log in for two or more weeks will be called by telephone. If approved by the participant, PCPs are informed when their patients are enrolled. PCPs also receive 3 progress reports (4-6 weeks post-baseline, after the 6 month assessment, and after the 12 month assessment) and are contacted if questions or concerns arise that cannot be resolved by the research team.

3. * **Will blood samples be obtained for research purposes?**

● **Yes** ○ No

* **Provide the volume per withdrawal, total volume and frequency, and qualifications of individual performing the procedure:**

If needed an in-person finger stick will be obtained to determine eligibility to participate based on Hba1c and will only be done once. A 5 µL sample of blood will be taken after finger puncture with a sterile lancet. Results will be reported in less than 10 minutes. This will be done by a trained staff person.

All venipuncture blood draws will be performed at a Quest lab by Quest staff. Quest staff are certified and experienced in drawing blood. This will be performed 3 times during the study (baseline, 6-months, and 12-months visits). Less than 15ml of blood will be drawn at each assessment.

Consent Process

Enter N/A in response to the following questions if a Waiver of Consent is requested for all research activities or if no subjects are being enrolled.

1. * **Indicate where the consent process will take place and at what point consent will be obtained:**
After performing certain screening procedures, but prior to performing any of the research interventions/interactions informed consent will be obtained for the main study.

Screening consent: Screening consent will be obtained verbally over the phone or in-person for in-person screening. The PI or trained study staff will use a script to first obtain consent and then perform a short screening. If a participant must complete a second in-person screening for cardiometabolic eligibility confirmation then an addition written consent for those screening measures will be done prior to the in-person screening.

Main Study Consent: Eligible and interested participants will then be sent a copy of the study consent form to look over. The PI or study staff will then follow-up with the potential participant to see if they have questions and/or are interested in scheduling a baseline visit. In-person consent will be obtained at the baseline visit, prior to any study measures being performed. Consenting will either be done by the study PI or by trained staff using a script.

Individuals will be given the opportunity to ask questions throughout the process.

2. * **Describe the steps that will be taken to minimize coercion and undue influence, including assurance that there is sufficient time for subjects to make an informed decision:**
The study PI, Dr. Rockette-Wagner or a trained staff person will be reviewing the consent process/ form with individuals for both prior to screening and the main research study.

For screening: To avoid coercion potentially eligible participants will be given study information and will contact study staff to initiate the screening process. In the event that study staff are available in-person at GIMO for recruitment, they will not approach patients, but will be willing to discuss the study with interested participants who approach them. Participants will be informed of their rights to end the screening at any time and to refuse to answer any questions. To avoid coercion or undue influence staff will follow a script and will be trained not to deviate from the script. All staff will receive proper training and have completed relevant CITI modules before interacting with participants to reduce the possibility of coercion or undue influence.

Main study consent: To avoid coercion or undue influence eligible individuals will not be consented for the study immediately following the phone screen. Instead after

phone screening, participants will be provided with study information and the consent form by the PI or study staff. Participants will be given as much time as needed to review the consent form on their own and the PI or study staff will be available via phone or through the study email to answer questions regarding study participation. To avoid undo coercion staff will be given a guide to follow when discussing the consent with potential participants. Interested persons who indicate that they would like to sign a consent will be scheduled for an in-person visit at which the consent form will be explained to the participant by trained staff. They will be informed that attending an in-person visit does not obligate them to sign the consent form. Participants will also be informed that this study is separate from their health care and whether they choose to participate in this program or not or withdraw not will not effect their relationship with their healthcare provider or with the University of Pittsburgh. They able to login on their own anytime during open recruitment and consent to participate.

3. **For studies that involve multiple visits, describe the process to ensure ongoing consent:**
At subsequent visits (6 and 12-months) participants will be given the opportunity to ask questions about the consent form. The PI and study staff will also be available throughout the project via phone and email to answer questions about the study consent.

4. * **Steps to be taken to ensure the subjects' understanding:**
The study PI, Dr. Rockette-Wagner or a trained staff person will be reviewing the consent process/ form with individuals for both prior to screening (via telephone) and the main research study (in-person). Participants will be given as much time as they need to make a decision to participants. Participants will be informed of the study purpose, risks/benefits, right to withdraw and voluntary nature of participation.

5. * **Are you requesting an exception to the IRB policy related to the informed consent process:**
● **Yes** ○ No

* **Provide a justification and describe the qualifications of the individuals who will obtain consent:**
This is a minimal risk study. For the phone screening, in-person screening, and main consent, the consenting process will either be conducted by the PI or a trained staff person who has completed all CITI modules for human subjects research and has been trained in the consenting process.

For the main study consent: Eligible participants will be sent a consent form to read. Interested participants will be scheduled for an on-campus clinic visit where they can ask questions and be consented for the study. Baseline measures will be collected at the visit.

Consent Forms

1. **Consent Forms:**

	Document	Category	Date Modified	Document History
View	Inperson Screen Consent(5)	Consent Form	2/23/2022	History
View	Main Study Consent(6)	Consent Form	2/23/2022	History

Refer to the following templates and instructional documents:

- Guidance - Consent Wording
- Template - Consent Document - Short Form
- HRP-090 - SOP - Informed Consent Process for Research
- HRP-091 - SOP - Written Documentation of Consent

Waiver to Document Informed Consent

This waiver to document informed consent can be requested 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, such as with phone screening).

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:

Phone Screening

2. * Select the regulatory criteria applicable to your request:

- ○ 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.
- ● 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
- ○ 45 CFR 46.117(c)(3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm.

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

Initial screening: Interested persons will be contacted by phone. The attached script will be used to complete the telephone screening.

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

We believe that the phone screening involves no more than standard questions that might be asked in scheduling a routine visit for individuals with cardiometabolic risk factors and therefore presents no more than minimal risk of harm to subjects."

3. * Upload Scripts:

	Document	Category	Date Modified	Document History
View	script to schedule in person screen(0.01)	Waiver Script	2/23/2022	History
View	Screening Phone Script_2_22_22.docx(3)	Waiver Script	2/23/2022	History
View	Telephone Screening Guide.docx(0.01)	Waiver Script	4/28/2020	History

Medical Records

1. You are required to submit this study to the Research Informatics Office, Health Record Research Request (R3). Per UPMC Policy HS-RS0005, all research projects that access or involve UPMC electronic protected health information (e-PHI) must be submitted to R3, with the exception of clinical trials that are contracted through the UPMC Office of Sponsored Programs and Research Support (OSPARS).

   Complete the R3 intake form available at http://rio.pitt.edu/services. An R3 representative will conduct a review. You will be notified once your R3 review is complete or if anything further is needed.

*** Describe the protected health information that will be collected from the covered entity and/or the research derived information that will be placed into the medical records:**

Body mass index, blood pressure, and blood glucose and the diagnosis of the following conditions: diabetes, coronary artery disease, stroke, arrhythmia, congenital heart defect, cardiomyopathy, abdominal aortic aneurism, and myocardial infarction will be collected. Reports to physicians will include participant changes in physical activity and session attendance.

2. *** Describe what protected health information will be obtained from a non-UPMC/Pitt covered entity for research purposes and how the HIPAA requirements will be met:**

Only if necessary, to confirm inclusion/exclusion criteria:
Height and weight taken within the last 18 months
Diagnosis of coronary artery disease, stroke, arrhythmia, congenital heart defect, cardiomyopathy, abdominal aortic aneurism, or previous myocardial infarction.
Diagnosis/ current treatment of high blood pressure, pre-diabetes
Recorded blood pressure, Hba1c, blood glucose, cholesterol, triglycerides within the past 18 months.

Information will be requested from the otherwise eligible participant. Individuals who have been screened as eligible from the phone interview, but are not UPMC patients, will be asked to either have their physician sign a statement verifying that they meet the eligibility criteria and identifying which of the three cardiometabolic criteria pertains to them (overweight/obese, high blood pressure, high glucose) or the participant can bring a copy of their medical records showing proper diagnosis/ current treatment of any above listed conditions to an in-person screening that will take place prior to their consent/in-person baseline visit. The reviewing staff member will record the presence/absence of diagnosis/treatment on a de-identified study clinic form, which will be signed by the staff member and verified by another staff member and the study PI. The medical record will be returned to the participant and the de-identified study form will be stored in a secure location with the participant files (in the department of Epidemiology). Use of medical records will also be reported to Dr. Mctigue, who will review the criteria used to determine eligibility/ ineligibility.

Electronic Data Management

1. * **Will only anonymous data be collected (select NO if identifiers will be recorded at anytime during the conduct of the study)?**

○ Yes ● No

Select all identifiers to be collected during any phase of the research including screening:

Name:	☑	**Internet Protocol (IP) Address:**	☐
E-mail address:	☑	**Web Universal Resource Locators (URLs):**	☐
Social security #:	☑	**Social security # (for Vincent payment only):**	☑
Phone/Fax #:	☑	**Full face photo images or comparable images:**	☐
Account #:	☐	**Health plan beneficiary #:**	☐
Medical record #:	☑	**Device identifiers/serial numbers:**	☐
Certificate/license #:	☐	**Vehicle identifiers/serial #/license plate #:**	☐
		Biometric identifiers, finger and voice prints:	☐

* **a: Will you be collecting any of the following location data: geographic subdivisions smaller than a State such as street address, city, county, precinct, zip, geocodes, etc.?** ● **Yes** ○ No

* **b: Will you be collecting any date information such as birth date, death, admission, discharge, date of surgery/service?** ● **Yes** ○ No

c: List any other unique identifying numbers, characteristics or codes related to an individual that are to be collected:

d: Will you be collecting any data subject to the General Data Protection Regulation (GDPR)? ○ Yes ● **No**

* **e: Provide a justification for recording Social Security numbers including why it's required, where it's stored, how it's protected and who will have access:**

Social security numbers may be used to obtain medical record data for a participant.

Data is also collected for Vincent payment. Social security numbers are obtained at the in-person baseline visit and are typed directly into Vincent. They are not written or stored any where else.

* **For ALL identifiable data collected, will you be coding the data by removing the identifiers and assigning a unique study ID/code to protect the identity of the participant?** ● **Yes** ○ No

* **Will the data be** HIPAA de-identified**?**

● **Yes** ○ **No**

* **Briefly describe your plan to store coded data separately from the identifiable data:**

Backup and security policies will help ensure the safety and confidentiality of electronic data. Backup procedures include system backup, daily incremental backup and off-site fireproof storage. Security procedures include logon and link password protection, remote password logon and dial-back modems, and for internet access, separate web servers which use SSL and encryption algorithms. Regularly updated virus scanning software is used routinely to check personal computers for computer viruses. University computing facilities provide support in the event of a disaster. The University maintains confidentiality of patient data and emerging results per a confidentiality policy, which every staff member is required to sign annually.

De-identified data will be stored on a passcoded database on PITT servers. Paper records will be kept in a locked cabinet in a secured room in the graduate school of public health. Identified data will be stored in a separate id passcoded database on Pitt servers and paper records with identified data will be stored in separate files in a locked cabinet within the graduate school of public health

2. **During this study, will restricted data as defined by the University's Data Risk Classification matrix (** https://www.technology.pitt.edu/security/data-risk-classification-and-compliance **) be processed, stored, or transmitted?**

○ Yes ● **No**

3. * **During this study, will sensitive data (**https://www.hrpo.pitt.edu/electronic-data-security**) be collected where disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, educational advancement, reputation or place them at risk for criminal or civil liability?**

● **Yes** ○ No

4. * **Select all locations where data will be stored or archived(including e.g.,** personal / employer laptop or desktop**): If you have access to University owned or controlled resources, facilities, or repositories, such as computer servers, please choose that option to comply with the** Research Data Management Interim Policy R1 14**.**

Please note that to address Research Security Requirements, University data must be stored in University owned, controlled, or approved repositories, such as Pitt OneDrive. If UPMC or external electronic repositories must be used, they must be approved by Pitt IT.

	Storage Device	Description	Identifiable Data	Sensitive Data	De-Identified/Anonymous Data
View	Server: Pitt Department Managed Server	Data accessed on a PITT owned desktop computer may be stored on a server managed by the Epidemiology Department.	yes	no	yes
View	PITT owned desktop, laptop or other device	Data will be accessed from a desktop computer in a secured office in the department of Epidemiology at the University of Pittsburgh.	no	no	yes
View	Other: Storage device/server	RedCAP managed through PITT CHRC.	yes	no	yes
View	Cloud: Pitt Box	Deidentified data may be stored in Pitt Box toward manuscript preparation.	no	yes	yes
View	UPMC: Departmental or Hospital Server	Data on ActiveGOALS program usage will be stored on a UPMC server, managed by PITT CHRC. The online program is stored on the server and collects data on usage minute, as well as, workbook page answers completed by participants.	yes	no	no

5. * **Select all technologies used to collect data, interact with subjects, or store subject data. Technologies selected in this section may require a Vendor Security Risk Assessment, which can be requested** here**.**

Mobile App
Wearable device (also select mobile app if it will be used with the device)
Text messaging
Web-based site, survey, or other tool

6. * **Mobile App – identify all mobile applications, including text messaging apps, used to collect data during any phase of the research:**

name	Identifiable
Fitbit	no

7. * **Wearable Device - identify all wearable devices used to collect data during any phase of the research:**

name	Identifiable
Fitbit wristworn monitor	no
Actigraph GT3x	no

8. * **Text Messaging - Identify all uses of SMS / cellular text messaging:**

name	Identifiable
Text Message	no

9. * **Web Based Technologies – identify all web based technologies to be used to collect data during any phase of the research:**

	name	Identifiable
View	Pitt Redcap Version	
View	Other (survey, tool, etc.)	no

Data Safety and Monitoring

1. * **Describe your plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor:**
   A data and safety monitoring plan will be implemented by the Principal Investigator and her primary mentor (Drs. Rockette-Wagner and Mctigue) to ensure that there are no changes in the risk/benefit ration during the course of the study and that confidentiality of research data is maintained. Each member of the study team will meet with the PI and review confidentiality issues and complete a confidentiality agreement, prior to having contact with research subjects. Investigators and study personnel will meet weekly to discuss the study, including study goals and modifications of those goals, subject recruitment and retention, intervention delivery, progress in data coding and analysis, documentation, identification of adverse events or research subject complaints, and violations of confidentiality) and address any issues or concerns at that time. Minutes will be kept for these meetings and will be maintained in the study regulatory binder. Any instances of adverse events will be reported immediately to the University of Pittsburgh IRB using standard forms and/or procedures that have been established by the IRB.

2. * **Describe your plan for sharing data and/or specimens:**
   Although I do not currently have a data sharing plan, should I decide to share data in the future, I will contact the Office of Research, before sharing de-identified research data/materials to determine whether an agreement needs executed. The research data/documents will be coded and subject identifiers removed prior to access by any external persons.

3. **If any research data is collected, stored, or shared in a paper format, address what precautions will be used to maintain the confidentiality of the data:**
   To maintain the confidentiality of participants' responses, all data gathered, questionnaires, screening information and data forms will be coded with a subject identification number only. A separate file with participants' personal information (e.g., name and phone numbers) will be maintained. All participant information will be stored in a locked file cabinet in the research offices of the University of Pittsburgh. Only the Principal Investigator or a member of this research team will have access to participant files.

   Consent forms that identify the participant by name will be sorted in a locked cabinet separately from the remainder of the data collection forms. The data collection forms will be assigned a code number to identify each participant, and participants will be instructed not to identify themselves by name on any of the forms. The data file linking the names and code numbers will be accessible only to the investigators named on this proposal and their research staff. The data collected from each individual will be entered into a computer file by the code number. If the data are used in scholarly presentations or journal articles, the investigators will protect the anonymity of individual participants and will report only aggregate data (e.g., group

means) where appropriate. The Principal Investigator will review data confidentiality processes periodically or as indicated with the project staff.

Return of Results to Subjects or Others

1. * **Indicate when personal results will be disclosed:**
   - (●) Routinely to all research subjects or others
   - ( ) Only upon the request of a research subject

2. * **Indicate how subjects will be informed of their personal results:**
   Participant results will be mailed via postal mail to the address provided by the participate.

3. * **When will the study results be disclosed?**
   Screening results will be disclosed at the screening visit. Results of clinical assessment measures will be provided within 45 days of receiving all results (from in-person visit and Quest Labs results).

   Individual End-of-Study results will be provided after all study measures are completed on all participants.

4. * **Describe how results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., subject's primary care provider):**
   Individual end-of-study subject results will be provided via mail and will be send to the address provided by the participant. These results will contain a comparison to mean values for the entire study cohort.

   End-of-study results will also be send via postal mail to their referring physician, using the address for the physician provided by the participant. The referring physician will also receive a participant progress report, via postal mail, 4-6 weeks after the participant has started the intervention.

5. * **If applicable, is the laboratory performing the analyses on the biological specimens CLIA certified?**
   Quest Labs in Pittsburgh is CLIA certified. Their liscensure current expires 08-07-20. Lic. #39D0938116.

6. * **Will the banked biological specimens or data derived from them be provided with subject identifiers to any secondary investigators or external entities?**
   ( ) Yes (●) **No**

7. * **Will research subjects be remunerated in the event of the future commercial development of inventions or products based on the research use of their biological specimens?**
   ( ) Yes (●) **No**

Risk and Benefits

1. * **Enter all reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to subjects' participation in the research:**

View

Research Activity	**Clinical Measures- height, weight, waist circumference**
Common Risks	**none**
Infrequent Risks	**There is a minimal risk that measurement of height, weight, and waist could result in psychological discomfort for the participant. No other risks or events are anticipated.**
Other Risks	***No Value Entered***

View

Research Activity	**Clinical measures- blood pressure**
Common Risks	**None**
Infrequent Risks	**There is a minimal risk that blood pressure measurement could result in psychological discomfort for the participant. Tightness or rubbing from the measurement device could also cause temporary discomfort. No other risks or events are anticipated.**
Other Risks	***No Value Entered***

View

Research Activity	**Phone Screening**
Common Risks	**none**
Infrequent Risks	**Questionnaires, Surveys, and Interviews. There is a minimal risk that revealing thoughts and perceptions regarding overall mental and physical functioning could result in psychological discomfort for the participant. No other risks or events related to completing questionnaires or surveys are anticipated. Subjects will be informed that they are free not to answer any questions they do not wish to answer.**
Other Risks	***No Value Entered***

View

Research Activity	**Actigraph GT3x+ monitor**
Common Risks	**None**
Infrequent Risks	**Accelerometer. One potential risk when utilizing the accelerometer although rare, is skin irritation or minimal bruising of the skin from wearing the belt for the accelerometers. It is believed that this should occur in less than 1% of the participants.**
Other Risks	***No Value Entered***

View

Research Activity	**Clinical Measures- Blood Draw**
Common Risks	**None**
Infrequent Risks	**The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting.**

Other Risks	***No Value Entered***

View

Research Activity	**Questionnaires, Surveys, and Interviews**
Common Risks	**none**
Infrequent Risks	**There is a minimal risk that revealing thoughts and perceptions regarding overall mental and physical functioning could result in psychological discomfort for the participant. There is also a minimal risk of breach of confidentiality. No other risks or events related to completing questionnaires or surveys are anticipated.**
Other Risks	***No Value Entered***

View

Research Activity	**Fitbit Monitors**
Common Risks	**None**
Infrequent Risks	**Skin irritation or minimal bruising of the skin can occur from wearing the monitor. If Fitbit monitor data is directly uploaded to the ActiveGOALS platform there is a chance that there could be a breach of data.**
Other Risks	***No Value Entered***

View

Research Activity	**Intervention**
Common Risks	**None**
Infrequent Risks	**Physical Activity. It is possible that subjects will experience physical exertion or physical fatigue from increasing their programmed physical activity and adopting a more physically active lifestyle during the course of the intervention. The potential risks from physical activity range from minor adverse events such as dehydration or electrolyte imbalance , breathlessness, dizziness, nausea, bumps, bruises, muscle soreness, strains, sprains, hyper/hypoglycemia, or asthma attacks to the extremely remote possibility of a fatal event. There may be additional risk of heart problems for those who have a chronic disease or experience symptoms with exercise, although this risk is extremely minimal considering the intensity of the recommended exercise, i.e., walking. The level of exercise recommended in the intervention is thought to be more beneficial than harmful, but there is a very small risk of heart attack or sudden death during exercise. Heart attack has been estimated to occur less than once out of 500,000 hours of exercise in people without known heart disease. The risk is greater in people with heart disease.**
Other Risks	***No Value Entered***

View

Research Activity	**Clinical Measure-Finger Stick**
Common Risks	***No Value Entered***
Infrequent Risks	**The risks of having your blood drawn by finger stick include temporary discomfort from the needle stick, possible bruising or redness of the skin, lightheadedness, and on rare occasion, infection.**
Other Risks	***No Value Entered***

2. * Describe the steps that will be taken to prevent or to minimize risks:

Subjects will be informed that they are under no obligation to participate in the study. They will be informed that they may withdraw at any time. To maintain the

confidentiality of participants' responses, all data gathered, questionnaires, screening information and data forms will be coded with a subject identification number only. A separate file with participants' personal information (e.g., name and phone numbers) will be maintained. All participant information will be stored in a locked file cabinet in the research offices of the University of Pittsburgh. Only the Principal Investigator or a member of this research team will have access to participant files. Participants will be reminded of the possibility that, in addition to access given to Dr. Rockette-Wagner and her research staff, individuals from the agencies funding the research or other appropriate government agencies may be given access to research records. At all times, participant information will be handled in a confidential manner consistent with other research records, and individual names or results will not be specifically identified in any research publication.

Telephone Screening: No identifying information will be collected until the initial screening questions are answered and the individual has expressed interest in the study. All identifiable data collected during screening will be kept in a locked and secure area.

The following section highlights specific plans to protect against potential risks identified in obtaining questionnaires, surveys, and interviews; and finally, physical activity risk:

ActiGraph GT3X+Accelerometer. To help minimize the small risk of skin irritation or bruising from the accelerometer, we will instruct the participants on the proper placement and wear of the belts for the monitors. Additionally, participants will be instructed to contact the research staff in the event of skin irritation so that we can have the opportunity to reinstruct the participant on proper wear. Monitors will not contain identifiable information and no monitor data will be transferred electronically. Mail back envelopes for monitors will be pre-addressed with the study site information- labels will not contain participant names or addresses.
Fitbit monitors: To help minimize the small risk of skin irritation or bruising from the accelerometer, we will instruct the participants on the proper placement and wear of the monitors. Monitors will not contain identifiable information. Paticipants using Fitbit data will be required to upload data, but will also be given the option to hand-enter the data. In the case that data is uploaded, it will be uploaded directly to the secured ActiveGOALS platform using an API developed by programmers at the CRHC data center.

Clinic Measures: Questionnaires, Surveys, and Interviews: Staff will be trained to be sensitive to the risk of participant embarrassment or other psychological discomfort when administering surveys. They will speak with subjects quietly and work to ensure confidentiality of the information. In addition, subjects may refuse to answer questions that are distressing or anxiety provoking and will be provided the opportunity to discuss any question with the Principal Investigator and study staff under her supervision. Subjects will be informed that they are free not to answer any questions they do not wish to answer.

Blood Samples: If an HbA1c is needed to confirm eligibility: A laboratory technician who is proficient at finger stick will collect the sample. Participants will be seated and

made comfortable and monitored for any ill effects. For the baseline and follow-up venipuncture: A Quest laboratory technician who is proficient at venipuncture will collect the sample. Participants will be seated and made comfortable and monitored for any ill effects.

Physical Activity Intervention: The potential risks during intervention are minimized by including in the study only those individuals who are in sufficient physical condition (confirmed by having physician approval) to participate in the intervention. However, this risk is mitigated by the fact that most subjects will adopt a safe and progressive walking routine (30 minutes per day, 5 days per week). In addition, subjects are initially referred by their physician and are advised to contact their primary care physician if they develop diabetes, heart disease or other related health problems during the study that their primary care physician is unaware of. Participants will be informed that they are free to withdraw from the study at any time. Cases of dehydration or electrolyte imbalance caused by physical exertion can be prevented or ameliorated with timely fluid intake and replacement. All physical assessment staff and physical activity intervention coaches will be certified annually in CPR and First Aid training. Intervention coaches will be required to have a background in physical activity and health or exercise physiology. Any injury or complication will be immediately reported and all appropriate emergency procedures will be followed. The PI and her primary mentor, as well as the onsite providers, will be available to help staff make decisions regarding the need for emergent medical care.

Data analyses will be conducted on de-identified data. Research records including identifiable data will be securely stored for seven years. Data will be anonymized, and the link destroyed (shredded) after this time.

Data Collection: All efforts will be made to keep patient information private including use of identification numbers, keeping charts secure and identifiable information separate.

ActiveGOALS platform data: Tracking data and data on platform usage will be collected and stored on a secure server at the University of Pittsburgh Center for Research on Health Care (CRHC) data center.

3. **Financial risks - will the subject or insurer be charged for any research required procedures?**
   ○ Yes ● **No**

4. **Describe the steps that will be taken to protect subjects' privacy:**
   A private room will be used for all clinic assessments.

5. **What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the study:**
   Individuals identified with a clinically significant, unexpected condition such as

glucose level in the diabetes range or greatly elevated lipid results will be
1) Given their results with a clear explanation of the problem, and
2) Advised to follow up with their health care provider as soon as possible.

6. Describe the potential benefit that individual subjects may experience from taking part in the research or indicate if there is no direct benefit. Do not include benefits to society or others:

Participants may not receive any benefit from taking part in this project. Intensive lifestyle interventions containing a physical activity component have been shown to reduce the onset of type 2 diabetes and the metabolic syndrome. Participation in this study may help reduce the risk of developing diabetes and/or cardiovascular disease. Participation in this study may benefit society by leading to the development of a feasible clinical prescription program for physical activity and sedentary behavior improvement that could reduce risk factors for diabetes and cardiovascular disease as well as other conditions for which physical activity has been shown to be beneficial.

Accomplishing the goals set out by this proposal will have the potential for making a feasible prescription program for physical activity and sedentary behavior improvement available for use within clinical practice (and throughout large health systems. This information could be used toward the development of future intervention strategies that are feasible for adult clinical care patients.

7. Do you anticipate any circumstances under which subjects might be withdrawn from the research without their consent?

● **Yes** ○ No

* **Describe the circumstances and any procedures for orderly termination:**

If for some reason they are unable to complete the majority of the sessions. If their health status changes, it is also possible that their referring physician could withdraw their permission for participant.

8. Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection and data already collected:

Any identifiable research or medical information recorded for, or resulting from, participation in the study prior to the date the participant formally withdraws consent may continue to be used and disclosed by the investigators for the purposes described in the study protocol.

Ancillary Reviews

1. **Ancillary reviews or notifications selected below are required based on previous answers to questions. If a selection is incorrect, return to the appropriate page and adjust the answers to questions on that page:**

- [ ] Conflict of Interest (**COI**)
- [ ] Clinical and Translational Research Center (**CTRC**)
- [x] Data Security
- [ ] Honest Broker
- [ ] UPMC Investigational Drug Service
- [ ] Pitt Medical School Review
- [ ] Pitt Nursing School Review
- [x] Pitt+Me
- [ ] IND & IDE SUPPORT (**IIS**)
- [ ] Radioactive Drug Research Committee (**RDRC**)(study involves the evaluation or use of procedures that emit ionizing radiation)
- [ ] RCCO Business **Manager** (required for industry sponsored studies)
- [ ] Religious Directives
- [ ] Scientific Review
- [x] Health Record Research Request (**R3**) (required if using UPMC clinical data and authorization for other UPMC data sources for research)
- [x] UPMC Office of Sponsored Programs and Research **Support** (using UPMC facilities and/or UPMC patients during the conduct of the study)

2. **Additional ancillary reviews the PI may choose to include as needed for the research:**

- [ ] Human Stem Cell Oversight (**hSCRO**)
- [ ] Institutional Biosafety Committee (**IBC**)(study involves deliberate transfer of recombinant or synthetic nucleic acid molecules)

Good Clinical Practice (GCP) Training

1. * **Regardless of funding source, is this study a clinical trial (**as defined by the NIH**)?**
   - ● **Yes** ○ No

ClinicalTrials.gov Information

Visit the University of Pittsburgh Office for ClinicalTrials.gov website or contact ctgov@pitt.edu for further information.

1. * **Was this study registered, or will it be registered, on ClinicalTrials.gov?**
   - ● **Yes** ○ No

2. * **Is the University of Pittsburgh or UPMC the Sponsor Organization for this study record?**
   - ● **Yes** ○ No

   * **Who will be the Responsible Party for this study record?**

   Principal Investigator of this IRB application

Clinical Study Registry (CSR)

Visit the Health Sciences managed Clinical Trials Office website or contact CTOHelp@pitt.edu for further information regarding health sciences studies that must be registered.

1. * **Has this study been registered with Clinical Study Registry maintained by Pitt's Clinical Trials Office within the Health Sciences?**

Add Storage Information

1. * **Select a Storage Type:**
   Server: Pitt Department Managed Server

2. **Description:**
   Data accessed on a PITT owned desktop computer may be stored on a server managed by the Epidemiology Department.

3. * **Will identifiable data be stored in this location?**
   ● **Yes** ○ No

4. * **Will sensitive data be stored in this location?**
   ○ Yes ● **No**

5. **Will de-Identified or anonymous data be stored in this location?**
   ● **Yes** ○ No

6. **Provide additional information as needed:**
   Information for recruitment (including name, address, phone, email) will be stored on the PITT server in a secure location with limited access. Deidentified datasets will also be stored on the PITT server in a seperate secured location with limited access.

Add Storage Information

1. * **Select a Storage Type:**
   PITT owned desktop, laptop or other device

2. **Description:**
   Data will be accessed from a desktop computer in a secured office in the department of Epidemiology at the University of Pittsburgh.

3. * **Will identifiable data be stored in this location?**
   ○ Yes ● **No**

4. * **Will sensitive data be stored in this location?**
   ○ Yes ● **No**

5. **Will de-Identified or anonymous data be stored in this location?**
   ● **Yes** ○ No

6. * **Is anti-virus software installed and up to date on all devices and are the operating systems kept up-to-date on all devices?**
   ● **Yes** ○ No

7. **Provide additional information as needed:**

Add Storage Information

1. * **Select a Storage Type:**
   Other: Storage device/server

2. **Description:**
   RedCAP managed through PITT CHRC.

3. * **Will identifiable data be stored in this location?**
   ● **Yes** ○ No

4. * **Will sensitive data be stored in this location?**
   ○ Yes ● **No**

   * **Define your encryption methods:**
   - **BitLocker (Windows)** (Turn on device encryption)
   - **File Vault (Mac)** (Use FileVault to encrypt the startup disk on your Mac)
   - **SecureZIP** (SecureZIP: Getting Started (Windows) | University of Pittsburgh)

   Backup and security policies will help ensure the safety and confidentiality of electronic data. Backup procedures include system backup, daily incremental backup and off-site fireproof storage. Security procedures include logon and link password protection, remote password logon and dial-back modems, and for internet access, separate web servers which use SSL and encryption algorithms. Regularly updated virus scanning software is used routinely to check personal computers for computer viruses. University computing facilities provide support in the event of a disaster. The University maintains confidentiality of patient data and emerging results per a confidentiality policy, which every staff member is required to sign annually.

5. **Will de-Identified or anonymous data be stored in this location?**
   ● **Yes** ○ No

6. **Provide additional information as needed:**
   The RedCAP database is the main storage database for the project. The database is passcoded and access to identified data is further restricted within the project file.

Add Storage Information

1. * **Select a Storage Type:**
   Cloud: Pitt Box

2. **Description:**
   Deidentified data may be stored in Pitt Box toward manuscript preparation.

3. * **Will identifiable data be stored in this location?**
   ○ Yes ● **No**

4. * **Will sensitive data be stored in this location?**
   ● **Yes** ○ No

5. **Will de-Identified or anonymous data be stored in this location?**
   ● **Yes** ○ No

6. **Provide additional information as needed:**
   Deidentified data, using study assigned ID #s may be stored in Pitt box-toward manuscript preparation. This could include the resuts of clinical study mesaures and blood draw. Additional diagnosis from self-report and EHR data could also be stored here (all deidentified). Most deidentified data stored in Pitt Box will be grouped data, not individual level data. All data will be removed from the box after manuscript completion.

7. **Will access to the files or folders be restricted to only those research team members involved in the study(e.g., Specific people are granted access)?**
   ○ Yes ○ No

Add Storage Information

1. * **Select a Storage Type:**
   UPMC: Departmental or Hospital Server

2. **Description:**
   Data on ActiveGOALS program usage will be stored on a UPMC server, managed by PITT CHRC. The online program is stored on the server and collects data on usage minute, as well as, workbook page answers completed by participants.

3. * **Will identifiable data be stored in this location?**
   ● **Yes** ○ No

4. * **Will sensitive data be stored in this location?**
   ○ Yes ● **No**

5. **Will de-Identified or anonymous data be stored in this location?**
   ○ Yes ● **No**

6. **Provide additional information as needed:**
   Participants are identified by name in the program and interact with their coach through the platform, using their names. Study assigned ids are not stored in the ActiveGOALS program.

   Backup and security policies will help ensure the safety and confidentiality of electronic data. Backup procedures include system backup, daily incremental backup and off-site fireproof storage. Security procedures include logon and link password protection, remote password logon and dial-back modems, and for internet access, separate web servers which use SSL and encryption algorithms. Regularly updated virus scanning software is used routinely to check personal computers for computer viruses. University computing facilities provide support in the event of a disaster. The University maintains confidentiality of patient data and emerging results per a confidentiality policy, which every staff member is required to sign annually.

View: Pitt Risk

Risk

1. * **Research Activity:**
   Clinical Measures- height, weight, waist circumference

2. **Common Risks:**
   none

3. **Infrequent Risks:**
   There is a minimal risk that measurement of height, weight, and waist could result in psychological discomfort for the participant. No other risks or events are anticipated.

4. **Other Risks:**

Risk

1. * **Research Activity:**
   Clinical measures- blood pressure

2. **Common Risks:**
   None

3. **Infrequent Risks:**
   There is a minimal risk that blood pressure measurement could result in psychological discomfort for the participant. Tightness or rubbing from the measurement device could also cause temporary discomfort. No other risks or events are anticipated.

4. **Other Risks:**

Risk

1. * **Research Activity:**
   Phone Screening

2. **Common Risks:**
   none

3. **Infrequent Risks:**
   Questionnaires, Surveys, and Interviews. There is a minimal risk that revealing thoughts and perceptions regarding overall mental and physical functioning could result in psychological discomfort for the participant. No other risks or events related to completing questionnaires or surveys are anticipated. Subjects will be informed that they are free not to answer any questions they do not wish to answer.

4. **Other Risks:**

View: Pitt Risk

Risk

1. * **Research Activity:**
   Actigraph GT3x+ monitor

2. **Common Risks:**
   None

3. **Infrequent Risks:**
   Accelerometer. One potential risk when utilizing the accelerometer although rare, is skin irritation or minimal bruising of the skin from wearing the belt for the accelerometers. It is believed that this should occur in less than 1% of the participants.

4. **Other Risks:**

Risk

1. * **Research Activity:**
   Clinical Measures- Blood Draw

2. **Common Risks:**
   None

3. **Infrequent Risks:**
   The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting.

4. **Other Risks:**

Risk

1. * **Research Activity:**
   Questionnaires, Surveys, and Interviews

2. **Common Risks:**
   none

3. **Infrequent Risks:**
   There is a minimal risk that revealing thoughts and perceptions regarding overall mental and physical functioning could result in psychological discomfort for the participant. There is also a minimal risk of breach of confidentiality. No other risks or events related to completing questionnaires or surveys are anticipated.

4. **Other Risks:**

Risk

1. * **Research Activity:**
   Fitbit Monitors

2. **Common Risks:**
   None

3. **Infrequent Risks:**
   Skin irritation or minimal bruising of the skin can occur from wearing the monitor. If Fitbit monitor data is directly uploaded to the ActiveGOALS platform there is a chance that there could be a breach of data.

4. **Other Risks:**

Risk

1. * **Research Activity:**
   Intervention

2. **Common Risks:**
   None

3. **Infrequent Risks:**
   Physical Activity. It is possible that subjects will experience physical exertion or physical fatigue from increasing their programmed physical activity and adopting a more physically active lifestyle during the course of the intervention. The potential risks from physical activity range from minor adverse events such as dehydration or electrolyte imbalance , breathlessness, dizziness, nausea, bumps, bruises, muscle soreness, strains, sprains, hyper/hypoglycemia, or asthma attacks to the extremely remote possibility of a fatal event. There may be additional risk of heart problems for those who have a chronic disease or experience symptoms with exercise, although this risk is extremely minimal considering the intensity of the recommended exercise, i.e., walking. The level of exercise recommended in the intervention is thought to be more beneficial than harmful, but there is a very small risk of heart attack or sudden death during exercise. Heart attack has been estimated to occur less than once out of 500,000 hours of exercise in people without known heart disease. The risk is greater in people with heart disease.

4. **Other Risks:**

Risk

1. * **Research Activity:**
   Clinical Measure-Finger Stick

2. **Common Risks:**

3. **Infrequent Risks:**
   The risks of having your blood drawn by finger stick include temporary discomfort from the needle stick, possible bruising or redness of the skin, lightheadedness, and on rare occasion, infection.

4. **Other Risks:**