IRB# _____ Date Submitted: 12/08/2023
(The above to be completed by the IRB Office)

SYRACUSE UNIVERSITY
INSTITUTIONAL REVIEW BOARD
Full Board Review or Expedited Review Application

Check which type of review is requested:

☒ Expedited Review- One signed copy of my application for **expedited** review.
Expedited review covers research that involves only minimal risk procedures. See Standard Operating Procedure 012. http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-012-Expedited.pdf for guidance.

☐ Full Board Review- One signed copy of my application for **full board** review.
Includes research that cannot be reviewed using the expedited process involving more than minimal risk to the participant and requires review by the full IRB. See Standard Operating Procedure 013. http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-013-Full-Board.pdf for guidance.

Application Checklist:

☒ All questions on the application have been answered.

☒ The application has been signed by the investigator/faculty advisor and when appropriate, the student.

☒ Copies of all appropriate, consent and/or assent documents (written, electronic, or oral consent script) are included.

☒ Copies of any research instruments (surveys, questionnaires, interview questions, etc.) are included.

☒ Copies of all recruitment tools (flyers, emails, posters, newspaper ads, etc.) are included.

☒ All required appendices, including a list of references are included.

☒ Copies of other IRB approvals or letters of cooperation are included. When the investigation is to be carried out in cooperation with another institution or with an investigator at another institution, a letter indicating the willingness of the institution to cooperate in the study must be included with the proposal.

☒ The principal investigator/faculty member and student/research staff have completed the appropriate **C**ollaborative **I**nstitutional **T**raining **I**nitiative (CITI) Web-based Training Program for Human Subjects required by SU.*

☒ All students/research staff or any other individuals listed in the application who will have direct contact with participants and/or identifiable human participant data have completed the appropriate **C**ollaborative **I**nstitutional **T**raining **I**nitiative (CITI) Web-based Training Program for Human Subjects required by SU.*

* Submission of CITI Training Certificate is required **only** if CITI training was completed at another institution.

I/We assure the IRB that the following statements are true: All information provided in this form is correct. I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as appropriately trained staff, necessary facilities and equipment. I will seek and obtain prior written approval from the IRB for ***any modifications*** including changes in procedures, investigators/research staff, consent forms, questionnaires, surveys, etc. I will promptly report any unanticipated problems that may occur in the course of this study. I will report any significant findings which may affect the risks and benefits to participation. I will not begin my research until I have received written notification of final IRB approval. I will comply with all IRB requests to report on the status of my study. I will maintain records of this research according to IRB standards. If any of the above conditions are not met, I understand that approval of this research may be suspended or terminated.

Faculty Member/Principal Investigator

Signed_____ Date: 12/6/2023
Name (typed): Joon Young Kim

Student/Research Staff

Signed: Wonhee Cho Date: 12/6/2023
Name (typed): Wonhee Cho

Signed: Alaina Galsgow Date: 12/6/2023
Name (typed): Alaina Galsgow

Signed: Andrew Heckel Date: 12/6/2023
Name (typed): Andrew Heckel

Signed: Eleanor Date: 2/14/2024
Name (typed): Eleanor Kwacz

Signed: Julianna Date: 10/08/2024
Name (typed): Julianna Verni

This application must be typewritten and all questions must be answered. To complete form, tab to each field. Incomplete forms will be returned to the investigator for additional information. Outdated applications will not be accepted for review.

To edit the content of the form/unprotect the document as follows:

Microsoft Office Users

Unlock Document:

- Open the Document, Click the ***Enable Editing*** box and/or select the ***View*** Tab and select ***Edit***, on the Ribbon across the top choose the ***Review*** Tab>Click on ***Restrict Editing*** (Image of Paper/Lock)>Select box for ***Stop Protection*** (at the very bottom of the page). Leave the side bar open until you have completed your edits.

Protect Document:

- Once your edits to the document have been completed, to protect or re-lock the document please ensure the following boxes are checked on the right hand side:
  1. Formatting restrictions [Limit formatting to a selection of styles],
  2. Editing restrictions [Allow only this type of editing in the document:], drop down to second option ***Filling in Forms***
  3. Start enforcement click the box Yes, Start Enforcing Protection.
  Click ***OK*** with no password entered at the prompt.

1. Protocol Information

Title of Protocol: Differential effects of HIIT vs. TRE on type 2 diabetes risk in youth and younger adults.

Principal Investigator Eligibility: Faculty at the assistant, associate, or full professor level, academic, research, or professor-of-practice faculty, department chair/dean, or administrative staff with the position of director or higher may serve as the Principal Investigator (PI) or Co-Investigator (Co-PI). If you have any questions regarding this Syracuse University institutional policy, call the IRB office at 315.443.3013 for guidance.

Principal Investigator/Faculty Member Information

First Name: Joon Young	Middle Initial:	Last Name: Kim
Title: Assistant Professor		
Department: Exercise Science	College: David B. Falk College of Sport and Human Dynamics	
Campus Address: 430 White Hall, Room 430H		
Campus Phone : x1411	Fax : 315-443-9375	
Email: jkim291@syr.edu	Cell Phone (optional):	

Student/Research Staff Information ☐ **NA**

First Name: Wonhee	Last Name: Cho
☒ Graduate Student ☐ Undergraduate Student ☐ Other:	
Department: Exercise Science	College: David B. Falk College of Sport and Human Dynamics
Local/Campus Address: 820 Comstock Ave	
Local/Campus Phone:	Fax: 315.443.9375
Email: wcho02@syr.edu	Cell Phone (optional): 626.727.0270

First Name: Alaina	Last Name: Glasgow
☒ Graduate Student ☐ Undergraduate Student ☐ Other:	
Department: Exercise Science	College: David B. Falk College of Sport and Human Dynamics
Local/Campus Address: 820 Comstock Ave	
Local/Campus Phone:	Fax:
Email: acglasgo@syr.edu	Cell Phone (optional): 330.671.0811

First Name: Andrew	Last Name: Heckel
☒ Graduate Student ☐ Undergraduate Student ☐ Other:	
Department: Exercise Science	College: David B. Falk College of Sport and Human Dynamics
Local/Campus Address: 820 Comstock Ave	
Local/Campus Phone:	Fax: 315.443.9375
Email: arheckel@syr.edu	Cell Phone (optional): 904.382.9961

First Name: Eleanor	Last Name: Kwacz
☐ Graduate Student ☒ Undergraduate Student ☐ Other:	
Department: Exercise Science	College: David B. Falk College of Sport and Human Dynamics
Local/Campus Address: 820 Comstock Ave	
Local/Campus Phone:	Fax: 315.443.9375
Email: ekkwacz@syr.edu	Cell Phone (optional):

First Name: Julianna	Last Name: Verni
☐ Graduate Student ☒ Undergraduate Student ☐ Other:	
Department: Biology	College: College of Arts and Sciences
Local/Campus Address: 107 College Pl	
Local/Campus Phone:	Fax: 315.443.9375
Email: jmverni@syr.edu	Cell Phone (optional):

2. Funding Information

2.1. Will/has the research been submitted as a grant or contract proposal? ☒ **No** ☐ **Yes**

Will/has the research been submitted through OSP? ☒ **No** ☐ **Yes**

If yes, who is the proposed sponsor and what is the title of the proposal submitted to OSP?

Sponsor: _____

Title: _____

2.2. Is this research currently being funded in part or in whole? ☐ **No** ☒ **Yes (indicate below)**

☒ **Internal Funding (check all that apply):**

☐ **Departmental Funds**	☐ **No cost study**	☐ **Personal Funds**
☐ **Gifts**	☒ **Other, specify:** Dr. Kim's start-up funds	

☐ **External Funding (list all that apply and insert additional rows if needed):**

Agency/Sponsor	**Funding Mechanisms**	
_____	☐ **Grant**	☐ **Contract**
_____	☐ **Grant**	☐ **Contract**

2.3. Is this research to be performed:

for faculty research	☐ **No**	☒ **Yes**
for a masters thesis	☒ **No**	☐ **Yes**
for a doctoral dissertation	☐ **No**	☒ **Yes**
for an honors thesis	☒ **No**	☐ **Yes**
for undergraduate research	☒ **No**	☐ **Yes** **If Yes, please choose one of the options below:**

This research will be conducted as part of a course requirement:

☐ **It is a student project designed as a systematic investigation that will lead to generalizable knowledge (i.e.-Capstone /Honor's /SOURCE Thesis, or other student work generated as a result of this research that will be displayed on the SU website, shared at workshop/conference, or shared outside of the classroom and/or Syracuse University community at a conference/workshop, etc.).**

OR

☐ **It is a student project designed solely to fulfill a course requirement.**
Student projects involving human participants that are conducted solely to fulfill course requirements and to receive a course grade and will not be shared outside the classroom and/or the Syracuse University community do not require IRB review. For additional information please consult: **Student-Projects**

☐ **None of the above. Other purpose (explain):** _____

NOTE REGARDING APPLICATON PREPARATION: When there is more than one researcher listed in the protocol as part of the research team, please avoid the use of pronouns or references to "the research team/member/s of the research team" or the use of similar terminology. Instead, all such references should include the names of the members of the research team listed in either Sections 1 or 6 of the protocol application as appropriate.

3. Study Rationale

3.1. Using non-technical language, describe the objective of this proposed research including purpose, research question, hypothesis, etc. From your description, the IRB should be able to determine how this proposed study adds to the knowledge on the research topic in order to judge the risks and benefits to the research participants. NOTE: A reference list citing relevant background information must be provided as an appendix with this application.

As of 2015 an estimated 2 billion individuals were overweight (body mass index [BMI] $\geq$ 25 kg/m^2) and one third of them obese (BMI $\geq$ 30 kg/m^2).[1] Obesity has become a serious health concern due to its related comorbidities including cardiovascular disease (CVD), and type 2 diabetes (T2D).[2–5] While adolescents and young adults are considered low risk for development of CVD, individuals with obesity are still are greater risk of CVD development

than individuals without obesity.[6] Changes to dietary and fitness habits are currently the first line recommendations to prevent weight gain and improve cardiometabolic health in adolescents and young adults.[7]

Caloric restriction (CR) (reducing caloric intake up to 50% of normal calorie intake per day)[8] is a common dietary interventional approach for weight management and cardiometabolic health improvement in adolescents and adults with obesity.[9] However, studies have shown that CR is hard to maintain, and individuals tend to re-gain the weight after the intervention is completed.[10] Time restricted eating (TRE) has been suggested as an alternative to CR.[11] TRE, a type of short-term fasting, is defined as periods of no energy (calories) intake followed by periods of ad libitum (as much as desired) energy intake.[12] The fact that TRE does not intentionally limit energy intake, while CR does, could make it more appealing to individuals with respective to adherence, acceptability and efficacy.[13] TRE has been shown to be an effective strategy in reducing body fat percentage and waist circumference in adolescents and adults with obestiy.[13,14]

Moreover, high-intensity interval training (HIIT), repetitions of a short period of intense activity followed by a low intensity break, has shown to be effective in improving cardiometabolic health (including lipids, blood pressure, and insulin sensitivity) in adults with obesity compared with other traditional exercise.[15] In addition to its benefits on cardiometabolic health, previous studies have suggested that HIIT can be a time-efficient strategy to enhance body composition and cardiopulmonary fitness in adults with obesity.[16]

However, it is unknown if TRE or HIIT will produce a greater improvement of cardiometabolic health. Therefore, the goal of this proposed study is to examine the independent and combined effects of a 4-week TRE and HIIT intervention on cardiometabolic biomarkers in adolescents and young adults.

4. Methods

4.1. Provide a detailed description of what participants will be required to do; including any technical terms or procedures.

Participants: A total of 50 adolescents (age 14-17 years old with sex- and race-specific BMI percentile $\geq 85^{th}$) and young adults with overweight and obesity (age 18 to 30 years old with BMI ≥ 25 kg/m^2) will be recruited for the study. This is a randomized control trial with 50 participants randomly being assigned into 3 groups: TRE intervention (n=20) or HIIT intervention (n=20), and control (n=10). The following below outlines what participants will be asked to do during each lab visit and during the 4-week of intervention.

A) Pre-lab Contacts:

Participants will be recruited via flyers and social media posting. Those who are interested in participating in the study will tell the researchers if they are interested in participating in the research study or will reach out via email. We will explain the purpose of the study, as well as study procedures to the potential participant. We will also provide copies of the written consent document and confirm that participants meet the inclusion criteria during this initial exchange. During this initial exchange, we will verify that the potential participant has met each of the inclusion criterion, listed on the flyer. If the participants need further clarity, or have more questions, we will provide them will a phone number for them to call us so we can answer their questions with more detail. If the potential participant expresses continued interest in enrolling in the study, we will schedule a time for them to come to the Clinical Research Laboratory (CRL) on the Syracuse University campus (Women's Building Room 303) so that we may guide them through the written consent document and begin the consent process.

If participants are interested and eligible, they will be instructed via email (1-2 days prior to actual visit days) to wear comfortable, normal, everyday athletic wear for their in-person visits. Participants will be asked to come to the SUNY Upstate Clinical Research Unit followed by SU Clinical Research Laboratory Visit after an overnight fast of 10-12 hours.

B) Pre-Intervention Lab Visits:

All data are collected following standardized procedures and by the same investigators at all timepoints to minimize potential errors of measurements. All participants will provide written informed consent prior to study involvement in accordance with university institutional review board guidelines. The following outlines the specific measurements that will be taken and the specific protocol for lab visit one.

(a) SUNY Upstate Visit (Clinical Research Unit):

After 10- to 12-hr of overnight fasting, participants will come to SUNY Upstate (Clinical Research Unit; Institute For Human Performance Rm# 1223) to undergo their 2-hour oral glucose tolerance test (OGTT) with multiple blood draws (venous blood samples will be obtained at -15, 0, 30, 60, 90 and 120 min), directed by Dr. Ruth Weinstock (a director of Clinical Research Unit) and/or registered nurses (Suzan Bzdick, RN, CCRC). At time 0 min, participants will drink a standard 75 g glucose solution purchased commercially. Youth will be administered 1.75 g glucose per kg (not to exceed 75 g). After the last blood sample (t = 120 min), participants will be provided a snack and allowed for the Syracuse University Visit.

Note that Dr. Weinstock, a director of Clinical Research Unit, upon Dr. Kim's agreement, will submit a separate IRB application to the SUNY Upstate Medical School.

(b) Syracuse University Visit (Clinical Research Lab & Human Performance Lab):

- After the SUNY Upstate Visit (at the Clinical Research Lab at SU), participants' standing height and weight will be assessed without shoes, wearing light clothing, to the nearest 0.1 cm using a stadiometer and balance beam scale to the nearest 0.1 kg, respectively. Body composition and visceral fat will be estimated by multi-frequency bioelectrical impedance (BIA) InBody (Inbody 770, South Korea). For the InBody assessment, participants stand barefoot on the platform of the device with the soles of their feet on the electrodes. They then grasp the handles of the unit with their thumb and fingers to maintain direct contact with the electrodes and remain still for ~1 min while keeping their elbows fully extended and their shoulder joint abducted to around 30° angle (Figure 1).

- We will measure waist and hip circumferences. Participants will stand straight with their arms out while a tape measure is wrapped around their waist and hip. Measurements will be taken to the nearest cm.

- Participants' lipid profile will be collected by Cholestech Analyzer using a blood sample obtained via a finger stick (Figure 2). Participants will select which finger they wish to use, then the researcher (wearing gloves) will clean the fingertip with an alcohol swap. Then, the researcher will "stick" the finger to draw blood. The first drop of blood will be wiped away, and the second drop will be collected and used for analysis. This may cause slight discomfort but is relatively quick and painless. After this the researcher will provide a clean gauze, to clean the area, and a band-aid (if needed).

- We will gain parameters related to cardiovascular function by using a blood pressure monitor. Participants will be asked to sit quietly for five minutes with minimal movement. After this we will place the cuff on their right upper arm (bicep area) and start the measurement. The cuff will inflate, deflate, and then reinflate again. We will ask participants not to move during this process. All of the equipment will be disinfected prior to distribution with disposable wipes (antiviral/antibacterial/antifungal) by a researcher wearing gloves before and after every time collection is performed on a participant.

- We escort participants across the hall (less than 10 feet) to the Human Performance Lab where we will take the following pre-clinical marker (Carotid-femoral pulse wave velocity [PWV]) of CVD. Participants will be escorted to a padded exam table. They will lie down and rest for approximately 5 minutes. Blood pressure in the upper arm will be measured using an automated device with a cuff that wraps around the upper arm and inflates and deflates, applying pressure to the arm. Next, we will obtain blood pressure in the wrist (radial artery), neck (carotid artery), and upper leg (femoral artery) using an applanation tonometer (SphygmoCor, AtCor Medical). This technique is non-invasive, requiring approximately 5 minutes for completion. A picture of the technique is attached. A tonometer is a very sensitive force transducer (similar in appearance to a watch battery affixed to a pen). This pen is placed over the artery of interest providing an accurate recording of the blood pressure wave. With each pulsation of the arterial pulse, a force is generated against the tonometer. The tonometer records this force wave

and reconstructs it into a pressure wave. From this wave, we can estimate blood pressure in this artery and calculate the stiffness (or how elastic the artery is). This measure takes 5-minutes to complete.

C) Randomization:

Upon competition of the Pre-Intervention Lab Visit, participants will be randomly assigned into one of three groups: (a) TRE, (b) HIIT, and (c) Control. The randomization will be done separately for adolescents and young adults [with the exploratory purpose of future analysis on age-specific difference in interventional effects on cardiometabolic health]. Within each group, we anticipate that there will be an equal number of adolescents and young adults.

(a) Time Restricted Eating (TRE) trial:

Participants randomized into the TRE group will be instructed to consume all their calories within a 10-hour period. We will instruct participants that they can choose their time-window (early TRE [7am – 5pm] or late TRE [1pm – 11pm]), but it must remain constant for the duration of the study. Further, we will give no restrictions on the type of foods and/or the quantities individuals can consume. We will ask individuals to maintain their diet for the duration of the study. Participants will be given clear instructions on their diet and how to use the "MyFitnessPal" application. Participants will have their total daily energy requirement calculated using the following formula (Basal metabolic rate [BMR] x activity level) and will be told to eat that amount within their allotted time window. BMR will be calculated when participants have their body composition taken by the InBody. Participants will be told to start their 4-week diet the following day after visit.

(b) High Intensity Interval Training (HIIT) trail: The 4-week HIIT intervention will use a stationary bicycle performed 3 times/week (a total of 12 sessions over the 4-week), performing at the CRL. All participants will perform a 20-minute HIIT protocol (20 repetitions of 10-seconds work time followed by 50-seconds resting/active recovery for the first two weeks, and 10 repetitions of 20-seconds work time followed by 100-seonds resting/active recovery for the rest of two weeks; targeted 90% HR_{max}) after 5-minute warm-up (10% HR_{max}). The supervisor (PI: Joon Young Kim and/or Graduate researcher: Wonhee Cho) will provide encouragement and supervision for exercise adherence. Heart rate (Polar, Polar Electro Oy, Kempele, Finland) and rating of perceived exertion (RPE; detail described in the questionnaire section) will be recorded.

(c) Control group: Participants randomized into the control group will be told to maintain their daily lifestyle and dietary habits for the duration of the four weeks.

D) Post-Intervention Lab Visits:

Following completion of the 4-week intervention, individuals will be asked to come back to undergo same screening/measurements of the Pre-Intervention Lab Visit (SUNY Upstate and Syracuse University visits). An email will be sent to participants on their last day of the intervention with available time and dates for their visit. This will ensure all individuals will be tested with a similar fasting schedule, regardless of what group they were in.

4.2. Describe how you will have sufficient time to conduct and complete the research?

The anticipated time for each visit (Pre- and Post- Intervention Visits) will take approximately 5-6 hours including our measurements performed and transportation between SU and SUNY Upstate. PI (Dr. Joon Young Kim) and graduate researchers (Wonhee, Andrew, Alaina) haven already been involved in similar projects so that team members can split hours or days to secure successful completion of the study (performing study procedure and supervising participants during the intervention) in time. This study is designed to be completed in one year. We do not anticipate any issues around time constraints for completing this study. Dr. Kim has generally 2+2 teaching load with minimal service dedication thereby securing his time commitment to the research. Dr. Weinstock is a director of Clinical Research Unit at SUNY update and agreed (as a scientific consultant) that we will have all participants being underwent OGTTs at the cite (i.e., research/service cost: ~$150, covered by Dr. Kim's startup funds) will be paid to the Research Unit).

4.3. Surveys, interviews, questionnaires will be conducted:

☐ **No (Skip to 4.4)**

☒ **Yes Include all research instruments including surveys, questionnaires, sample interview questions, etc. as separate appendices. If the survey instrument is commonly used in your discipline, only provide a citation to the instrument.**

4.4. Community Based Participatory Research (CBPR) is described as research that is conducted as an equal partnership between traditionally trained "experts" and members of a community. Is this research categorized as CBPR?

☒ **No. (Skip to 4.5)**

☐ **Yes. Please explain: _____**

4.4.1. In CBPR research studies, the community participates fully in all aspects of the research process including conception, design, and analysis.
With this in mind, describe how you plan to engage community members in your research study:

_____

4.4.2. Describe how you plan to provide community members with appropriate training for human subjects research? Include in your description what training will be provided.

_____

4.4.3. Describe your plan to disseminate research findings with members of the community throughout the course of your study.

_____

4.5. Will this research be conducted by SU investigators in foreign countries?

☒ **No. (Skip to 4.6)**

☐ **Yes. An International Research Form must be completed and submitted with this application.**
http://researchintegrity.syr.edu/wp-content/uploads/2016/10/International-Research-Form-2013.doc

4.6. Will this research involve genetic testing?

☒ **No. (Skip to Section 5)**

☐ **Yes. A Genetic Research Form must be completed and submitted with this application.**
http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Genetics.doc

5. Performance Site Information

5.1. Describe how you will have adequate facilities to conduct your research. Please describe where the researchers will conduct the research and data analysis. Will these activities be conducted on campus using campus facilities, classrooms, laboratories, offices, etc.? Will they be conducted off campus at the researcher(s) home/private office, using agency/organization space, in public spaces, etc. ? A combination?

The proposed study is being conducted in the homes of the individual participants as well as the Clinical Research lab (CRL) & the Human Performance lab (HPL) located at the Women's Building (Dept. of Exercise Science), and SUNY Upstate (Clinical Research Unit). Both CRL and HPL are dedicated to the research only, i.e., not being used for teaching. Thus, this space will be available for all aspects of the proposed study. Specifically, the CRL (Women's Building #303) has ~550 sq ft devoted to laboratory research for Dr. Joon Young Kim. The CRL is a newly constructed facility for the purpose of human research in obesity, metabolism, type 2 diabetes, and cardiometabolic disease. This lab is divided into two separate rooms as described: 1) Exam room (~200 sq ft) is for physical (body composition by InBody770) and metabolic testing (oral glucose tolerance test) furnished with outpatient bed, phlebotomy chair, sink and TV/video screening, and for the present study questionnaires from participants will be taken in this space; and 2) Specimen processing & data collection room (~350 sq ft) is for the analysis of the metabolic (blood) samples obtained from the project equipped with YSI 2500 Glucose and Lactate analyzer, Luminex MAGPIX analyzer aligned with desktop PC/software, Labconco Biosafety Logic+ Class II biosafety cabinet, refrigerated centrifuge, vortexer, Bead mixing/dissociation, plate shaker, water bath sonicator and other wet lab

supplies. All measurements collected on participants will be taken in the exam room, and all metabolic markers will be analyzed in the specimen processing & data collection room.

The Human Performance Lab (Women's Building #306) is a 900 sq foot research space dedicated to the non-invasive measurement of vascular structure and function (former direction: Dr. Haffernan; currently being managed by Dr. Kim). The pre-clinical Markers of CVD measurements will be performed at HPL. The proposed study is being conducted in the Human Performance Lab (HPL). The HPL is a 900 sq foot research space dedicated to the non-invasive measurement of vascular structure and function. The space consists of a separate conference room area for a private consent process, dedicated cardiovascular testing space, and separate cubicles for graduate students. For the purposes of this specific study, the HPL is equipped with 1 Bod Pod, 1 Bioelectrical Impedance Scale, 1 laser stadiometer, 3 digital scales, 8 blood pressure monitors with central hemodynamic capabilities, 2 heart rate monitors (First Beat), a Watt bike for testing exercise capacity, a clinical-caliber high-end ultrasound, and Sphygmocor tonometer machine for the assessment of arterial stiffness and an Angioscan device to measure finger blood vessel reactivity. Moreover, Clinical Research Unit at SUNY Upstate, directed by Dr. Weinstock (scientific consultant of Dr. Kim), have been dedicated to the metabolic testing including oral glucose tolerance test with the purpose of research projects related to individuals with type 2 diabetes. The approval letter from SUNY-Upstate Medical University's IRB Office will be submitted once the protocol is approved. Furthermore, the data analysis will be conducted on Syracuse University campus, including Dr. Kim's Office (430H White Hall), CRL and HPL in Women's Building using computers and programs provided by the department.

5.2. List all Performance Sites Other than SU *(insert additional rows if needed).*
(*This may apply when a SU investigator collaborates with a non-SU investigator or institution or an agency/organization will provide space to perform the research. Please check all that apply and add additional sites. Each will require a letter of cooperation and/or IRB approval*.)

Check all that apply	Name of Performance Site (list all participating sites below)	IRB Approval and/or Letter of Cooperation
☒	SUNY Upstate Medical University	☒ Attached ☐ Pending
☐	*Syracuse City Schools	☐ Attached ☐ Pending
☐	*Other, specify site: _____	☐ Attached ☐ Pending

**The following additional information is required: contact information for the site, if the site has an IRB, and whether the IRB has approved the research, or plans to defer review to SU's IRB:*

Dr. Weinstock (email: WeinstoR@upstate.edu)

5.3. Will this research be conducted in a school or is it funded by the US Department of Education?
☒ **No (Skip to 5.4)**
☐ **Yes. If yes, complete the form found at:**
http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Department-of-Education-Schools-Form.doc

5.4. Is this a multi-center research project in which Syracuse University will function as the coordinating center/lead institution? (*A multi-center study is one where different PIs at different institutions are conducting the same study*.)
☒ **No**
☐ **Yes. If yes, describe the plans to manage information obtained in multi-site research that may be relevant to the protection of research participants such as: unanticipated problems involving risks to participants or others, interim results, and protocol modifications:**
_____

6. Research Qualifications

CITI training is required for the faculty member listed below and all researchers and research staff who have direct contact with participants and/or identifiable human participant data. NOTE: If training is not completed at the time of submission, approval of your application will be delayed.

6.1. List the names and research qualifications of the primary investigator/faculty advisor listed in Section 1 of this application. Briefly describe the qualifications of the person listed including: Professional Experience, Education (earned degrees only), Licensure (when applicable), Research Experience, CITI Human Research Training modules. Please do not copy and paste your resume or C.V. qualifications. Qualifications should be appropriate to the type of research being conducted and the targeted population/s involved in the research.

Joon Young Kim, PhD, is an Assistant Professor in the Department of Exercise Science, Syracuse University. His research focuses on pathophysiology of youth- vs. adult-onset prediabetes/type 2 diabetes, identification of novel phenotypic biomarkers and genetic targets of obesity and type 2 diabetes, and effects of lifestyle intervention on type 2 diabetes risk in obese youth. His work is published in multiple high-impact journals including Diabetes Care, Diabetes, Journal of Clinical Endocrinology, and Metabolism: Clinical and Experimental. Dr. Kim has completed all necessary CITI training (Appendix B).

6.2. List the names and research qualifications of the student/research staff listed in Section 1 of this application. Qualifications should be appropriate to the type of research being conducted and the targeted population/s involved in the research. This might include any pertinent coursework and/or involvement in other research projects. Please add CITI training certification information.

Wonhee Cho will assist with data collection. Wonhee is a fourth-year doctoral student in the Exercise Science Department at Syracuse University. He is certified by the American College of Sports Medicine (ACSM) as a Certified Personal Trainer® (ACSM-CPT). He has received all training in saliva markers and pre-clinical markers of CVD collections and has completed all necessary CITI training. Wonhee Cho will have direct contact with the participants and with data. He has completed all necessary CITI training (Appendix B).

Alaina Glasgow is a third year PhD student in the Exercise Science Department at Syracuse University and will assist in cardiovascular measurement collection. She completed an advanced research methods course with Dr. Heffernan where she learned all laboratory techniques across the span of a semester. Additionally, Alaina has been trained in all cardiovascular measurement protocols (that will be used in this study) as part of other IRB approved studies (IRB # 17-359, 20-231, 21-251, 22-414, and 23-129). Alaina has completed all necessary CITI training. Alaina will have direct contact with the participants and with data. She has completed all necessary CITI training (Appendix B).

Andrew Heckel is a PhD student in the Exercise Science Department at Syracuse University and will assist in cardiovascular measurement collection. He has gained considerable experience with all research methods as a result of helping with other approved studies (Racial Differences in Vascular, Cognitive Health; Cardiorespiratory Function in Young Adults with a History of COVID-19, and Reliability and Validity of a Semi-Automated Device to Determine Blood Vessel Reactivity). Andrew has completed all necessary CITI training. He has completed all necessary CITI training (Appendix B).

Eleanor Kwacz is a freshman undergraduate student in the Exercise Science Department at Syracuse University. Eleanor has completed all the necessary CITI training and has received training in body composition and cardiometabolic testing by Dr. Kim (PI) for this project. She will have direct contact with the participants and with data under the supervision of Dr. Kim.

Julianna Verni is an undergraduate student in the Department of Biology at Syracuse University. Julianna has completed all the necessary CITI training and has received training in body composition and cardiometabolic

testing by Dr. Kim (PI) for this project. She will have direct contact with the participants and with data under the supervision of Dr. Kim.

6.3. List the name(s) <u>and</u> research qualifications of all other individuals who will be involved in this research and will have direct contact with participants and/or identifiable human participant data. Qualifications should be appropriate to the type of research being conducted and the targeted population/s involved in the research. This might include any pertinent coursework and/or involvement in other research projects. Please add CITI training certification information.

Ruth S. Weinstock, MD PhD is the Medical Director of the Clinical Research Unit and Joslin Diabetes Center at Upstate Medical University. Dr. Weinstock will oversee the OGTT portion of the study at the Clinical Research Unit. Dr. Weinstock has over 35 years of clinical trial experience and has been the Principal Investigator for numerous clinical trials on Type 1 and Type 2 Diabetes, diabetic complications, device studies, obesity and other endocrine disorders. She is current in all necessary CITI training.

David Hansen, MD, MPH is an Assistant Professor of Pediatrics at the Joslin Diabetes Center, specializing in diabetes. Dr. Hansen will serve as the sub-Investigator for the OGTT portion of this study. Dr. Hansen has been the Principal Investigator on multiple diabetes clinical trials involving children and adolescents, including ones that require an OGTT. He has completed all required CITI training.

Suzan Bzdick, RN, CDCES, CCRC is the Clinical Trials Manager for Endocrine Research and has been working in clinical trials for over 30 years at Upstate Medical University. Suzan is a Certified Diabetes Care and Education Specialist (Association of Diabetes Care and Education Specialists) and a Certified Clinical Research Coordinator (Association of Clinical Research Professionals - ACRP). As a research nurse, she is experienced in the OGTT procedure and the overall coordination and management of clinical trials. Suzan has completed all necessary CITI training.

Jane Bulger, MS, CCRC is a Clinical Research Associate for Endocrine Research and has been coordinating clinical trials at Upstate for 16 years. Jane is a Certified Clinical Research Coordinator (ACRP) and has been the Lead Coordinator on numerous diabetes trials at the Clinical Research Unit. She has completed all necessary CITI training.

Lynn Agostini, CCRP is a Clinical Research Associate for Endocrine Research. She has been coordinating clinical trials at Upstate for 8 years. Lynn is a Certified Clinical Research Professional (Society of Clinical Research Associates) and has been the Lead Coordinator for several diabetes trials, including ones that involve OGTTs. Lynn has completed all required CITI training.

SriLaxmi Veerapaneni. MD, MSc, is a clinical research associate at SUNY Upstate Medical University. She is a new addition to our project as she will be in responsible for assignment of participants to the metabolic testing. SriLaxmi has completed all the necessary CITI training.

The Clinical Research Unit at Upstate Medical University is staffed with a nurse manager, a nurse practitioner and several nurses who are solely dedicated to clinical trials. They will assist with the OGTT procedure under the direction of Dr. Weinstock. All CRU staff have completed the necessary CITI training.

6.4. How will you ensure that all persons listed in Section 6 will remain informed about the protocol and their research related duties and functions (e.g.-weekly meetings, via email, phone, etc.)?

The study design was developed over a series of in-person meetings; roles and responsibilities for all research personnel have been explicitly identified, as well as a timeline of activities. Wonhee Cho has been informed of the protocol and specific research-related duties and functions and will be supervised by Joon Young Kim, PhD throughout all phases of the study. Prior to enrolling participants, we will hold regular lab meetings (weekly emails, Zoom meetings) to review specific roles.

6.5. Explain why you do not need additional qualified staff, other than those listed in Sections 1 and 6, to conduct your study.

Dr. Kim, Dr. Weinstock, Dr. Hansen, and Wonhee Cho will be fully responsible for the primary study. Given its simplicity of data collection procedure, consent form, anthropometric and blood draw, will be collected by these four investigators.

7. Characteristics of Participants

7.1. Approximate Number of Participants to be recruited: 50

7.2. Age Range of Participants: 14-30

7.3. If your age range includes an upper limit, justification must be provided: The ages of 14-30 are considered adolescents and young adulthood and has recently been recognized as a critical time period for the development of obesity related diseases such as CVD and T2D. It is during this life stage that young adults begin to establish health behavior patterns (e.g., physical activity and eating habits) that last into late adulthood. Therefore, it may be beneficial to develop strategic ways specifically targeting emerging young adulthood to delay the onset of obesity related diseases.
If not, please indicate ☐ No.

7.4. Does this study target a vulnerable population such as children, those with decisional impairments, or prisoners? Does the study target a specific population, gender, social, or ethnic group?

☐ **No. (Skip to 7.5)**
☒ **Yes. If yes, answer 7.4.1. and 7.4.2. below.**

7.4.1. If yes, check all that are targeted/vulnerable populations and when appropriate provide a copy of the required form. *The forms can be found on the IRB Website under Special Populations: http://researchintegrity.syr.edu/human-research/forms/

☒ **Children/minors - *Requires additional form***
☐ **Decisionally impaired - *Requires additional form***
☐ **Prisoners - * Requires additional form***
☐ **Pregnant women - *Requires additional form***
☐ **Legally restricted, non-prisoner**
☐ **Educationally disadvantaged**
☐ **Economically disadvantaged**
☐ **Elderly/aged**
☐ **Other, specify: _____**

***NOTE*: These additional forms can be found on the IRB Website (under Special Populations): http://researchintegrity.syr.edu/human-research/forms/**

7.4.2. Explain the rationale for using this particular group(s): _____

7.5. List all study specific inclusion/eligibility criteria (e.g.-gender, age range, population characteristics, location, etc.):

A) Adolescents (age 14-17 years old with sex- and race-specific BMI percentile $\geq 85^{th}$) and young adults with overweight and obesity (age 18 to 30 years old with BMI ≥ 25 kg/m^2)

B) Free from the following chronic medical conditions: heart disease, arrhythmias, diabetes, thyroid disease, bleeding disorder, history of pulmonary disease, hypertension, hepatorenal disease, musculoskeletal disorder, neuromuscular/neurological disease, autoimmune disease, cancer, peptic ulcers, anemia, or chronic infection (HIV).

C) Have not taken any heart, pulmonary, thyroid, anti-hyperlipidemic, hypoglycemic, anti- hypertensive, endocrinologic (e.g., thyroid, insulin, etc.), emotional/psychotropic (e.g., Prednisone, Ritalin, Adderall), neuromuscular/neurological, or androgenic medications (anabolic steroids).

D) Live in the greater Syracuse area.

E) Does not have a pacemaker.

F) For females: are not pregnant or lactating.

We will explain details of the health conditions for the participants to make sure they understand each health condition completely. We will also examine their body composition before we determine whether they are qualified to participate in the study. During the study, if participants have concerns regarding their health conditions, they are free to refuse to participate, or to withdraw from the study at any time. If there is concern about their medical safety, we may recommend participants seek medical attention. During the initial visit, physicians are not being consulted.

Inclusion criteria will be monitored by Dr. Joon Young Kim and Wonhee Cho, when they contact him and communicate about the study procedure via email and/or phone (i.e., potential eligible participants screened by the initial email/phone contact will be determined).

The reason we are looking at individuals with overweight and obesity exclusively (Inclusion A), is because we are targeting individuals at high risk for cardiometabolic diseases, such as type 2 diabetes and cardiovascular disease with the purpose of disease prevention. The reason for inclusion criteria B-D is those factors have been shown to impact weight, and therefore could be potential confounders. Due to the two required visits to the lab (i.e., pre- and post- intervention), we need participants who are local (Inclusion E). Since we will be measuring body composition with a BIA device, these individuals will not be able to partake (Inclusion F).

7.6. List all study specific the exclusion/ineligibility criteria. The exclusion criteria must parallel the inclusion criteria:

A) Adolescents (age <14 years old and/or sex- and race-specific BMI percentile <85th) and adults with normal weight or overweight adults (Age >30 years old and/or BMI <25 kg/m^2) will be excluded in the study.

B) Have at least one of the following chronic medical conditions: heart disease, arrhythmias, diabetes, thyroid disease, bleeding disorder, history of pulmonary disease, hypertension, hepatorenal disease, musculoskeletal disorder, neuromuscular/neurological disease, autoimmune disease, cancer, peptic ulcers, anemia, or chronic infection (HIV).

C) Have taken any of the following medications: heart, pulmonary, thyroid, anti-hyperlipidemic, hypoglycemic, anti- hypertensive, endocrinologic (e.g., thyroid, insulin, etc.), emotional/psychotropic (e.g., Prednisone, Ritalin, Adderall), neuromuscular/neurological, or androgenic medications (anabolic steroids).

D) Does not live in the greater Syracuse area.

E) Has a pacemaker.

F) For females: are not pregnant or lactating.

We will explain details of the health conditions for the participants to make sure they understand each health condition completely. We will also examine their body composition and blood glucose before we determine whether they are qualified to participate in the study. During the study, if participants have concerns regarding their health conditions, they are free to refuse to participate, or to withdraw from the study at any time. If there is concern about their medical safety, we may recommend participants seek medical attention.

Exclusion criteria will be monitored by Dr. Joon Young Kim and Wonhee Cho, when they contact him and communicate about the study procedure via email and/or phone.

7.7. Does this research involve participants likely to be vulnerable to coercion or undue influence?

☒ **No. (Skip to 7.8)**

☐ **Yes. If yes, describe the additional protections included in the protocol to protect their rights and welfare.**

7.8. General state of Health: ("Unknown"- *unless you will obtain health data on participants prior to beginning the study.*)

As we indicated in the inclusion criteria, this study will recruit adolescents (age 14-17 years old with sex- and race-specific BMI percentile ≥85th) and young adults with overweight and obesity (age 18 to 30 years old with BMI ≥25 kg/m^2). Therefore, general state of health of all participants will be weight status (normal weight, overweight, obese) determined by age and BMI obtained prior to beginning the study (when we check participants' eligibility).

8. Recruitment of Participants

8.1. Describe in detail how participants will be identified and recruited. Include in your description how you will have access to a population that will allow recruitment for the number of participants required for your research. Do not merely state "Volunteers".

The study population will consist of individuals recruited from Syracuse University, other local colleges/universities as well as individuals in the local communities. Participants will be recruited via paper flyers and social media postings. Flyers will also be attached to departmental research boards around the Syracuse campus. If participants are interested in our study after seeing the flyer, they will contact us at the e-mail provided in the flyer. If participants are interested in the study after seeing the social media (CRL and HPL official Instagram accounts) post, they will contact us at the e-mail provided in the post. The flyers will be used for the social media post. The script for recruitment is as follows:

"Dear (name),

My name is Wonhee Cho, and I am a doctoral student in the department of Exercise Science at Syracuse University. I am emailing you regarding your potential interest in our research study.

We are interested in how time restricted eating and high intensity interval training will impact the metabolic health of individuals under the age of 31, with a body mass index of 25 or higher. We will have one group randomly assigned into a group that only eats during a ten-hour window per day, one group that performs a high intensity interval training 20-minute workout three times per week, on group that does both, and one group that does neither. This study will last for four weeks. Before the intervention starts, and after the intervention is completed, we will ask you to come to the Clinical Research Lab (third floor of the Women's Building, room 303), where we will assess your height, weight, body composition. Then we will escort you to SUNY Upstate for a two-hour oral glucose tolerance test, where you will have your blood drawn every 30-minutes. Each of these two lab visits will take about three hours to complete. After each lab visit is finished, you will be compensated via Amazon gift cards.

If this still sounds like something you would be interested in, or if you have any additional questions, you can email me back or call me on the phone (518)281-5617. I have attached the consent form to this email as well, so this way you can look it over at your leisure.

Thank you for your time and potential interest in our study."

8.2. Describe who will recruit participants.

Wonhee Cho will recruit participants.

8.3. Identify all applicable recruitment methods that apply: NOTE:Copies of all advertising materials including flyers, posters, ads, letters, scripts or detailed descriptions; including graphics MUST be provided with your application. (See SOP 036 for Recruitment/Advertising).

☒ **Flyers** ☐ **E-mail** ☐ **SU Today News Service**

☐ **Internet Posting** ☐ **Posters** ☐ **Television**
☐ **Letter** ☐ **Newspaper** ☒ **Departmental Research Boards**
☐ **Telephone** ☐ **Radio** ☒ **Social Media**
☐ **Other (describe):** _____

8.4. Will participants be compensated?
☐ **No. (Skip to Section 9)**
☒ **Yes. If yes, answer 8.4.1. and 8.4.2. below.**
Note: All information regarding compensation must be included in consent/assent documents.

8.4.1. If Yes, specify the method of compensation (e.g. monetary, course credit, gift card, toy, etc.), the amount of compensation, and how the compensation will be awarded (per task, per session, etc.).
Compensation will be given out after each visit via Amazon gift cards.
50 dollars will be given out after completion of visit one (pre-intervention visit).
50 dollars will be given out after participates complete the first two weeks of the intervention (with the exception of control group).
50 dollars will be given out after participants complete the last two weeks of the intervention (with the exception of control group).
50 dollars will be given out after completion of visit two (post-intervention visit).
In total, 200 dollars will be given out for participants who complete the study protocol. Participants in the Control will obtain 100 dollars upon their completion of the visits.

8.4.2. Describe how compensation will be awarded if the participant withdraws after beginning the study. Compensation cannot be contingent upon full participation and must be pro-rated in a manner that recognizes the time and effort of the participant prior to withdrawal. Provide a copy of the pro-rating schedule.
For the intervention group, there will be four time points for participants receiving compensation. The first and last compensation will be for the time and effort of one-time visit (i.e., one-day measurement visit). If participants come to the lab but are not able to complete all tasks or measurements during the visit, they will receive $10 for their time and effort for the visit. The second and third compensation will require 2 weeks of intervention. Each compensation will be provided based on their time and effort with the pro-rating schedule below.
[HIIT intervention: lab visit] 1st week of intervention: $8/day; 2nd week of intervention: $9/day; 3rd week of intervention: $8/day; 4th week of intervention: $9/day
[TRE intervention: home-based food track survey] 1st week of intervention: $3/day; 2nd week of intervention: $4/day; 3rd week of intervention: $3/day; 4th week of intervention: $4/day
For the control group, the compensation will be given based on their one time visit so pro-rating schedule will not be applicable.

9. Informed Consent Procedures

Consent is required for all human subject participants. Final copies of ALL consent/assent documents (including electronic or oral scripts) must be provided for IRB approval and date stamping. Informed consent/assent documents must be on *official SU departmental letterhead.*
Must use NEW consent form templates as indicated for the type of consent you plan to use.

9.1. How many consent documents are included with this application? 2

9.2. How many assent documents are included with this application? 1

9.3. Is more than one consent/assent document included with this application?
☐ **No. (Skip to 9.4.)**
☒ **Yes. If yes, follow instructions below (9.3.1 and 9.3.2).**
9.3.1. Assign form numbers to each individual document and add it to the footer of the document-e.g. Consent form 1, Consent form 2, Assent form 1, etc.
9.3.2. Create a separate log as an appendices identifying each document-e.g. Consent form 1-

parental consent, Consent form 2-adult participant consent; Assent form 1-child assent, etc.)

9.4. Using the guidance below, indicate the type of consent you will obtain for your study (check all that apply).

9.4.1. Written Consent ☒ (ATTACH COPY)

Written Consent is signed documentation of consent. Written consent is required for all research conducted in-person. Researchers should retain signed copies of all consent documents for three years after the research is complete, after which they can be destroyed.

NEW Template: http://researchintegrity.syr.edu/wp-content/uploads/2019/04/New-Consent-TemplateWritten.docx

Provide a brief statement of what will be said when the consent process is initiated. For example, how will consent be introduced/explained to participants.

For an adult participant:

"The purpose of this form is to provide you with information about participation in a research study and offer you the opportunity to decide whether you wish to participate. You can take as much time as you wish to decide and can ask any questions you may have now, during or after the research is complete. Your participation is voluntary."

For a youth participant's parents:

"The purpose of this form is to provide you with information about your child's participation in a research study and offer you the opportunity to decide whether you wish to allow your child to participate. You can take as much time as you wish to decide and can ask any questions you may have now, during or after the research is complete. Your child's participation is voluntary."

9.4.2. Electronic Consent ☐ (ATTACH SCRIPT)

Electronic Consent is only appropriate for research when there is no direct contact with the participant; either in-person or remotely (i.e., via electronic surveys, etc.).

NEW Template: http://researchintegrity.syr.edu/wp-content/uploads/2019/04/New-Consent-Template-Electronic.docx

9.4.3. Oral Consent ☐ (ATTACH SCRIPT)

Oral Consent is a request for the waiver of documentation of signed consent (written consent). Oral consent is most conducive for research conducted in situations when the collection of signatures is not practicable. Oral consent should be used for research conducted remotely using video conferencing platforms via the Internet, for phone interviews, in sensitive situations where the collection of signature is the only thing that connects the participants to the research and places them at risk of a breach of confidentiality, and/or for distinct cultural groups/communities in which signing forms is not the norm. Oral consent may also apply if participants have a low literacy level and forms must be read to them and when research is conducted in a field and the transporting of signed documents is not practicable and presents additional risk. Oral consent should be documented in the researchers' field notes.

NEW Template: http://researchintegrity.syr.edu/wp-content/uploads/2019/04/New-Consent-Template-Oral.docx

Provide the justification for the waiver of written consent:

_____

Provide a brief statement of what will be said when the consent process is initiated. For example, how will consent be introduced/explained to participants.

_____

9.4.4. N/A ☐ Data Analysis Only, no consent form required.

9.5. Provide the name/s of the members of the research team listed in Sections 1 and/or 6 who will conduct the consent interview?

Wonhee Cho and Alaina Glasgow will conduct the consent procedure.

9.6. How will you ensure that prospective participants have sufficient opportunity to consider whether or not to participate in your study?

This will be a multi-stage process of information dissemination allowing participants ample time to make a measured decision. Participants interested in participating in the study procedures will be asked to email Wonhee Cho. Those who express interest in the study will then be sent an email outlining the study procedures to read at their leisure. After that point, participants will be invited to participate in a meeting with an investigator (Wonhee Cho) to discuss the study procedures in more detail and outline the risks associated with the study. Potential participants are given the opportunity to ask any additional questions they may still have about the study. During the meeting review of the consent document, we will highlight the risks and benefits of study participation and ask participants if they consent to participate in the study procedures outlined in the consent document. Only when written consent has been obtained will we proceed with the study procedures.

9.7. What steps will be taken to minimize the possibility of coercion or undue influence?

All researchers and research assistants have completed the CITI training (Appendix B) and have also been unequivocally educated by Joon Young Kim not to pressure participants into signing the consent form. We are all very aware that participants are just that, participants, and not research subjects. Our aim is to be respectful of their rights to choose whether they want to participate, and we intend on respecting that right. For potential participants who may be enrolled in courses taught by Dr. Kim (EXE 497 & EXE 500), or Wonhee Cho (EXE 195), then another member of the research team will conduct all consent procedures.

9.8. An ASSENT statement is required for participants who cannot legally give consent themselves. Assent statement:

☐ **No (Skip to 9.9)**

☒ **Yes (ATTACH COPY)**

9.8.1. From whom will consent be obtained and by what means for minors or the individuals considered to be cognitively impaired in their decision making ability? ☐ **N/A**

This study will recruit children so that they cannot legally give consent themselves. The consent will be obtained from children's parents and an assent will be obtained from children.

9.8.2. If subjects are minors, will they still be involved in the study when they reach the age of majority (18)?

☐ **No**.

☒ **Yes. If yes, outline your plan to re-consent these participants when they reach the age of majority.**

We will track the age of 17-year-old participants and consent them using the adult consent form for research conducted after they turn the age of 18).

☐ **N/A**

9.9. Will non-English speaking individuals be participants in the research?

☒ **No (skip to Section 10)**

☐ **Yes If yes, indicate how consent will be documented from non-English speaking participants?**

☐ **A translated written informed consent document in a language understandable to the participant. This should be an accurate translation of the full informed consent. (ATTACH COPY)**

Identify the name of the individual or translation service that provided the translation of the consent document.

_____

List the qualifications of the individual or translation service that provided the translation of the consent document.

_____

☐ **Orally, using a qualified translator to translate the English informed consent document to the participant, and a translated short form in a language understandable to the participant (ATTACH COPY)**

Identify the name of the individual or translation service that will provide translation for the consent process and during the conduct of the research.

_____

List the qualifications of the individual or translation service that will provide translation for the consent process and during the conduct of the research.

_____

☐ **A signed confidentiality statement is required (link to form: http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Confidentiality-Agreement-Template-SAMPLE.doc)**

10. Potential Financial Conflict of Interest

A conflict of interest exists when any investigator or personnel listed in this research protocol's financial interests may reasonably be affected by research, scholarship, educational or other externally funded activity. Or, when the immediate family* of anyone in such a role, have significant financial interests that may compromise, or have the appearance of compromising, an investigator's professional judgment that could directly and significantly affect the design, conduct, or reporting of the research, proposed, or funded.

Federal Guidelines emphasize the importance of assuring there are no conflicts of interest in research projects that could affect the welfare of human participants. If this study involves or presents a potential conflict of interest, additional information will need to be provided to the Vice President for Research.

The following significant financial interests must be disclosed if interest is in the sponsor of the research, or the product being tested:

Significant Financial Interest – Anything of monetary value – aggregated for the Investigator and the Investigator's spouse, domestic partner, and dependent children – that reasonably appears to be related to the Investigator's institutional responsibilities including but not limited to the following:

a. Salary or other payment for services (e.g. consulting fees) that exceeded in the previous twelve months or is reasonably expected to exceed in the next twelve months $5,000
b. Equity interests (e.g. stocks, stock options or other ownership interests) that meet the following tests:
    i. exceeds $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value (e.g. most recent sales price recognized by the company), or
    ii. constitutes more than a 5% ownership interest in any single entity.
c. Intellectual property rights (e.g. patents, copyrights and royalties from such rights) upon receipt of income related to such rights and interests.
d. Services as an officer, director, or in any other executive position in an outside business, whether or not remuneration is received for such service.
e. Reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and is not reimbursed).

Syracuse University Policy on Conflict of Interest for Research Investigators:
http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-032-Institutional-Conflict-of-Interest.pdf
**Immediate family means a spouse, domestic partner or dependent children.*

10.1. Do any of the investigators or personnel listed in this research protocol, or members of the immediate family of the investigators or personnel, have a financial interest associated with this study that requires disclosure?

☒ **No (Skip to question 10.3)**
☐ **Yes; If yes, identify the individual(s):** _____

10.2. Has this financial interest been disclosed and managed?

☐ **Yes. The Office of Research Integrity and Protections will verify that a management plan is in place with the Vice President for Research.**

☐ **No. Action is required. Please contact the Office of Research Integrity and Protections for further information and guidance at orip@syr.edu .**

10.3 To your knowledge, did the University, or your School/Department receive a gift or equipment donation, or promises thereof, from commercial sponsors of this research project?

☒ **No**

☐ **Yes; If yes, identify the sponsor: _____**

Final IRB approval cannot be granted until all potential conflict matters are settled. The IRB requires a recommendation from the Vice President for Research regarding disclosure to participants and management of the conflict.

11. Data Collection, Storage of Data and/or Confidentiality

Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

11.1. PRIOR TO CODING: Simply list the individually identifiable data you will obtain, use or disclose others (e.g.-participant names, email/home addresses, phone numbers, audio/video recording, photographs, IP addresses, or any other identifiable data that can link the participant to the data being collected).

Identifiable data will include participant first and last name, parents names, email, and home address for communication of meetings and scheduling purposes.

11.2. Describe: a) How data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device); b) How you will maintain the confidentiality and data security, (e.g., password protected computer, encrypted files, locked cabinet and office); and c) Who will have access to the data (e.g., research team, sponsors, consultants). Provide the names of the members of the research team listed in either Sections 1 or 6 of the protocol application and/or any other persons outside of the research team who will have access to the data (e.g., sponsors, consultants, etc.).

Data collected will contain only participant study ID numbers. Participant names will not appear on any data collection sheets, nor will names be used as part of data acquisition software. Similarly, only participant study IDs will be used for data analysis spreadsheets. A computer located in the CRL that will house data and data spreadsheets are password protected. All spreadsheets containing data will be password protected. Dr. Kim, Wonhee Cho, Alaina Glasgow, Andrew Heckel, Eleanor Kwacz, and Julianna Verni (under the supervision of Dr. Kim) will have password access to spreadsheets. All remaining data (software data entry) are de-identified and will only include participant study ID.

Blood samples obtained from the OGTT will be stored at the HPL (-80 freezer) at Syracuse University. The sample will be stored with the participants' study ID numbers in boxes (no identification on the boxes). All the assay/analysis results will be kept at the password-protected database at the lab at Syracuse University. If the participants withdraw from the study, samples that are designed for the repository will be destroyed but all samples and data that were collected up to that point as part of the research study will be retained for data analysis.

11.3. If you will be sharing data between members of the research team and/or with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). Please provide the names of the members of the research team listed in either Sections 1 or 6 of the protocol application or any other persons outside of the research team with whom you will share data. If transmitted via electronic networks, describe how you will secure the data while in transit. Specify whether the data you will share is identifiable.

Data will be shared with Dr. Kim, Wonhee Cho, Alaina Glasgow, Andrew Heckel, Eleanor Kwacz, and Julianna Verni (under the supervision of Dr. Kim) via Syracuse University One Drive. The data will include identifiable information while it is protected with password and will not be shared any other person outside of the research team.

11.4. If you plan to code the data linking to the participant, describe the method in which it will be coded. Coding in this instance refers to the use of pseudonyms or the assignment of ID#'s that links identifiable data to the participant. Please provide the names of the members of the research team listed in Sections 1 or 6 of the protocol application that will have access to the key to the code.

A study ID consisting of 3 random letters and random 3-digit numbers will be generated. Participants will be assigned to these study ID letters and numbers and the association between participant name and their IDs will be kept in a separate database that will be password protected. Participant's data will be entered on a spreadsheet where they will be identified by subject ID only. A spreadsheet containing participant names and contact information such that they can be reached to confirm appointments and in case of emergency will be maintained by the study PI and Wonhee Cho. As stated above, all the spreadsheets are password protected (in Microsoft – save as – tools general options – encryption).

All other forms, data spreadsheets, and identifiers used as part of software data acquisition will use participant study ID numbers only. Contact information (name, email, home address) along with study ID will be maintained in a separate spreadsheet (password protected) such that no one, except for only select members of the research team (Mr. Wonhee Cho and Dr. Joon Young Kim) will have access. The spreadsheet containing contact information will be stored on a password protected laptop with an encrypted file (Dr. Joon Young Kim, Wonhee Cho), which is password protected and locked when not in use.

All data collection will occur in the CRL, HPL and SUNY Upstate. Only the participant and the research staff will be in attendance. Although, given that these spaces can be accessed by other students and faculty not in this research protocol, anonymity cannot be guaranteed. Also, both labs are in a publicly accessible building. Thus, privacy when entering/exiting the facility cannot be guaranteed.

11.5. How have Principal Investigator (P.I.) and research team members listed in Sections 1 and 6 worked together to ensure appropriate measures are in place to protect the privacy interests of the participants and the confidentiality of data collected in the research design? How will the P.I. and research team members continue to do so while the research is being conducted.

All research staff have completed CITI training (Appendix B) and are aware of general ethical guidelines regarding research participant privacy and confidentiality. We will have weekly laboratory meetings to discuss study progress and during these meetings, we will continue to review aforementioned policies to ensure all staff are maintaining participant privacy and confidentiality standards.

All other forms, data spreadsheets, and identifiers used as part of software data acquisition will use participant study ID numbers only. Contact information (name, email, home address) along with study ID will be maintained in a separate spreadsheet (password protected) such that no one, except for only selected members of the research team (PI Dr. Joon Young Kim and Wonhee Cho) will have access. The spreadsheet containing contact information will be stored on a password protected lab computer (CRL) with an encrypted file (Dr. Joon Young Kim, Wonhee Cho), which is password protected and locked when not in use.

Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

11.6. Describe what provisions are in place to protect the privacy interests of participants, where "privacy interest of participants" refers to the participant's desire to limit interventions or interactions with others and to limit access of others to their private information. The description should include: a) the location of data collection (i.e.-private location vs. public location, a private space with a closed door, the use of

headphones for remote interviews conducted via the Internet etc.), b) the method of data collection (focus groups, one-on-one interviews, questionnaires/surveys, via telephone, via identified remote Internet platforms, via email/posted mail communications, etc.), and c) the type of data that will be that will be collected (i.e.-written, oral, recorded, etc.). All locations of data collection must be specified. For example, if the research will be conducted on campus, specify the location of the campus facilities/classrooms/offices. If the research will be conducted off-campus, specify the location (i.e.-home office, public spaces, community/agency spaces, etc.).

Data collection will occur in the CRL, HPL, and SUNY Upstate. Only the participant and the research staff will be in attendance. Although, given that this space can be accessed by other students and faculty not in this research protocol, anonymity cannot be guaranteed. Also, our lab is in a publicly accessible building. Thus, privacy when entering/exiting the facility cannot be guaranteed. All information will be coded as to preserve individual's privacy. With respect to recruitment, participants will email study personnel directly in response to advertisements.

Additional participant information will be shared with SUNY Clinical Research Unit (CRU) for the OGTT, including participant name, date of birth, address, phone number, gender, and other required PHI (protected health information) that is needed to create and schedule participants for OGTT at SUNY CRU. Sharing additional PHI with SUNY CRU will allow participants to be scheduled for their OGTTs at the CRU. This information will only be shared with members of SUNY CRU and the SU research team.

11.7. Will participants be recorded in any manner (i.e.-audio, video, film, still photographs, via Zoom or other internet platform)?

☒ **No. (Skip to Section 12)**

☐ **Yes. If yes, specify the medium you will use: _____**

11.7.1. Describe how and where the recordings/photographs will be stored.

_____

11.7.2. Describe the purpose for the recordings and how they will be used. Will they be used for data analysis only or will they be shared in presentations, at professional conferences/workshops or in any other manner?

_____

11.7.3. Name the persons listed in either Sections 1 or 6 of the application who will have access to the recordings.

_____

11.7.4. How long will the recordings be kept and what is the disposition of the recordings once the research is complete?

_____

NOTE: ***Specific permission for each type of recording must be sought in the consent form and should be indicated at the end of the document using checkboxes (I agree to be audio recorded _Yes _No; I agree to be videotaped _Yes _No, etc.)***

12. Risk to Participants

12.1. Describe in detail any possible physical, psychological, social, political, legal, economic, or other risks to the participants, either immediate or long range. Risk may be minimal but never totally absent. Do not say "No Risk".

BIA (used for body composition measures [InBody]) is a system where a safe, low-level electrical signal is transmitted through the body. This electrical signal is not felt by the participant. As this electrical signal encounters body fat, the transmission of the electrical signal is slowed, whereas as the signal encounters water, as would be found in muscle, the speed of transmission is increased. Based on the speed of the electrical signal, and the height, weight, sex, and age of the individual, body fat percentage is estimated. The system we will use is a simple digital scale that requires participants to stand on a digital scale barefoot. Height, sex, and age will be entered into the system by the researcher. Then, the participant will stand on the scale to obtain weight and estimated body composition. The

assessment of body composition takes no more than 60 seconds after standing on the scale. These systems are available for commercial purchase for use at home and have been approved by the FDA. Therefore, we feel that the risk of using such a system is minimal.

While the blood pressure cuff may cause some slight discomfort for individuals, the cuff will only be on for a short time. Once the cuff deflates the pressure will be dissipated.

Blood Draw have a minor risk of infection associated with having participants' blood drawn, which occurs in less than 1 in 1,000 people. Some people may faint or become sick to the stomach at the sight of a needle or when they see blood. This occurs in about 1 in 20 people. There can be some discomfort or bruising at the site after the blood is drawn, occurring in about 1 in 4 people.

There will be potential risks associated with HIIT (e.g., muscle soreness, cramping) or TRE (e.g., light-headedness, hunger).

There might be a risk of the loss of confidentiality. Participants might be seen entering or leaving the labs, but it cannot be guaranteed that others will not assume they are research participants.

12.2. Describe what procedures will be used to minimize each risk you have stated above. Also, include in your description the availability of medical or psychological resources that participants might require as a consequence of the research, if applicable. If participants need to be debriefed at the end of the study, a copy of the debriefing statement must be attached.

The InBody only possess a risk for individuals with a pacemaker. However, if individuals have a pacemaker, they will not be eligible for this study since that is one of the exclusion criteria.

The blood pressure cuff possesses only a slight risk of causing mild discomfort for the participant. However, we will thoroughly instruct the participants of the procedure and let them know the cuff will not be on their arm for long.

Trained nursed at SUNY Upstate will administer the oral glucose tolerance test and draw blood from the participants. The area will be cleaned and disinfected prior to collection of blood. After the blood draw is complete, participants will be handed a sterile gauze and a band-aid to minimize risk of infection. Furthermore, participants will be in a phlebotomy chair with a protective bench in front, in case they may become faint. If this does occur, the blood draw will cease immediately.

Participants will be instructed to have enough warm-up stretching and to do workout within their limit to minimize potential risks associated with HIIT (e.g., muscle soreness, cramping). In order to minimize potential risk associated with TRE (e.g., light-headedness, hunger), participants will be instructed to drink water as needed.

12.3. Does this research involve more than minimal risks to participants?

☒ **No. (Skip to Section 13)**

☐ **Yes. If yes, please provide plan for monitoring the data collected to ensure the safety of participants. (Your data safety monitoring plan must include the following: Description of who will monitor the data, what data will be monitored, how frequently will it be monitored, what analysis will be performed on the data, what decision rules (e.g. stopping rules) will be considered, if unexpected harms will be detected promptly, if an increased frequency or severity of unexpected harms will be detected promptly, if the protocol will be stopped once harms are proven to outweigh benefits.).**

13. Benefits

13.1. Describe any benefits to the participants in general. Incentives, such as course credit, payment, gift cards, entry into a raffle, etc. are considered an inducement to participate in the research and should NOT be described as a benefit.

By participating this research, all participants will examine how they are healthy and be given their health information such as metabolic function, body composition, blood pressure, lipid profile, cardiovascular function with no cost.

Time restricted eating has been shown to be an effective strategy in reducing BMI, and body fat percentage in overweight and obese adults. By partaking in this study, participants could potentially reduce their weight, which has been shown to improve cardiometabolic health.

13.2. Society at large.

TRE and HIIT may prove to provide beneficial effects on cardiovascular health. Heart disease is the leading cause of death in the world and places a major economic burden on the health care system.[17]

13.3. Explain how the benefits outweigh the risks involved.

There are minimal risks to this study. For instance, TRE and HIIT are not currently contraindicated for individuals with overweight and obesity. During the two visits to the CRL, only minimally invasive techniques (i.e blood draws) are used and poses little risk for all involved. Therefore, with minimal risk and the potential of cardiometabolic improvements through weight loss, we feel the benefits outweigh the risks.

A number will be assigned to your protocol. Please refer to it whenever calling or writing for information.

- **All supporting documentation including list of references, consent and/or assent form(s), survey instruments, interview questions, recruitment materials, letters of support, IRB approvals from other institutions, etc. must be included with the application.**
- **Applications can be submitted as an attachment to an email sent to orip@syr.edu.**
- **All correspondence will be directed to the Principal Investigator listed in the protocol. Other persons listed in Section 1 will be cc'd only on email correspondence.**
-

Office of Research Integrity and Protections
214 Lyman Hall
Syracuse University
Syracuse, NY 13244
Phone: 315-443-3013
Email: orip@syr.edu

Table of Contents

References:

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Appendix A – Figures

Figure 1- InBody (photo taken from our lab)

Figure 2- Cholestech Analyzer (photo taken from Abbot Point of Care website)
(https://www.globalpointofcare.abbott/us/en/product-details/cholestech-ldx-system.html)

Appendix B – Citi Training

CITI PROGRAM

Completion Date 10-Jul-2023
Expiration Date 10-Jul-2026
Record ID 52148978

This is to certify that:

Jbon Young Kim

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

Group 4-Principal Investigators BIOMEDICAL
(Curriculum Group)
Group 4-Principal Investigators BIOMEDICAL
(Course Learner Group)
2 - RCR Refresher
(Stage)

Under requirements set by:

Syracuse University

CITI
Collaborative Institutional Training Initiative

101 NE 3rd Avenue, Suite 320
Fort Lauderdale, FL 33301 US
www.citiprogram.org

Verify at www.citiprogram.org/verify/?w2fb46675-a253-4916-b4e2-53c77739b248-52148978

CITI PROGRAM

Completion Date 10-Jul-2023
Expiration Date 10-Jul-2026
Record ID 52148976

This is to certify that:

Jbon Young Kim

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

Basic/Refresher Course - Human Subjects Research
(Curriculum Group)
Biomedical Research
(Course Learner Group)
2 - Refresher Course
(Stage)

Under requirements set by:

Syracuse University

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Collaborative Institutional Training Initiative

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www.citiprogram.org

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CITI PROGRAM

Completion Date 17-Sep-2020
Expiration Date 17-Sep-2023
Record ID 38499110

This is to certify that:

Jared Rosenberg

Has completed the following CITI Program course:

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

Group 2- Graduate Students PHYSICAL SCIENCE (Curriculum Group)
Group 2- Graduate Students PHYSICAL SCIENCE (Course Learner Group)
1 - RCR (Stage)

Under requirements set by:

Syracuse University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w42848e64-fc79-4d92-b2d2-da79e20998be-38499110

CITI PROGRAM

Completion Date 17-Sep-2020
Expiration Date 17-Sep-2023
Record ID 38498982

This is to certify that:

Jared Rosenberg

Has completed the following CITI Program course:

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

Basic/Refresher Course - Human Subjects Research (Curriculum Group)
Students - Class projects (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Syracuse University

CITI
Collaborative Institutional Training Initiative

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CITI PROGRAM

Completion Date 23-Jan-2023
Expiration Date 23-Jan-2026
Record ID 48641376

This is to certify that:

Alaina Glasgow

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

Basic/Refresher Course - Human Subjects Research
(Curriculum Group)
Biomedical Research
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Syracuse University

CITI
Collaborative Institutional Training Initiative

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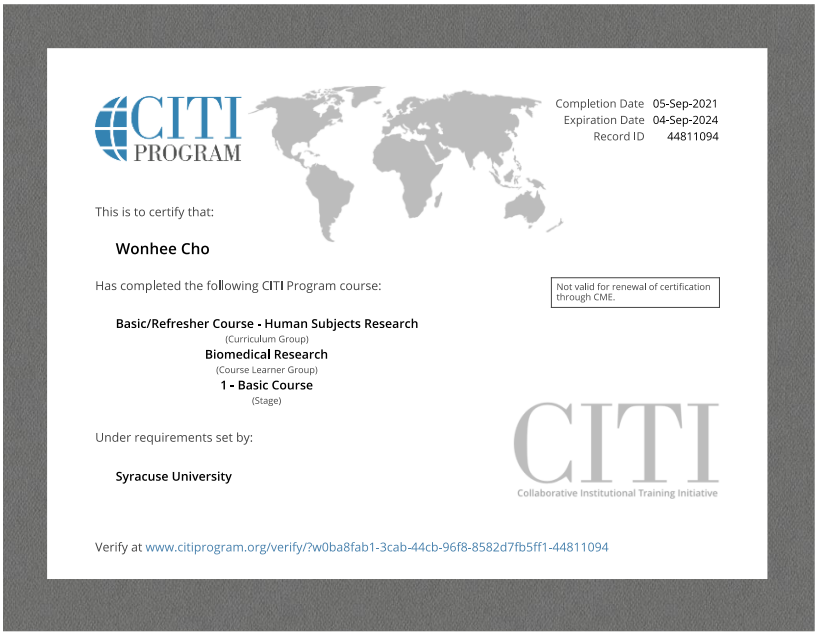

CITI PROGRAM

Completion Date 05-Sep-2021
Expiration Date 04-Sep-2024
Record ID 44811094

This is to certify that:

Wonhee Cho

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Basic/Refresher Course - Human Subjects Research
(Curriculum Group)
Biomedical Research
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Syracuse University

CITI
Collaborative Institutional Training Initiative

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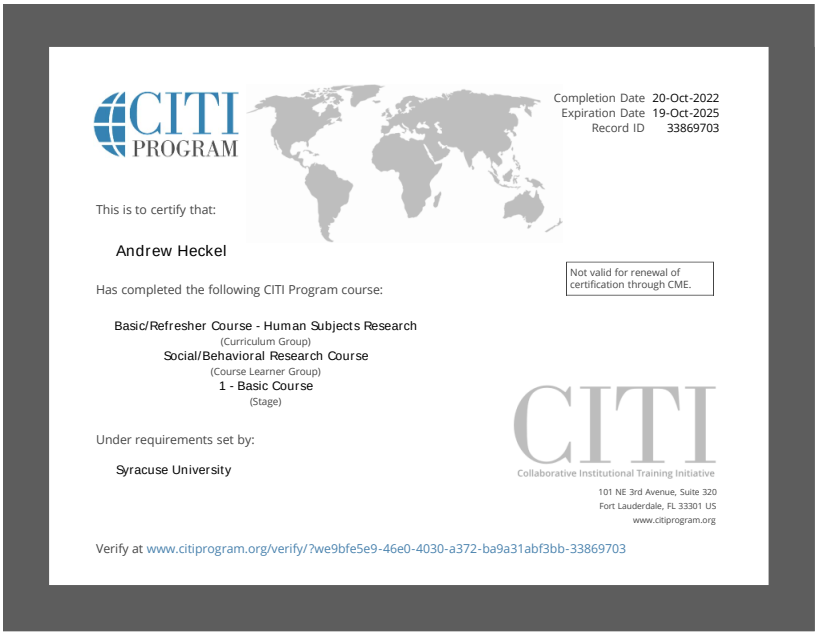

CITI PROGRAM

Completion Date 20-Oct-2022
Expiration Date 19-Oct-2025
Record ID 33869703

This is to certify that:

Andrew Heckel

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

Basic/Refresher Course - Human Subjects Research
(Curriculum Group)
Social/Behavioral Research Course
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Syracuse University

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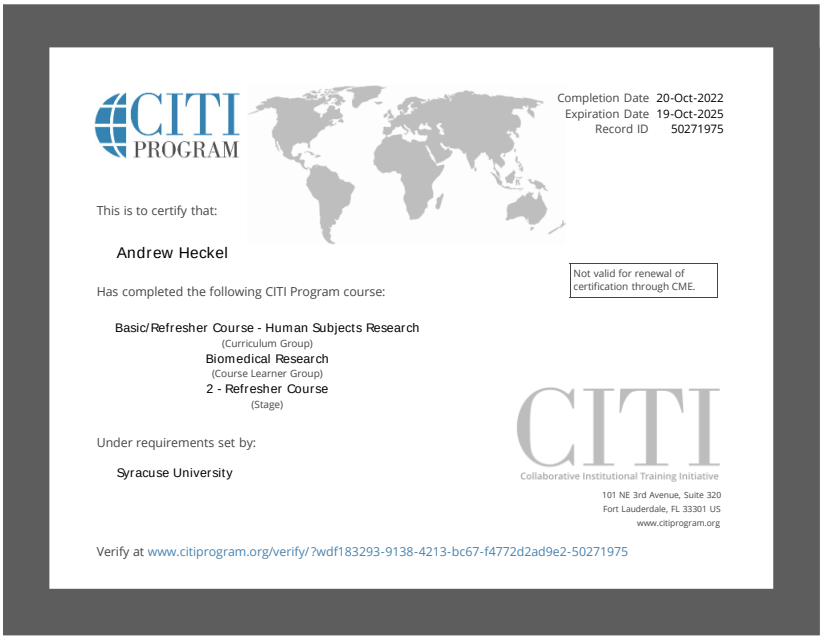

CITI PROGRAM

Completion Date 20-Oct-2022
Expiration Date 19-Oct-2025
Record ID 50271975

This is to certify that:

Andrew Heckel

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

Basic/Refresher Course - Human Subjects Research
(Curriculum Group)
Biomedical Research
(Course Learner Group)
2 - Refresher Course
(Stage)

Under requirements set by:

Syracuse University

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CITI PROGRAM

Completion Date 08-Nov-2021
Expiration Date 07-Nov-2024
Record ID 34893360

This is to certify that:

Ruth Weinstock

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Human Research
(Curriculum Group)
Group 1.Biomedical Investigators and Key Personnel - Including Drug & Device Research
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

SUNY Upstate Medical University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w184e18f2-8316-44ff-bc4f-239fe5534c70-34893360

CITI PROGRAM

Completion Date 07-Sep-2022
Expiration Date 06-Sep-2025
Record ID 49594068

This is to certify that:

Suzan Bzdick

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Human Research
(Curriculum Group)
Group 1.Biomedical Investigators and Key Personnel - Including Drug & Device Research
(Course Learner Group)
2 - Refresher Course
(Stage)

Under requirements set by:

SUNY Upstate Medical University

CITI
Collaborative Institutional Training Initiative

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CITI PROGRAM

Completion Date 21-Dec-2021
Expiration Date 20-Dec-2024
Record ID 45426433

This is to certify that:

Jane Bulger

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Human Research
(Curriculum Group)
Group 1.Biomedical Investigators and Key Personnel - Including Drug & Device Research
(Course Learner Group)
2 - Refresher Course
(Stage)

Under requirements set by:

SUNY Upstate Medical University

CITI
Collaborative Institutional Training Initiative

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CITI PROGRAM

Completion Date 21-Mar-2022
Expiration Date 20-Mar-2025
Record ID 46412886

This is to certify that:

Lynn Agostini

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Human Research
(Curriculum Group)
Group 1.Biomedical Investigators and Key Personnel - Including Drug & Device Research
(Course Learner Group)
2 - Refresher Course
(Stage)

Under requirements set by:

SUNY Upstate Medical University

CITI
Collaborative Institutional Training Initiative

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CITI PROGRAM

Completion Date 31-Jul-2021
Expiration Date 30-Jul-2024
Record ID 42221024

This is to certify that:

David Hansen

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Human Research
(Curriculum Group)
Group 1.Biomedical Investigators and Key Personnel - Including Drug & Device Research
(Course Learner Group)
2 - Refresher Course
(Stage)

Under requirements set by:

SUNY Upstate Medical University

Collaborative Institutional Training Initiative

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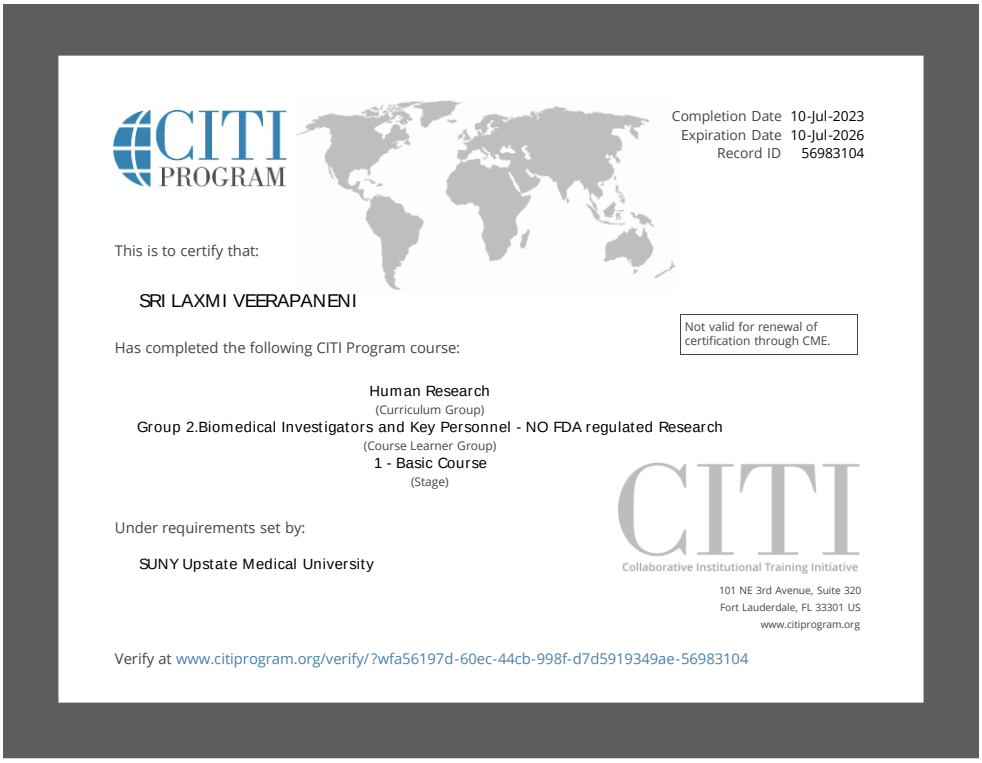

CITI PROGRAM

Completion Date 10-Jul-2023
Expiration Date 10-Jul-2026
Record ID 56983104

This is to certify that:

SRI LAXMI VEERAPANENI

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Human Research
(Curriculum Group)
Group 2.Biomedical Investigators and Key Personnel - NO FDA regulated Research
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

SUNY Upstate Medical University

Collaborative Institutional Training Initiative

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CITI PROGRAM

Completion Date 22-Jan-2024
Expiration Date 22-Jan-2027
Record ID 60485811

This is to certify that:

Eleanor Kwacz

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

Basic/Refresher Course - Human Subjects Research
(Curriculum Group)
Students - Class projects
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Syracuse University

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CITI PROGRAM

Completion Date 09-Sep-2024
Expiration Date 09-Sep-2027
Record ID 65055702

This is to certify that:

Julianna Verni

Not valid for renewal of certification through CME.

Has completed the following CITI Program course:

Basic/Refresher Course - Human Subjects Research
(Curriculum Group)
Biomedical Research
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Syracuse University

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Collaborative Institutional Training Initiative

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Appendix C – Consent/Assent Forms

Consent form-1: Young adult consent form.

Consent form-2: Adolescent consent form (for parents).

Assent form (for adolescent participants)

Appendix D – Borg Scale

Rating	Descriptor
6	No exertion at all
7	Extremely light
8	
9	Very light
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard (heavy_
16	
17	Very hard
18	
19	Extremely hard
20	