Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

Personnel Info 3
Participant Population 4
Study Location 4
General Checklist 5
Funding 7
Resources 7
Expedited Category 9
Purpose 10
Radioisotopes or Radiation Machines 13
Drugs, Reagents, Chemicals, Devices 14
Medical Equipment for Human Subjects and Laboratory Animals 14
Participant Population(a-g) 14
Participant Population(h-m) 16
Risks(a-d) 17
Risks(e) 18
Privacy And Confidentiality 19
Conflict Of Interest 21
Consent Background 21
Assent Background 23
Hipaa 24
Attachments 25

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

Obligations 25

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

Protocol Director

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Admin Contact

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Investigator

Name		Degree (Program/year if student)		Position, e.g. Assistant Professor, Resident, etc.
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CITI Training current				Y

Other Contact

Name		Degree (Program/year if student)		Position, e.g. Assistant Professor, Resident, etc.
Department		**Phone**		**E-mail**
CITI Training current				

Academic Sponsor

Name		Degree (Program/year if student)		Position, e.g. Assistant Professor, Resident, etc.
Department		**Phone**		**E-mail**
CITI Training current				

Other Personnel

Name	Degree (Program/year if student)	Position, e.g. Assistant Professor, Resident, etc.

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

Nicole Elizabeth Dunkel				Assistant Clinical Research Coordinator
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Name Jasmine Guadalupe Lopez		**Degree (Program/year if student)**		**Position, e.g. Assistant Professor, Resident, etc.** Assistant Clinical Research Coordinator
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CITI Training current				Y

Name Claire Sakura Swihart		**Degree (Program/year if student)** B.A. Candidate		**Position, e.g. Assistant Professor, Resident, etc.** Clinical Research Assistant
Department Vice Provost for Undergraduate Education		**Phone**		**E-mail** cswihart@stanford.edu
CITI Training current				Y

Participant Population(s) Checklist	**Yes/No**
• Children (under 18)	Y
• Pregnant Women and Fetuses	N
• Neonates (0 - 28 days)	N
• Abortuses	N
• Prisoners	N
• International Participants Please enter the countries separated by comma	N
• Impaired Decision Making Capacity	N
• Cancer Subjects	N
• Laboratory Personnel	N
• Healthy Volunteers	N
• Students Stanford students N Other students Y	Y
• Employees	N
• Other (i.e., any population that is not specified above)	N

Study Location(s) Checklist	**Yes/No**

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

- Stanford University — Y
- Clinical & Translational Research Unit (CTRU)
- Stanford Medicine Health Care
  Tri-Valley
- Stanford Medicine Children's Health
- VAPAHCS (Specify PI at VA)
- Other (Click ADD to specify details) — Y

Location / Country	Location	Contact Name	Contact Phone	Contact Email
High School and College campuses	US			

General Checklist

Multi-site — **Yes/No**

- Is this a multi-site study? A multi-site study uses the same protocol to conduct human subjects research at more than one site. — N

Cooperative/Collaborative Study? — **Yes/No**

- Are there any collaborating institution(s)? A collaborating institution is generally an institution that collaborates equally on a research endeavor with one or more institutions. — N

Cancer Institute — **Yes/No**

- Cancer-Related Studies (studies with cancer endpoints), Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Specimens (e.g., blood, tissue, cells, body fluids with a scientific hypothesis stated in the protocol). — N

Clinical Trials — **Yes/No**

- Investigational drugs, biologics, reagents, or chemicals that are being studied? ? — N
- Commercially available drugs, reagents, or other chemicals administered to subjects that are being studied? — N
- Investigational Medical Device / Commercial Medical Device used off-label that is being studied? — N
- IDE Exempt Device (Commercial Medical Device used according to label, Investigational In Vitro Device or Assay, or Consumer Preference/Modifications/Combinations of Approved Medical Devices) — N

- Will this study be registered on clinicaltrials.gov? (See Stanford decision tree) — N

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

Tissues and Specimens	**Yes/No**
• Human blood, cells, tissues, or body fluids (tissues)?	N
• Tissues to be stored for future research projects?	N
• Tissues to be sent out of this institution as part of a research agreement? For guidelines, please see Material Transfer Agreements	N

Biosafety (IBC)	**Yes/No**
• Are you submitting a Human Gene Transfer investigation using a biological agent or recombinant DNA vector? If yes, please complete the Gene Transfer Protocol Application Supplemental Questions and upload in Attachments section.	N
• Are you submitting a Human study using biohazardous/infectious agents? If yes, refer to the ; Administrative Panel on BioSafety website prior to performing studies.	N
• Are you submitting a Human study using samples from subjects that are known or likely to contain biohazardous/infectious agents? If yes, refer to the ; Administrative Panel on BioSafety website prior to performing studies.	N

Human Embryos or Stem Cells	**Yes/No**
• Human Embryos or Gametes?	N
• Human Stem Cells (including hESC, iPSC, cancer stem cells, progenitor cells)	N

Veterans Affairs (VA)	**Yes/No**
• The research recruits participants at the Veterans Affairs Palo Alto Health Care System(VAPAHCS).	N
• The research involves the use of VAPAHCS non-public information to identify or contact human research participants or prospective subjects or to use such data for research purposes.	N
• The research is sponsored (i.e., funded) by VAPAHCS.	N
• The research is conducted by or under the direction of any employee or agent of VAPAHCS (full-time, part-time, intermittent, consultant, without compensation (WOC), on-station fee-basis, on-station contract, or on-station sharing agreement basis) in connection with her/his VAPAHCS responsibilities.	N
• The research is conducted using any property or facility of VAPAHCS.	N

Equipment	**Yes/No**
• Use of Patient related equipment? If Yes, equipment must meet the standards established by Biomedical Engineering (BME) (650-725-5000)	N

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

• Medical equipment used for human patients/subjects also used on animals?	N
• Radioisotopes/radiation-producing machines, even if standard of care? https://ehs.stanford.edu/topic/radiation-safety More Info	N

Payment	**Yes/No**
• Subjects will be paid/reimbursed for participation? See payment considerations.	N

Funding	**Yes/No**
• Training Grant?	N
• Program Project Grant?	N
• Federally Sponsored Project?	N
• Industry Sponsored Clinical Trial?	N

Funding

NONE

Funding - Grants/Contracts/Agreements

Funding - Fellowships

Gift Funding

Dept. Funding

Other Funding

Resources :

a) Qualified staff.

Please state and justify the number and qualifications of your study staff.

The study staff will consist of investigator Dr. Eric Stice. Sareena Shaw is an undergraduate student at Stanford University, and will aid in implementation of procedures. She is also trained to lead Body Project groups and Overvaluation of Weight and Shape Reduction Intervention workshops. The Overvaluation of Weight and Shape Reduction Intervention is called ?Priorities?.

b) Training.

Describe the training you will provide to ensure that all persons assisting with the research are informed about the protocol and their research-related duties and functions.

All of the current study personnel who will be working on the study have completed the Human Subjects

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

Research Protections - Group 7: IRB BioMed/GCP Research (All Medical Investigators and Staff) through the CITI program and the HIPAA training, and have experience with this subject of research. Particular to the study, they will also receive a copy of the IRB, including study materials, and a walk through of study protocol from the PI, with the opportunity to ask any questions. Any additional study personnel will receive the above training and certification.

c) Facilities.

Provide the location(s) where the research will be conducted, including physical address if not conducted on site at Stanford University, Stanford Hospital on Pasteur Dr., Lucile Packard Children's Hospital on Welch Rd. or VAPAHCS. Describe the facilities and resources available to conduct the research at these sites.

Priorities and the Body Project will have all group sessions administered by facilitators in a reserved space within the given College?s or High School?s campus.
All research protocols that the Stanford site is responsible for will be conducted at Stanford University at 401 Quarry Road, Palo Alto.

d) Sufficient time.

Explain the time that you and your research team will allocate to perform the research activities, including data analysis.

During month 1, we will apply for IRB approval, create advertisements for recruitment, develop a Qualtrics site for surveys and enrollment of participants, and train facilitators to implement virtual and in-person Priorities and Body Project workshops as needed. Data collection will begin in month 1 and continue throughout the duration of the academic year. We plan to recruit all participants and implement all Body Project and Priorities workshops in 1-3 months (up to 6 pilot groups). Post-test assessments will occur in months 2-4. We will analyze the data and revise the Priorities workshop in this time frame as necessary. We estimate the amount of time dedicated to this study per week to be 15 hours/week.

e) Access to target population.

Explain and justify whether you will have access to a population that will allow recruitment of the required number of participants.

This study is evaluating the effectiveness of shifting self worth away from weight and shape ideals. Priorities workshops will take place within the campus of the conducting schools. These schools contain students that have expressed interest in these workshops. Even so, a recruitment process will occur to confirm willing participants to have a workshop (up to 80 participants). The Body Project, a successful program, has been implemented in the same population and has had successful recruitment, so Priorities (which is similar in structure and content) will have this same access.

f) Access to resources if needed as a consequence of the research.

State whether you have medical or psychological resources available that participants might require as a consequence of the research when applicable. Please describe these resources.

The risks of this pilot study are extremely low. This is a behavioral, non-invasive program which reduces harm. Participation in this research will not interfere with access to any of the participant's resources. We intend on providing all participants with a robust list of of relevant resources, such as mental health organizations with national locations/chapter, Stanford-specific resources (Counseling and Psychological Services (CAPS), the Bridge Peer Counseling Center, Vaden Student Health Services, the Confidential Support Team (CST)), help hotlines, and other online support services.

g) Lead Investigator or Coordinating Institution in Multi-site Study.

Please explain (i) your role in coordinating the studies, (ii) procedures for routine communication with other sites, (iii) documentation of routine communications with other sites, (iv) planned management of

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings.

Title

Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project

Expedited Form

A protocol must be no more than minimal risk (i.e., "not greater than those ordinarily encountered in daily life") AND must only involve human subjects in one or more of the following paragraphs.

Select one or more of the following paragraphs:

1. N **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**
   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b) Research on medical devices for which
      i) an investigational device exemption application (21 CFR Part 812) is not required; or
      ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. N **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
   a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. N **Prospective collection of biological specimens for research purposes by non invasive means.**

4. N **Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)**
   Examples:
   a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
   b) weighing or testing sensory acuity;
   c) magnetic resonance imaging;
   d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   e) moderate exercise, muscular strength testing, body composition assessment, and flexibility

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

testing where appropriate given the age, weight, and health of the individual.

5. N **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**

6. Y **Collection of data from voice, video, digital, or image recordings made for research purposes.**

7. Y **Research on individual or group characteristics or behavior(including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)**

1. Purpose

a) In layperson's language state the purpose of the study in 3-5 sentences.

Priorities aims to reduce body image concerns, prevent eating disorders, bolster self-esteem, and promote mental and emotional health by helping participants identify and nurture alternative sources of self-worth. Priorities would use group discussions, role-plays & behavioral challenges, homework assignments & letter-writing, and self-worth activism to achieve this. The Priorities intervention will be compared to The Body Project (an existing and successful harm reduction and eating disorder prevention program) for its effectiveness of reducing body image concerns and eating disorder outcomes. This study aims to evaluate whether there is a more effective eating disorder prevention program than The Body Project.

b) State what the Investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.

Aim 1: Determine if participants can shift self worth to intellectual, athletic, creative, or social matters rather than basing their self-worth on body size, appearance, and weight. Aim 2: Determine if Priorities? workshop approach is more successful in reducing body image concerns and eating disorder outcomes than The Body Project. Aim 3: Solidify a successful Priorities program to be implemented in a range of education establishments.

c) Explain why human subjects must be used for this project. (i.e. purpose of study is to test efficacy of investigational device in individuals with specific condition; purpose of study is to examine specific behavioral traits in humans in classroom or other environment)

This study must use humans due to the nature of body image disturbances and eating disorders occurring only in humans, but not in other animals to our knowledge. Because the programs require speech as a method of communication, human subjects are necessary due to the fact animals do not engage in this form of communication.

2. Study Procedures

a) Please SUMMARIZE the research procedures, screening through closeout, which the research participant will undergo. Sections in the protocol attached in section 16 can be referenced, BUT do not copy the clinical protocol. Be clear on what is to be done for research and what is part of standard of care. For research involving collaborators, please specify the respective roles of Stanford and each

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

collaborator on the protocol.

1) Adolescents experiencing concerns with their body image and self worth will learn about the study through the study team's recruitment efforts, for colleges: online advertisements through email, flyers posted near college campuses, flyers posted in high traffic areas on campus, (dorms, dining halls and distributed/promoted by Vaden Student Health Services, listservs for different communities/clubs, social media platforms (Instagram, Facebook, Twitter, Reddit). For high schools emails, info sessions, fliers in high traffic areas, and social media posts will attract attention. See "Email template for schools" and Priorities Flyer". Online advertisements will be set up so that security setting do not allow participants or others from the public to post on the advertisement (in order to prevent participants from posting PHI on a publicly available ad).

2) Potential participants who express interest ("Priorities Interest form") will be given a link to a secure Qualtrics Screening questionnaire, or Google questionnaire with the same questions, for the research study ("Priorities Screener"). Upon completion of the questionnaire, potential participants will then be contacted via phone or email.

3) After it has been determined that potential participants meet eligibility criteria for the study (i.e., Female-identifying High School and College Adolescents ages 14-22 as determined by the PI) and they have offered consent to participate, they will be instructed to complete a pre-test survey ("Priorities Questionnaire- updated"). Priorities and The Body Project will have the same surveys including the following measures: self-report measure of weight/shape overvaluation, thin-ideal internalization, body dissatisfaction, harms from social media scale and mental health scales, depression questionnaire, anxiety questionnaire, PANAS scale for negative affect, as well as the self-report Eating Disorder Diagnostic Screen (assessing eating disorder symptoms using the Eating Disorder Diagnostic Survey (EDDS), a brief self-report scale. The EDDS symptom composite contains convergent validity with the Eating Disorder Diagnostic Interview (EDDI) as well as closely aligned diagnosis).

4) For each prevention program enrollment will follow: randomizing half of the people we recruit to the Priorities intervention and half to the Body Project intervention. Both Priorities and the Body Project are cognitive dissonance based group interventions (6-8 participants). We will be prepared to offer both programs either in-person or virtually, though in-person will be the preferred mode. The intervention facilitator will be a research team member who is trained in facilitating both interventions. The Body Project is the current gold-standard ED prevention program, and Priorities is being evaluated as a potentially more effective ED prevention program. The interventions will all be 4 session programs. The Body Project's focus is on going against the thin-ideal present in modern beauty standards, whereas Priorities' focus will be on addressing overvaluation of weight and shape.?See attached documents for both intervention program scripts. We will plan to conduct both groups in-person, but virtual groups will be an option as necessary.?Pretest and posttest data will be collected.

5) Once the 4 sessions have been completed, participants will be contacted to complete a post test assessment ("Priorities Questionnaire- updated"). The post test surveys will be the same as pre-test surveys.

6) After 1-month, participants will be contacted to complete post-test 1-month follow-up surveys. These post test surveys will be the same as pre-test surveys.

b) Explain how the above research procedures are the least risky that can be performed consistent with sound research design.

The research procedures described above pose non-significant risks for participants and the research staff involved in this project are fully trained in their assigned responsibilities. Adherence to the program protocol will be monitored by the PIs for this pilot study and participants will be instructed that they may drop out of the study at any point.

c) State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an alteration of consent (in section 13). Submit a debriefing script (in section 16).

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

No deception will be used for Priorities or the Body Project.

d) State if photo, audio or video recording will occur. Describe what will become of the photos or recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.

Audio recordings will occur for sessions. The recordings are necessary to ensure adherence to protocol and quality of Priorities. No PHI (participant health information) or participant identifying information will be recorded. In the event that this does occur, this information will be edited out before it is saved to the hard drive and shared with any other study personnel. All video files will be downloaded and stored in the HIPPA compliant Stanford Medicine Box hard drive.

e) Describe alternative procedures or courses of treatment, if any, that might be advantageous to the participant. Describe potential risks and benefits associated with these. Any standard treatment that is being withheld must be disclosed in the consent process and form. (i.e. standard-of-care drug, different interventional procedure, no procedure or treatment, palliative care, other research studies).

This pilot study addresses Overvaluation of Weight & Shape and aims to reduce it with its corresponding negative effects. There will be no alternative courses of treatment to offer besides Priorities and the Body Project. Priorities is designed for reduction of overvaluation of Weight & Shape and other mental health issues, as well as preventing the likelihood of onset of an eating disorder. Thus, it is not intended to treat any conditions. The only other alternative would be to not participate in this study. There are no known risks associated with participation in this program, although some sensitive topics may cause participants discomfort, there will be counselors and help available for. This program has the potential to aid participants in resolving some or all struggles and difficulties with body image.

f) Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?

If there are participants who meet criteria for a DSM-5 eating disorder at the termination of the study, the appropriate referrals will be provided. This study will not interfere with their current levels of care or their future levels of care.

g) Study Endpoint. What are the guidelines or end points by which you can evaluate the different treatments (i.e. study drug, device, procedure) during the study? If one proves to be clearly more effective than another (or others) during the course of a study, will the study be terminated before the projected total participant population has been enrolled? When will the study end if no important differences are detected?

If there is such a discrepancy between the two different conditions, they will be evaluated by the principal investigators in terms of terminating the study prematurely. Otherwise, we shall examine the program's effectiveness at the end of the study and study participation will be completed within 24-weeks, including a 1-month follow up after the conclusion of the Priorities workshops.

3. Background

a) Describe past experimental and/or clinical findings leading to the formulation of the study.

Priorities:
Research suggests that when individuals derive most of their self-esteem from weight and shape, they are at higher risk for unhealthy body image concerns, disordered eating, negative mood, and relationship difficulties. Indeed, a larger prospective study found that overvaluation of weight/shape increased risk for future onset of all four types of eating disorders (Stice, Desjardins, Rohde, & Shaw, 2021). Such overvaluation often stems from internalizing cultural ideals perpetuated by media, social media, peers, and sometimes even family members. Culturally, these messages suggest that those who are ?thin? and attractive will reap benefits such as success, love, or admiration while obscuring the reality that many other attributes determine healthy self-worth. The Body Project is a dissonance based intervention that provides foundation for Priorities. Solely the Body Project has proved effective in a) reducing eating disorder risk

factors, symptoms, and onset through 2-4 year follow-up b) reduce these outcomes when compared to several other valid alternative interventions c) proven to affect the intervention target (appraisal of the thin ideal) d) affect objective biological outcomes (reduction in brain reward circuitry response to thin models) and e) produce effects that are consistently replicated independent of one another (Stice et al.,2017). The Body Project?s success makes it?s influence on Priorities valuable.

The Body Project is the only ED prevention program that has repeatedly reduced future onset of EDs, produced effects when evaluated by independent researchers, produced stronger effects than credible alternative interventions, and affected objective outcomes (Stice et al., 2019). The Body Project is a dissonance-based ED prevention program wherein high-risk young women with body image concerns collectively critique pursuit of the thin appearance ideal in verbal, written, and behavioral exercises. It has produced greater reductions in risk factors (pursuit of the thin ideal, body dissatisfaction, dieting, negative affect), ED symptoms, and future ED onset over a 2- to 4-year follow-ups than assessment-only control conditions and alternative interventions in over 25 controlled trials (e.g., Becker et al., 2010; Ghaderi et al.,2020; Halliwell & Diedrichs, 2014; Stice et al., 2000, 2006, 2008, 2011, 2013, 2017, 2020).

b) Describe any animal experimentation and findings leading to the formulation of the study.

No related animal experimentation or findings led to the formulation of this study.

4. Radioisotopes or Radiation Machines

a) List all standard of care procedures using ionizing radiation (radiation dose received by a subject that is considered part of their normal medical care). List all research procedures using ionizing radiation (procedures performed due to participation in this study that is not considered part of their normal medical care). List each potential procedure in the sequence that it would normally occur during the entire study. More Info

Identify Week/Month of study	Name of Exam	Identify if SOC or Research

b) For research radioisotope projects, provide the following radiation-related information:

Identify the radionuclide(s) and chemical form(s).

For the typical subject, provide the total number of times the radioisotope and activity will be administered (mCi) and the route of administration.

If not FDA approved provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature).

c) For research radiation machine projects, provide the following diagnostic procedures:

For well-established radiographic procedures describe the exam.

For the typical subject, identify the total number of times each will be performed on a single research subject.

For each radiographic procedure, provide the setup and technique sufficient to permit research subject dose modeling. The chief technologist can usually provide this information.

For radiographic procedures not well-established, provide FDA status of the machine, and information sufficient to permit research subject dose modeling.

d) For research radiation machine projects, provide the following therapeutic procedures:

For a well-established therapeutic procedure, identify the area treated, dose per fraction and number of fractions. State whether the therapeutic procedure is being performed as a normal part of

clinical management for the research participants's medical condition or whether it is being performed because the research participant is participating in this project.

For a therapeutic procedure that is not well-established, provide FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions.

5. Devices

a) List all Investigational Devices (including Commercial Devices used off-label) that are being studied in the table below.

b) List all IDE Exempt Devices (Commercial Device used according to label, In Vitro Device (ex Assay or Software), or Consumer Preference/Modifications/Combinations of Approved Devices) that are being studied in the table below.

6. Drugs, Biologics, Reagents, or Chemicals

a) Please list in the table below all investigational drugs, biologics, reagents or chemicals if they are being studied.

b) Please list in the table below all commercial drugs, biologics, reagents or chemicals if they are being studied.

7. Medical Equipment for Human Subjects and Laboratory Animals

If medical equipment used for human patients/participants is also used on animals, describe such equipment and disinfection procedures.

No medical equipment was/will be used for human patients and animals.

8. Participant Population

a) State the following: (i) the number of participants expected to be enrolled at Stanford-affiliated site(s); (ii)the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e. students, patients with certain cancer, patients with certain cardiac condition) and the reasons for using such participants.

(i) We expect to enroll 80 participants maximum for Priorities and the Body Project.
(ii) We expect to enroll 80 participants total at all sites. Stanford is the only coordinating site of this study, and will collaborate with local high schools.
(iii) Healthy adolescents attributing self-worth to weight/shape are the target population for Priorities and the Body Project. Using participants that fit these descriptions will enable the research team to evaluate the effectiveness of these prevention programs and discern the specific factors that may contribute to more success and what factors are less effective.

b) State the age range, gender, and ethnic background of the participant population being recruited.

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

Target participants will be high school and college age students, we will not exclude on the basis of ethnic background.

c) State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students). Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects and the additional safeguards that have been included in the protocol to protect their rights and welfare.

Young adult females are included in this study because they are at elevated risk for future eating disorder onset. Information on the risks and benefits of the program and their rights and welfare will be addressed in the Informed Consent forms. Dates of birth from all interested participants will be required during the screener in order to determine if they are at an appropriate age to participate in the study.

d) If women, minorities, non-English speaking individuals, or children are not included, a clear compelling rationale must be provided (e.g., disease does not occur in children, drug or device would interfere with normal growth and development, etc.).

The purpose of this study is to shift self worth from overvaluation of weight & shape to factors that lead to better mental health. As this issue is more present in adolescents, younger children are not the target population of this study.
We will not include non-English speaking individuals, as both the Priorities and Body Project interventions are group discussion-based, so inability to speak English would significantly impact the therapeutic benefit received and feasibility to conduct the study.

e) State the number, if any, of participants who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If payment is allowed, they should also receive it. Please see Stanford University policy.

Stanford students, employees, or laboratory personnel may be eligible to participate in the research study. We cannot estimate how many that might be. If any such participants are enrolled, they will follow standard procedure as any participant would and complete a consent form. Those collecting consent will not be in a direct reporting relationship with participants, as to not be in a position to impact the student's grades or a person's employment.

f) State the number, if any, of participants who are healthy volunteers. Provide rationale for the inclusion of healthy volunteers in this study. Specify any risks to which participants may possibly be exposed. Specify the measures being taken to minimize the risks and the chance of harm to the volunteers and the additional safeguards that have been included in the protocol to protect their rights and welfare.

The target population of this study are participants who have body image concerns due to its preventative nature as a body acceptance intervention. The risks for these volunteers is extremely low. There is potential for participants to feel distressed when disclosing personal information during the program. However, based on previous programs like The Body Project, the associated risk of this occurring is very low and the effects would be short-lived. There is a small risk that volunteers may experience some psychological stress as a result of finding out new information about their psychological health that was revealed in the course of the study. However participants are fully informed of these risks at the time of consent. All collected information is kept confidential in order to protect participant's identity and participants are informed that they are free to exercise their right to withdraw from the study at any time without adverse consequence. Those collecting consent will not be in a direct reporting relationship with participants

g) Describe your plan to identify and recruit potential participants including who will inform them about the study and how they will be initially contacted by the researchers (e.g., Participant Engagement services; chart review; treating physician; ads including social media posts). All final or revised recruitment materials must be approved by the IRB before use. Contacting potential participants is not permitted prior to IRB approval. See Recruitment Guidance for additional information.

Recruitment will take place using both online and in-person strategies. Emails will be sent to the school community (we will contact people from the school and ask for permission to use school listservs), and social media accounts can be created to boost interest for possible participants. Social media recruitments

will have security settings that do not allow the general public to post or comment on posts. In addition, flyers will be posted around the school's campus in high traffic areas.

Online - Ads will be posted on the internet using social media sites: Facebook and Instagram, community forums: Craigslist and Reddit, and the study website. Ads will utilize the Social Media Post-SS and Priorities Flyer-updated SS. We will manage an instagram and facebook page with postings about the study using the approved images and captions. All posts on the page will be moderated by the research coordinator and set to block commenting or posting by the public. Social media recruitment posts will be set up such that the security settings do not allow participants or others from the public to post on the wall/public forum. If this is not possible due to the social media platform's settings, the social media posts will be monitored and any disclosures of PHI removed. Emails will be sent to school communities and organizations (we will contact people and ask for permission to use school listservs). For Reddit, we will obtain any necessary permissions from the moderators before posting for research recruitment. We plan to use subreddits designated for research recruitment purposes, psychology studies, mental health, and students, including, but not limited to, R/samplesize and R/psychologystudents.

We will also contact doctor and clinical offices, such as gynecologist, psychologist, and pediatrician offices, to see if they post flyers or inform patients about our study. All recruitment materials will point to the screener.

Additionally, all families who call the Stanford clinic for services are asked about their willingness to be contacted for research. Parents of youth who indicated they are willing to be contacted for research and who may potentially meet study inclusion criteria may be called and asked if they are willing to hear about a Stanford research study.

We will partner with the Stanford Research Registry to invite participants. One of the methods we will use with the Stanford Research Registry is HonestBroker.

We are also going to try ResearchMatch.org

Flyers will be posted around the school?s campus in high traffic areas.

h) Inclusion and Exclusion Criteria.

Identify inclusion criteria.

i. Female-identifying High School and College Adolescents
ii. Ages 14-22

Identify exclusion criteria.

i. non-female identifying participants
ii. Outside of United States

i) Describe your screening procedures, including how qualifying laboratory values will be obtained. If you are collecting personal health information prior to enrollment (e.g., telephone screening), please request a waiver of authorization for recruitment (in section 15).

Interested participants (as determinde from the "Priorities Interest Form") will be asked to fill out a brief online screening questionnaire ("Priorities Screener"). Only information pertaining to inclusion & exclusion criteria will be included in the questionnaire. Participants have the option to terminate the online screening questionnaire at any time. Participants rights will be clearly stated before proceeding with the screening. Additionally, they can call the research personnel prior to continuing if they have any questions.

j) Describe how you will be cognizant of other protocols in which participants might be enrolled. Please explain if participants will be enrolled in more than one study.

As a part of the informed consent process, subjects will be asked if they are participating in any other research projects. Their participation in other protocols will not exclude them from participation in this study.

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

k) Payment/reimbursement. Explain the amount and schedule of payment or reimbursement, if any, that will be paid for participation in the study. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of participants and that they do not constitute undue pressure on participants to volunteer for the research study. Include provisions for prorating payment. See payment considerations

There will be no payment to participants in Priorities or the Body Project.

l) Costs. Please explain any costs that will be charged to the participant.

N/A

m) Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i) screening of participant; (ii) active participation in study; (iii) analysis of participant data.

The estimated duration of the entire study is around 4 months.
The screening will consist of the online questionnaire (about 10 minutes), Priorities or Body Project sessions will take 4 weeks (one session per week, 1 hour per session), repeated with up to 6 groups, with a 1 month follow up for each session, and analysis of data.

9. Risks

a) For the following categories include a scientific estimate of the frequency, severity, and reversibility of potential risks. Wherever possible, include statistical incidence of complications and the mortality rate of proposed procedures. Where there has been insufficient time to accumulate significant data on risk, a statement to this effect should be included. (In describing these risks in the consent form to the participant it is helpful to use comparisons which are meaningful to persons unfamiliar with medical terminology.)

The risks of the Investigational devices.

There are no risks from the investigational devices as investigational devices will not be used.

The risks of the Investigational drugs. Information about risks can often be found in the Investigator's brochure.

There are no risks of investigational drugs as drugs will not be used.

The risks of the Commercially available drugs, reagents or chemicals. Information about risks can often be found in the package insert.

There are no risks of commercially available drugs, reagents, or chemicals as none will be used.

The risks of the Procedures to be performed. Include all investigational, non-investigational and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).

There are no risks of procedures to be performed as no procedures will be performed.

The risks of the Radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy) and associated risks.

There are no risks of radioisotopes/radiation-producing machines or associated risks as no radioisotope/radiation-producing machines will be used.

The risks of the Physical well-being.

There are no risks to physical well-being.

The risks of the Psychological well-being.

Participants may feel distressed when disclosing personal information during the group sessions. Based on previous experience like The Body Project, the associated risk of this occurring is very low and the effects would be short-lived. These assessments have been used by thousands of young women with almost no distressing outcomes. Participants have the option to not answer any question if they feel uncomfortable. The risks associated with participation in Priorities are anticipated to be similar to that of the Body Project, as they are both dissonance-based group interventions. The added risk for participation in the Priorities

workshop is that we are pilot testing its efficacy in this trial, so it has yet to be clinically proven.

The risks of the Economic well-being.

There are no risks to economic well-being.

The risks of the Social well-being.

There is a small chance that participants may be assigned to a group led by a facilitator that they know outside of the context of this program. When workshops are assigned to the facilitator, we will ask them to check the list to ensure they do not have a personal relationship with any of the participants assigned to their group. In the case that they do, the participant will be placed into a different group led by a facilitator with whom they do not know. Additionally facilitators may know that a group member is participating in the program. However, they will be extensively trained on the importance of confidentiality and protecting participant information.

Students from the same school may be in a group together as participants, but confidentiality with groups will be emphasized.

b) If you are conducting international research, describe the qualifications/preparations that enable you to both estimate and minimize risks to participants. Provide an explanation as to why the research must be completed at this location and complete the International Research Form. If not applicable, enter N/A.

N/A

c) Describe the planned procedures for protecting against and minimizing all potential risks. Include the means for monitoring to detect hazards to the participant (and/or to a potential fetus if applicable). Include steps to minimize risks to the confidentiality of identifiable information.

i) If interested participants do not consent their information will not be retained.
ii) All electronic information will be maintained on password-protected files on encrypted devices at Stanford.
iii) Participants' data that will not contain PHI will be identified by assigned identification codes (ID numbers) that will not be determined by any personal identifiers so that participants' identification and privacy will be protected.
iv) Access to files and identifiers will be restricted to Stanford researchers involved in the study.
v) The study will protect against risks of confidentiality by securing all data containing PHI in locked files, assigning ID numbers for data collection, and reinforcing the policies of confidentiality among the study researchers according to Stanford's guidelines.

In the case that a study participant indicates suicidal ideation, the research team will report the information to the proper authorities (e.g. parents, school staff). We will also provide referrals for care. Research personnel will determine their ability to participate based on their ability to provide consent.

d) Explain the point at which the experiment will terminate. If appropriate, include the standards for the termination of the participation of the individual participant Also discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the participants.

Data collection for each participant will terminate once they've completed the study (4 weeks of Body Project Sessions, posttest and 1 month follow up assessments). The entire study will terminate when all session assessments have been completed for all participants. If the participant wants to terminate the experiment at any time, they can do so. If the investigator determines that participation would be harmful to the subject or investigator in any way, they can terminate the experiment.

e) Special Participant Populations

Children's Findings OHRP. As children are involved in your research, please select one or more regulatory categories (46.404 through 46.407) below that your research falls under and provide the necessary rationale for each determination. See full regulation citation.

Y 46.404 Research not involving greater than minimal risk. The research must present no greater than minimal risk to children and adequate provisions must be made for soliciting the assent of the

children and the permission of their parents or guardians. Please provide rationale for the above statement.

Rationale for category selected above

The risks of this pilot study are extremely low. This is a behavioral, non-invasive program which reduces harm.

10. Benefits

a) Describe the potential benefit(s) to be gained by the participants or by the acquisition of important knowledge which may benefit future participants, etc.

The most salient benefit is having participants place self-worth to areas that yield them better mental health instead of an idealized weight and shape. There is a possibility of reducing eating disorder risk factors/symptoms and the potential prevention of future eating disorders in participants. Additionally, participants could gain a better understanding of eating disorders, which would benefit themselves and others.

11. Privacy and Confidentiality

Privacy Protections

a) Describe the setting and method (e.g. crowded waiting room, patient exam room, telephone or email communication) in which interactions will occur and how the privacy interests of participants will be maintained. Note, high risk data such as PHI must be sent via "Secure:" email per Stanford policy.

Members of the research team are well-versed in the importance of protecting the privacy of research participants. Therefore, systems are in place to assure that the identities of participants are protected and will not be revealed. This includes: collecting participant consent in a private location, using SECURE in email subject lines when correspondence includes PHI, and separating PHI from data. Data will be downloaded on encrypted computers and saved using subject ID. Email will be sent using Stanford email service which can encrypt email as needed. For telephone calls we will use numbers provided by subjects and will only send mail to addresses provided by the subject.

Confidentiality Protections

b) Specify PHI (Protected Health Information). PHI is health information linked to HIPAA identifiers (see above). List BOTH health information AND HIPAA identifiers. If you are using STARR, use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol. Be consistent with information entered in section 15a.

Name
Date of Birth
Telephone Number
Email Address
Age
Gender
Ethnicity
medication history
eating behaviors and disorder history other health information relating to weight and weight management

c) You are required to comply with University Policy that states that ALL electronic devices: computers (laptops and desktops; OFFICE or HOME); smart phones; tablets; external hard disks, USB drives, etc. that may hold identifiable participant data will be password protected, backed up, and encrypted. See http://med.stanford.edu/datasecurity/ for more information on the Data Security Policy and links

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

to encrypt your devices.

Stanford University IT approved platforms (https://uit.stanford.edu/guide/riskclassifications) should be used for data management. Consult with your Department IT representative for more information.For data security policies and links to encrypt your devices see http://med.stanford.edu/irt/security and http://www.stanford.edu/group/security/securecomputing/mobile_devices.html. Additionally, any PHI data on paper must be secured in a locked environment.

By checking this box, You affirm the aforementioned. Y

All electronic information will be maintained on password-protected files on encrypted devices or servers. Any paper identifiers will be stored in locked files.
Participants' surveys will be identified by assigned identification codes (ID numbers)that will not be determined by any personal identifiers so that participants' number identification and privacy will be protected.

d) Describe how data or specimens will be labeled (e.g. name, medical record number, study number, linked coding system) or de-identified. If you are de-identifying data or specimens, who will be responsible for the de-identification? If x-rays or other digital images are used, explain how and by whom the images will be de-identified.

Participants' surveys will be identified by assigned identification codes (ID numbers) that will not be determined by any personal identifiers so that participants identification and privacy will be protected.

e) Indicate who will have access to the data or specimens (e.g., research team, sponsors, consultants) and describe levels of access control (e.g., restricted access for certain persons or groups, access to linked data or specimens).

Only Stanford research personnel indicated in the Personnel info will have access to the collected data via qualtrics or redcap.

f) If data or specimens will be coded, describe the method in which they will be coded so that study participants' identities cannot be readily ascertained from the code.

We will assign all participants a number at time of entry into the study. The number will not contain any identifying information.

g) If data or specimens will be coded, indicate who will maintain the key to the code and describe how it will be protected against unauthorized access.

The main investigator for the study will maintain the key to the code which will be kept in a password protected document on their Stanford encrypted computer.

h) If sharing data with others, describe how data will be transferred or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, confirm a Stanford University IT approved platform will be used (see https://uit.stanford.edu/guide/riskclassifications) or that data will be encrypted while in transit. Additionally, confirm appropriate agreements are in place to allow for the sharing (see https://ico.stanford.edu/stanford-researchers/who-will-handle-my-agreement). If using or sharing PHI, refer to the following policies: https://uit.stanford.edu/security/hipaa.

We will not be sharing data with others.

i) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data or specimens collected (e.g. conscious of oral and written communications, conducting insurance billing, and maintaining paper and electronic data)?

Research staff have all been trained in measures of confidentiality and have completed CITI and HIPAA training. They also have experience in maintaining subject privacy through working on previous similar research studies.

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

12. Potential Conflict of Interest

Investigators are required to disclose any outside interests that reasonably appear to be related/li to this protocol.

Outside Interest Tasks

Investigators	Role	Potential COI?	Date Outside Interest Answered	Date OPACS Disclosure Submitted	COI Review Determination
Eric Stice	PD	N	02/27/2025		N/A

13. Consent Background

13. 1 Consent Parent Consent

Sponsor's Consent Version Number: (if any) :

a) Describe the informed consent process. Include the following.

i) Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.)

ii) When and where will consent be obtained?

iii) How much time will be devoted to consent discussion?

iv) Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?

v) What steps are you taking to minimize the possibility of coercion and undue influence?

vi) If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration.

i)Research personnel will obtain consent from a parent and assent from the participating child. The research staff is knowledgeable about the study and are qualified to answer questions regarding the study. A discussion on consent will take place with parents, and a discussion on assent will take place with the child. These conversations will take place at the same time. If the participant is over 18yo, we will obtain their consent, there will still be a discussion and the ability to answer their questions. (ii) The consent will typically be collected via REDCap or Adobe sign (accompanied by a phone call to go over consent discussion) or an in person option (in a private room at their school). Participants will only need one or the other (i.e., if have online form to not need in-person form). Forms emailed to us can be either scanned. Once consent forms are received, we will ensure that participants have signed and dated the consent forms (over secure email). Consent will be obtained prior to the program, and after the study and participation requirements have been explained. (iii) The consent process can take anywhere from 10 minutes to longer. This depends on the number of questions the potential participant may have and the length of time it takes for them to read it through. (iv) These consent periods will provide ample time for the potential participants to consider their involvement in the study, as we will provide as much time as necessary for the subject to make their decision. There will be no time limit within a reasonable frame. (v) Potential participants who are already deemed eligible for participation will be informed that they will not be paid for their participation. Research staff will not express their opinions on whether the individuals should participate, if they are asked. Rather, the research personnel will hold that the choice remains with the individual and that any other questions that they have regarding participation can be addressed. (vi) It may not be logistically feasible to acquire the consent of both parents, if for instance the parents are divorced or one is deceased. Adobe Sign/REDCap consent form/assent form will mirror the approved consent form in section 13(e.g., the HIPAA Authorization will be in 14-point font and separate signature lines for the HIPAA Authorization and consent form).

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

b) What is the Procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See HRPP Chapter12.2 for guidance.

After reviewing each section of the consent or assent with the prospective participant, the research staff will stop to ask if there are any questions or concerns. If the potential participants cannot understand English, we will not consent to them as they will not be able to be completely informed of the research process, nor will they be able to participate in the study. Hearing impaired individuals may also not be able to participate in this research because the assessments and nature of the program were not created to be administered to that population.

c) What steps are you taking to determine that potential participants have the capacity to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent,(iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

Research personnel will determine their ability to participate based on their ability to understand the consent and the research process. We will not be enrolling any participants who are unable to provide assent if a child, or consent if an adult, as consent is a participation requirement.

13. 2 Waiver of Documentation Priorities Screener

Sponsor's Consent Version Number: (if any) :

a) Describe the informed consent process. Include the following.

i) Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.)

ii) When and where will consent be obtained?

iii) How much time will be devoted to consent discussion?

iv) Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?

v) What steps are you taking to minimize the possibility of coercion and undue influence?

vi) If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration.

(i) Members of the research team will obtain consent. The research team will be involved in all aspects of the study, hence they are knowledgeable about the study (ii) Potential participants who express interest will be given a link to a secure Qualtrics Screening questionnaire ("Priorities Screener"). Participants have the option to terminate the online screening questionnaire at any time. Participants rights will be clearly stated before proceeding with the screening. Additionally, they can call the research personnel prior to continuing if they have any questions. If screening is conducted via phone, consent to participate in the phone screen will be obtained verbally at the beginning of the phone screen. If a participant says yes, they will be asked questions to determine eligibility. If a participant says no, then the research team member will not continue with the phone screen, and the person will be ineligible for the study. (iii) There is no time limit placed on completion of the screening, participants can answer the questions at their own pace. If conducted via phone, the member of the research team conducting the phone screen will allow the participant to ask questions if they have any and not rush them to answer the questions. It is anticipated that the phone screen will take 10-15 minutes. (iv) Yes, this will provide sufficient opportunity for the participant to consider whether or not to participate in the screener. (v) We will make sure that the participants will be comfortable with any decision they make. The decision they make will not affect treatment. They may withdraw their consent at any point in the study. (vi) If a minor clicks on the ad (as indicated by their age), they are only prompted to fill out the "Priorities Interest Form" questions, which ask them to provide their parent's contact information. Our research team then reaches out to the parent via email to provide them with a secure Qualtrics link to the Screening questionnaire ("Priorities Screener")to fill out on behalf of their child. We only administer the pre-questionnaire after parental consent and child assent have been collected. For participants who are under 18, we will conduct the phone screen with the parent first, if phone is preferred. During the phone screen, we will ask if it is okay that we reach out to contact the adolescent to conduct the same phone screen. If the adolescent then wants to complete the phone screen we will, if not it is sufficient to conduct the phone screen with the parent. As the screener provides minimal risk, only consent from one parent is required as per 21 CFR 50.55.

b) What is the Procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See HRPP Chapter12.2 for guidance.

Participants will be asked questions to ensure that they understand the information contained in the consent. The research team member conducting the phone screen will be well-versed in the study and will be able to answer questions that the participant may have. Individuals who are not proficient in English or have any

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

impairment in communication that might compromise informed consent will be excluded from the study.

c) What steps are you taking to determine that potential participants have the capacity to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent,(iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

see (b) No adults will be enrolled who are unable to consent.

Select ALL applicable regulatory criteria for a Waiver of Documentation and provide a protocol-specific justification:

1)		**45 CFR 46.117(c)(1)(i)., that the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; each participant (or legally authorized representative) will be asked whether he/she wants documentation linking the participant with the research, and the participant's wishes govern.**
2)	Y	**45 CFR 46.117(c)(1)(ii)., that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.**
3)		**45 CFR 46.117(c)(1)(iii)., if participants or legally authorized representatives (LAR) are members of a distinct cultural group in which signing forms is not the norm, the research presents no more than minimal risk and there is an appropriate alternative mechanism for documenting that informed consent was obtained.**
4)		**21 CFR 56.109(c)(1)., presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.**

Rationale for above selection:

The screen presents no more than minimal risk of harm to the participants. The subject may feel uncomfortable when we ask for personal information that is required to determine eligibility. The subject will be told that s/he is not required to answer any questions if she/he does not want to.

14. Assent Background (less than 18 years of age)

14. 1 Assent Child Assent

Sponsors Assent Version Nbr: (if any) :

a) Describe the assent process. Include the following:

- **(i) Who is obtaining child assent? (The person must be knowledgeable about the study.)**
- **(ii) When and where will assent be obtained?**
- **(iii) Will a parent or guardian be present when assent is obtained?**
- **(iv) How much time will be devoted to the assent discussion?**
- **(v) Will these periods provide sufficient opportunity for the child to consider whether to assent?**
- **(vi) What steps are you taking to minimize the possibility of coercion and undue influence?**

(i) Research personnel will obtain consent from a parent and assent from the participating child. The research staff is knowledgeable about the study and are qualified to answer questions regarding the study. If a child turns 18 within the course of the study, they will be re-consented as an adult at the next scheduled visit (upcoming group session or upcoming assessment visit).
(ii) The assent will typically be collected via google form (google, Qualtrics, etc) or an in person option (in a private room at their school). Forms emailed to us can be scanned. Once assent forms are received, we will ensure that participants have signed and dated the assent forms. Assent will be obtained prior to the program, and after the study and participation requirements have been explained.
(iii) We will require that a parent or guardian sign a consent form, but it may not be feasible that the parent is physically present while the child signs the assent, as the child will be participating at school.
(iv) The assent process can take anywhere from 10 minutes to longer. This depends on the number of questions the potential participant may have and the length of time it takes for them to read it through.
(v) These assent periods will provide ample time for the potential participants to consider their involvement in the study, as we will provide as much time as necessary for the subject to make their decision. There will

be no time limit within a reasonable frame.
(vi) Potential participants who are already deemed eligible for participation will be informed that they will not be paid for their participation. Research staff will not express their opinions on whether the individuals should participate, if they are asked. Rather, the research personnel will hold that the choice remains with the individual and that any other questions that they have regarding participation can be addressed.

b) What is the procedure to assess the child's understanding of the information contained in the assent? How will the information be provided to the child if he/she does not understand English or has a hearing impairment? How will affirmative assent be obtained (e.g., oral response, signature on form, combination of methods, other)? Is there a possibility that the intervention or procedure involved in the research/clinical investigation holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research/clinical investigation and therefore assent may not be necessary?

After reviewing each section of the consent or assent with the prospective participant, the research staff will stop to ask if there are any questions or concerns. If the potential participants cannot understand English, we will not consent to them as they will not be able to be completely informed of the research process, nor will they be able to participate in the study. Hearing impaired individuals may also not be able to participate in this research because the assessments and nature of the program were not created to be administered to that population.

c) What steps are you taking to determine that the child has the capacity to participate in the decision-making process?

Research personnel will determine their ability to participate based on their ability to understand the assent and the research process. We will not be enrolling any participants who are unable to provide assent if a child, or consent if an adult, as this is a participation requirement.

15. HIPAA Background

15. 1 Waiver of Authorization for Recruitment

waiver of authorization for recruitment

a) Describe the protected health information (PHI) needed to conduct screening or recruitment. PHI is health information linked to HIPAA identifiers. List BOTH health information AND HIPAA identifiers. If you are using STARR, use the Data Privacy Attestation to ensure that your request will match your IRB-approved protocol.

Potential participants will be asked several questions related to their health history to determine their eligibility to participate in the study. This includes age, gender identity, sex, eating history, and contact information (name, phone, email, address).

b) Please Answer:

Y **Do you certify that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals?**

Y **Do you certify that the research could not practically be conducted with out the waiver?**

Y **Do you certify that you have adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted?**

Y **Do you certify that the research could not practically be conducted with out access to and use of the protected health information?**

c) Please describe an adequate plan to protect any identifiers from improper use and disclosure.

Verbal consent will be obtained before completion of the phone screen. If a subject does not meet eligibility criteria, then we will not collect their address and will delete their entry.

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

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

Identifiable information from online pre-screening will be destroyed 7 years after the study completion.

16. Attachments

Attachment Name	Attached Date	Attached By	Submitted Date
Priorities Script	04/04/2025	jsperry	
Priorities Home Exercises	04/04/2025	jsperry	
Body Project Script and Home Exercises	04/04/2025	jsperry	
EDDS	04/04/2025	jsperry	
Priorities Questionnaire-updated	04/15/2025	jsperry	
Email template for schools	04/15/2025	jsperry	
Letter of Agreement from Campbell Union High School District	04/25/2025	lunam1	
Priorities Flyer-updated SS	05/20/2025	jsperry	
Social Media Post-SS	05/20/2025	jsperry	
Protocol-79760_SSR	05/27/2025	lunam1	
Research Match Contact Message	07/30/2025	sshah04	
Priorities Interest Form Updated	07/31/2025	sshah04	

Obligations

The Protocol Director agrees to:

- Adhere to principles of sound scientific research designed to yield valid results
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection, ethical principles, regulations, policies and procedures
- Ensure all Stanford research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Ensure that, when de-identified materials are obtained for research purposes, no attempt will be made to re-identify them.

Title : Pilot Testing Overvaluation of Weight and Shape Intervention vs The Body Project
Approval Period: 04/23/2026 - 12/31/2999

- Disclose to the appropriate entities any potential conflict of interest
- Apply relevant professional standards.

Additional Responsibilities

- Any change or modification in the research protocol must be submitted to and approved by the IRB prior to the implementation of such change, except when necessary to eliminate apparent immediate hazards to the participant.
- For studies with expiration dates, submit a Continuing Review prior to the end of the approval period. An IRB Continuing Review (Renewal) Notice to Renew Protocol is sent to the Protocol Director prior to the expiration date of the protocol.
- https://irb.stanford.edu/for-researchers/prompt-reporting-to-IRB Report promptly any new information, complaints, possibly serious and/or continuing noncompliance, or unanticipated problems involving risks to participants or others.

Record Retention

All data, including signed consent forms when applicable, must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities (e.g. 6 years for studies conducted under HIPAA or VAPAHCS). (See also Research Policy Handbook Retention of and Access to Research Data)

Y By checking this box, I verify that I, as the Protocol Director (PD) responsible for this research protocol, have read and agree to abide by the above obligations, or that I have been delegated authority by the PD to certify that the PD has read and agrees to abide by the above obligations.

APPROVAL LETTER/NOTICE NOTE: List all items (verbatim) that you want to be included in your approval letter (e.g., Amendment date, Investigator's Brochure version, consent form(s) version(s), advertisement name, etc.) in the box below.

Amendment date