

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY
FOR AN ADULT
INFORMED CONSENT - PART I**

Title of Study: *Assessment of the Efficacy of the Female Athlete Body Project*

What you should know about a research study

- We give you this consent form so that you may read about the purpose, risks and benefits of this research study.
- The main goal of research studies is to gain knowledge that may help future patients.
- You have the right to refuse to take part, or agree to take part now and change your mind later on.
- Please review this consent form carefully and ask any questions before you make a decision.
- Your participation is voluntary.
- By signing this consent form, you agree to participate in the study as it is described.

1- Who is doing the study?

Investigator Information:

Principal Investigator: Tiffany M. Stewart, Ph.D.
225-763-2554

Medical Investigator: Dr. William Cefalu, M.D.
Day Phone: 225-763-2658
24-hr. Emergency Phone Nos.:
225-763-2672 (Weekdays 7:00 a.m.-4:30 p.m.)
225-765-4644 (After 4:30 p.m. and Weekends)

Co-Principal Investigator: Carolyn Becker, PhD Trinity University

Co- Investigator: Kelly MacKenzie, M.A. American University

Dr. Tiffany Stewart directs this study, which is under the medical supervision of Dr. William Cefalu. We expect about 500 people from three sites will enroll in this study. We expect 200 people from the Department of Athletics at Louisiana State University to enroll in the study. This study will take place over a period of five years. Your expected time in this study will be approximately three hours over the next 18 months or longer. This study is funded by the National Institutes of Mental Health (NIMH).

The investigator(s) of this study are interested in knowledge to be gained from this study and in your well-being. Investigators may obtain salary or other financial support for doing work with similar topic matter. You are under no obligation to participate in any research study offered to you.

2- Where is the study being conducted?

This study is being conducted at Louisiana State University.

3- What is the purpose of this study?

The purpose of this study is to evaluate a healthy body program that the Department of Athletics has decided to hold for its female athletes. Healthy body programs are used on many college campuses, and thus it is important to examine ways to improve these programs to make them more effective.

4- Who is eligible to participate in the study? Who is ineligible?

You are eligible for this study if you are:

1. Female
2. A member of a university sponsored athletic team at Louisiana State University
3. Willing and able to provide informed consent, attend all study visits and comply with the study protocol

5- What will happen to you if you take part in the study?

If you agree to participate, you will sign this informed consent. For this study, you will be asked to fill out a first set of questionnaires today after signing the consent and before the program begins. You will be asked to fill out another set of questionnaires at the end of the third session, during Week 3. You will also be asked to fill out a set of questionnaires at month 6, 12, and 18 at meetings or online, if you are no longer at LSU. You will be asked to provide the names of three people that know how to contact you so that we can attempt to contact you if you have left the university. These questionnaires assess attitudes and behaviors related to body image, eating, and cultural ideals. You will also be asked to participate in a brief phone interview to discuss your eating habits at Baseline, Week 3, 6 months, one year, and month 18. Your data will not be shared with the department of athletics and all questionnaires will be individual and anonymous. As part of being on the athletic team, you may take part in a healthy body program which will consist of three 1 ½ hour sessions and is not part of the research study.

6- What are the possible risks and discomforts?

The study provides minimal risks and discomforts. There is the possibility some of the questionnaires may cause some stress since they deal with personal issues.

7- What are the possible benefits?

We cannot promise any benefits from your being in the study. However, possible benefits include contribution to research that could aid the health behaviors of female collegiate athletes.

8- If you do not want to take part in the study, are there other choices?

You have the choice at any time not to participate in this research study. If you choose not to participate, any health benefits to which you are entitled will not be affected in any way.

9- If you have any questions or problems, whom can you call?

If you have any questions about your rights as a research volunteer, you should call the Institutional Review Board Office at 225-763-2693 or the Executive Director of PBRC at 225-763-2513. If you have any questions about the research study, contact Dr. Tiffany Stewart (Principal Investigator) at 225-763-2554. If you think you have a research-related injury or medical illness, you should call Dr. William Cefalu at 225-763-2658 during regular

working hours. After working hours and on weekends you should call the answering service at 225-765-4644. The on-call physician will respond to your call.

10- What information will be kept private?

Every effort will be made to maintain the confidentiality of your study records. However, someone at the Pennington Biomedical Research Center or the NIH may inspect and/or copy the records related to the study. Results of the study may be published; however, we will keep your name and other identifying information private. Other than as set forth above, your identity will remain confidential unless disclosure is required by law.

11- Can your taking part in the study end early?

Dr. Stewart, Dr. Cefalu, or the study sponsor can withdraw you from the study for any reason or for no reason. You may withdraw from the study at any time without penalty. Possible reasons for withdrawal include your choice to withdraw from the study or no longer meeting inclusion criteria. The Pennington Center may end the study early.

12- What if information becomes available that might affect your decision to stay in the study?

During the course of this study there may be new findings from this or other research which may affect your willingness to continue participation. Information concerning any such new findings will be provided to you.

13- What charges will you have to pay?

None

14- What payment will you receive?

If you agree to take part, you will be paid up to a total of \$250 for participation. You will receive \$20 each time you complete the questionnaire assessments and \$30 each time you complete the phone assessment (\$50 total for each time point) at baseline, week 3, and 6, 12 and 18 month follow up respectively in the form of Amazon gift cards. You will receive your Amazon gift cards at the appropriate milestone during the course of the study.

15- Will you be compensated for a study-related injury or medical illness?

No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from the Pennington Biomedical Research Center. In the event of injury or medical illness resulting from the research procedures in which you participate, you will be referred to a treatment facility. Medical treatment may be provided at your expense or at the expense of your health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. The Pennington Biomedical Research Center is a research facility and provides medical treatment only as part of research protocols. Should you require ongoing medical treatments, they must be provided by community physicians and hospitals. As noted in section 6, there are minimal risks associated with this study.

16- HIPAA

Records that you give us permission to keep, and that identify you, will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name,

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social security number, address, telephone number, or any other direct personal identifier in records disclosed outside of Pennington Biomedical Research Center (PBRC). For records disclosed outside of PBRC, you will be assigned a unique code number.

17- Signatures

The study has been discussed with me and all my questions have been answered. I understand that additional questions regarding the study should be directed to the study investigators. I agree with the terms above and acknowledge that I have been given a copy of the signed consent form.

With my signature, I also acknowledge that I have been given either today or in the past a copy of the Notice of Privacy Practices for Protected Health Information.

Printed Name of Volunteer

Signature of Volunteer

Date

Date of Birth of Volunteer

Signature of Person Administering Informed Consent

Date

Tiffany M. Stewart, Ph.D.
Principal Investigator

William Cefalu, M.D.
Medical Investigator