Clinical Trials.gov ICF Cover Sheet

Study Title: TOPS for African American Breast Cancer Survivors

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DUKE UNIVERSITY HEALTH SYSTEM

**Consent to Participate in a Research Study**
**ADULT**
Feasibility and Acceptability of a Community-Based Weight Loss Program Among African American Breast Cancer Survivors
Principal Investigator: Nia S. Mitchell, MD, MPH
Other Investigators:
Leah Zullig, Ph.D.

CONCISE SUMMARY

We are doing this research study to find out what African American breast cancer survivors who are overweight or obese think of TOPS (Take Off Pounds Sensibly), a low cost, community-based, peer led, weight loss program. We will look at the weight change of women who participate in the program. We are asking African American breast cancer survivors who may be overweight or obese to take part in this study.

As part of the TOPS program you will have weekly group virtual meetings where weight management topics will be discussed. For the study you will be asked to come to a Duke facility or community site to be weighed by the study team at the beginning and again at 3 months, 6 months, and 12 months. Prior to these appointments, for everyone's safety we may ask some screening questions related to Covid-19 as well as check your temperature. At 6 months you will be asked to participate in a virtual focus group and answer questions about your experience with TOPS, including your eating and exercise habits. The study team will audio-record the interview and it will be professionally transcribed to create written reports of what was said during the interview. Audio-recordings and transcripts will not include identifying information about you. You will only be identified by your study number in these recordings and documents. Your participation in the study will last for approximately 12 months.

We do not expect you to have any major physical risks from taking part in the study except for those with diabetes who are taking either insulin or medications known as sulfonylureas. Those participants may experience episodes of low blood sugar with weight loss if their insulin or medication is not adjusted. Low blood sugar can cause sweatiness, weakness, and heart palpitations. Very low levels, can cause confusion, seizures, and death. We will minimize this risk by asking your healthcare provider to agree to manage your insulin or medication needs while you take part in this study. The details of the study risks, inconveniences, discomforts, and other important information about the study are listed below.
If you are interested in learning more about this study, please continue reading below.

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask her to explain anything that you do not clearly understand. We encourage you to speak with family and friends before you decide to take part in this research study

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The Principal Investigator for the study is Dr. Nia S. Mitchell. A grant from the National Cancer Institute (NCI) of the National Institutes of Health (NIH), is funding this study. Part of the research team's salaries will be paid by this grant.

**WHO WILL BE MY DOCTOR ON THIS STUDY?**
You will continue to receive care from your usual healthcare providers while on this study. However, if you have diabetes and are on insulin or sulfonylureas you will be asked to obtain a signature from your primary doctor stating they agree that they will manage your medication requirements.

**WHY IS THIS STUDY BEING DONE?**
We are doing this research study to find out what African American breast cancer survivors who are overweight or obese think of TOPS (Take Off Pounds Sensibly), a low cost, community-based, peer led, weight loss program. We are asking African American breast cancer survivors who may be overweight or obese take part in this study.

**HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**
About 50 people will take part in this study.

**WHAT IS INVOLVED IN THE STUDY?**
If it is safe for you to participate and you agree to join this study, we will ask you to sign and date this form. Being in this study is voluntary, so you can refuse to participate with no penalty.

As a participant in this study you will be weighed by the study team at the beginning and again at 3 months, 6 months, and 12 months from the start of the study. During each of the appointments, the study team will take your weight, and at the first visit we will measure your height. The first appointment may take up to 30 minutes to complete and the remaining appointments will only take up to 15 minutes. Your participation in the study will last for approximately 12 months.

Once we have signed approval from your primary doctor you can begin the TOPS program. The details about the TOPS plan is explained below:

If you participate in the study you will:

- Be enrolled in the TOPS Program
- Be provided with a digital scale for recording at home weigh-ins
- Attend weekly group meetings virtually on your computer. (Meetings will be about an hour long. We understand that unexpected events can come up. You can continue in the study even if you miss some meetings.)

- Participate in virtual group discussions, and be given information to help you reach your goals at each weekly meeting.
- Complete in-person weight checks with the study team at study start, 3 months, 6 months, and 12 months.
- After 6 months we will ask you to participate in a virtual focus group that will be recorded, to discuss your thoughts about the program.
- Complete all study activities in about 12 months from the time you enroll in the study.

**HOW LONG WILL I BE IN THIS STUDY?**
If you agree to take part in this study, your involvement will last for approximately 12 months.

You may choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

After the study finishes, the study team will share the results of the weight loss study with your group. The study team will also provide copies of the scientific publications that are written from the study results.

**WHAT ARE THE RISKS OF THE STUDY?**
There are minimal risks of harm to you in this study. Weight loss has been shown to be safe in obese individuals. The TOPS program is being safely used throughout the United States and Canada.

If you have diabetes and are taking either insulin (injected or inhaled) or medications known as sulfonylureas, such as glipizide (Glucotrol), glyburide (DiaBeta or Micronase), or glimepiride (Amaryl) and you lose weight, you may experience episodes of low blood sugar with weight loss if your medication is not adjusted, based on your weight loss. Low blood sugar can cause sweatiness, weakness, and heart palpitations. Very low levels, can cause confusion, seizures, and death. We will minimize this risk by asking your healthcare provider to approve your participation in the study and to agree to manage your insulin or sulfonylurea needs.

We may ask you questions that may make you feel uncomfortable. If you do not want to answer, you can stop at any time.

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Your private information could become known. We will do all we can to keep your information private, but this cannot be guaranteed.

**ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**
If you agree to take part in this study, there may be benefits to you. You may lose weight, which can decrease your risk for heart disease and early death. You may make healthy lifestyle changes that may help improve medical issues such as Type II diabetes, hypertension, and obstructive sleep apnea.However, none of these benefits can be guaranteed.We also hope that what we learn from this study will benefit other African American breast cancer survivors.

**WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?**
Instead of being in this study you could enroll in a different weight loss program.

**WILL MY INFORMATION BE KEPT CONFIDENTIAL?**
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be seen by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

Your research records that are reviewed, stored, and analyzed at Duke University will be kept in a locked file cabinet in a secured area in the Department of General Internal Medicine at 200 Morris St., 3rd floor, Durham, NC 27701.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

We will keep your study records for at least six years after the study is done. After six years, we will destroy the records, or we will remove all information identifying you. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

**WHAT ARE THE COSTS TO YOU?**
There are no costs to you for participating in this study. The TOPS program membership costs up to $92 per year. The study will cover this payment for you.

**WHAT ABOUT COMPENSATION?**
You will receive a digital scale at your first in-person weight check, worth $20, to keep. You will receive $10 for each additional in-person weight check with the study team, at 3 months, 6 months, and 12 months. You will receive $25 after you complete the virtual focus group. Your total compensation for completing all study tasks will be will be up to $55, a digital scale, and a 12 month TOPS membership.

There is an additional opportunity for some participants to become a TOPS leader. This weight loss program requires peer leadership, which means one member of your group will be the leader. This involves reading the materials ahead of time and taking a training on TOPS leadership. You will receive an additional $10 for each training module completed to become a TOPS leaders.

**WHAT ABOUT RESEARCH RELATED INJURIES?**
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide money or free medical care to you if you are injured as part of the study. Dr. Nia S. Mitchell can be reached at 919-668-7202 during regular business hours, after-hours, weekend, and holidays.

**WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?**

You may choose not to take part. Or, if you chose to take part, you can decide to stop at any time. If you drop out of the study, we will ask you to continue showing up for study visits so that we can record your measurements. You can stop participating at any time without penalty or loss of the housing or care that you receive at your public housing community or senior center.

If you do decide to withdraw, we ask that you contact Dr. Nia S. Mitchell in writing and let her know that you are withdrawing from the study. Her mailing address is 200 Morris St., 3rd Floor, #3612 Durham, NC 27701.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. If this occurs, you will be notified and your study doctor will discuss other options with you.

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## WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Nia S. Mitchell at 919-668-7202 during regular business hours.

For questions about your rights as a study participant, or to discuss concerns, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

## STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

| _____ | _____ | _____ |
|---|---|---|
| Signature of Subject | Date | Time |

| _____ | _____ | _____ |
|---|---|---|
| Signature of Person Obtaining Consent | Date | Time |