RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: **Black Girls Move: A Daughter/Mother Intervention to Prevent Obesity by Increasing Physical Activity and Improving Dietary Intake among Black Adolescent Daughters: ORA: 21110208-IRB01**

Sponsor(s): **National Institutes of Health**

Name of Participant: _____

Note: If you are a parent, guardian or legal representative of a minor who is not able to consent for themselves], the terms "you" or "your" refer to the research participant.

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to test Black Girls Move, a school-linked daughter/mother physical activity and dietary behavior program, with 7-10th grade students. This program is designed to prevent obesity in Black adolescent females. Black Girls Move is a 12-session intervention to test an obesity prevention intervention.

If you agree to participate in this study, your participation may last up to six months and you will be asked to complete 12 visits over three months of study visits with a three month follow-up.

During these visits, you will be asked to set physical activity and diet goals and self-monitor goal

attainment. You will be asked to participate in structured activities designed to facilitate communication, problem solving, role assignment, and relationship quality. Black Girls Move includes the use of a variety of videos, role play, discussion, and activities to achieve session outcomes. Some of the sessions may be recorded. The sessions are led by trained facilitators who follow a standardized facilitator manual. You will be asked to wear a physical activity monitoring device (Fitbit) and log your food intake into an app on your electronic device.

There are risks to you for participating in this study. In this study, there is a risk of physical, psychological, social, cultural, financial, and risks to privacy and/or confidentiality. While unlikely, potential risks exist in increasing physical activity in Black adolescent females and women who have medical problems that contraindicate increased physical activity. Additional risks associated with a physical activity intervention include safety, injury, and loss of confidentiality. Participants could discuss group information outside of the intervention group meeting with non-participants. Measures for handling risks are addressed below. There are minimal known social, cultural, financial, or legal risks associated with involvement in this study.

You may benefit from taking part in this study. Based on experience with Black Girls Move with prior groups researchers believe it may be of benefit to Black adolescent females. However, because individuals respond differently, no one can know in advance if it will be helpful for you. Potential benefits may include improved physical activity. You may be given behavioral strategies for nutrition and physical activity related lifestyle change that should benefit you over the long term and decrease your risk for obesity related disease. The affirming potential benefit of the anti-racist content may improve your ability to navigate through a structurally racist environment. Participants keep the Fitbit® after the intervention period which can be used beyond the study timeframe to continue monitoring physical activity behaviors.

There are other options available to you if you decide not to participate in this study. You may choose to identify an alternative program or services to receive physical activity and dietary intervention services. You are also free to purchase physical activity monitoring devices such as Fitbit® or other monitoring devices outside the purview of the current study.

<u>Detailed Information</u>: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

<u>Why are you being invited to participate in this study?</u>

You are being asked to participate in this study because you may meet the criteria: Inclusion criteria for the daughters are (a) English-speaking; (b) Black; (c) grade 9 or 10; (d) daily access to the internet outside of school and/or work through an iOS or android smartphone, tablet, or personal computer; (e) either high-normal weight (between ≥50th and <85th percentile for age and gender) or overweight (between ≥85th and <95th percentile for age and gender) as the purpose of this study is weight maintenance and obesity prevention in at-risk daughters rather than obesity treatment; and (f) have either a poor diet, (defined as consuming <1 vegetable or <1 fruit per day) or inadequate physical activity (defined as < 60 minutes per day, 7 days per

week).

Inclusion criteria for mothers are (a) English-speaking; (b) Black; (c) co-residing biological mother or mother-figure and legal guardian of the participating daughter; (d) the person primarily responsible for meals in the household; and (e) access to the internet through an iOS or android smartphone, tablet or personal computer.

How many participants will take part in this study?
Approximately 192 daughters and their mothers are expected to take part in this study.

What are the activities you will be doing if you participate in this study?
After enrollment and completion of the baseline assessment, you will be randomized (assigned by chance, like a flip of a coin) to one of two groups (Black Girls Move or daughters-only comparison condition) in a 1:1 fashion:

Name: Black Girls Move
Description: Black Girls Move (BGM) is an obesity prevention which includes all mothers as active participants to leverage the daughter/mother relationship. Black Girls Move consists of 12 group sessions to instruct participants to set physical activity and dietary goals, as well as self-monitor progress towards goals. Dyads participate in structured activities designed to facilitate communication, problem solving, role assignment, and relationship quality. Dyads use a variety of videos, role play, discussion, and activities to achieve session outcomes. The sessions are led by trained facilitators who follow a standardized facilitator manual.

Name: Daughters-only comparison condition
Description: The daughters-only comparison condition (DOCC) runs parallel to the Black Girls Move (BGM) treatment intervention and includes daughters-only group meetings. The DOCC incorporates all components of BGM except mother strategies. Daughters in DOCC will receive physical activity and diet behavior content. DOCC facilitators will lead group meetings and discussions. All DOCC daughters will self-monitor their progress towards physical activity and diet goals.

Fitbit
Fitbit is a wrist-based wearable activity tracking device that uses technology to continuously monitor the following measures: steps, duration and intensity of physical activity and exercise, heart rate, sleep, and calories burned. It interfaces via Bluetooth with the Fitbit mobile app allowing users to sync and view their data on the app for self-monitoring purposes.

In order to use the Fitbit activity tracker given to you in this study, we will create a Fitbit account for you and download the Fitbit mobile app on your personal cell phone. Next, we will pair the Fitbit app with the activity tracker which will allow you to automatically sync and save your data to your account. To protect your identity from Fitbit and other third parties, we will use a study generic email address assigned to you at baseline.
When a new account is created, Fitbit asks for the user's demographic details including name, height, date of birth, and gender. To protect your identity, we will use dummy/fake data. We kindly ask you to NOT edit this information at any point during the study.

As part of our study, and for the research purposes described in this consent form, we will remotely collect the following Fitbit data from your tracker every time you sync with the app: activity and exercise (i.e., steps, intensity of activity, sedentary minutes), heart rate, and sleep. Fitbit data will be collected remotely from the Fitbit cloud server using iCardia - a secure, password-protected and encrypted system that is hosted in a Health Insurance Portability and Accountability Act (HIPAA)-compliant server at the University of Illinois at Chicago (performance site). Only authorized key research personnel associated with this study will have access to iCardia and your Fitbit data.

In order to further protect your identity all Fitbit-related GPS functionalities will be turned off during the study. We ask you to NOT turn on the GPS feature on your tracker or Fitbit app to record your geolocation during outdoor activities (e.g., walks, running, biking).

☐ Please check to confirm that you understand and agree to the above terms in relation to the use of Fitbit in this study.
☐ Please check to confirm that you understand and agree to the above terms in relation to the use of audio or video recording in the study sessions.
☐ Please check to confirm that you understand and agree to the above terms in relation to you completing surveys at baseline, at the end of your 12 sessions, and three month follow-up.

Will you be contacted about participating in future research?
If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?
While unlikely, side effects, risks, and/or discomforts from participation in this study may include:

- in increasing physical activity in Black adolescent females and women some may have medical problems that contraindicate increased physical activity. Additional risks associated with a physical activity intervention include safety, injury, and loss of confidentiality.
- Participants could discuss group information outside of the intervention group meeting with non-participants.
- There are no known social, cultural, financial, or legal risks associated with involvement in this study.

There may be other risks that may happen that we cannot predict.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?
This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Reed, her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Reed and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study.

Dr. Reed and her study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- To the Researchers
- The study Sponsor, National Institutes of Health and its representatives
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Reed is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings. Your protected information will be stored in a password protected and HIPAA compliant database at Rush

University College of Nursing, Chicago, Illinois 60612. Results will be stored by a code number. These recordings will be kept for one year after the publication from these findings is submitted, which we anticipate will be June 2025. At that time they will be deleted following HIPAA standards. Audio/video tapes or pictures of participants obtained for research may be used during dissemination of research findings. These audio/video tapes or pictures will be kept for one year after the publication from these findings is submitted, which we anticipate will be June 2025. At that time they will be deleted following HIPAA standards

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Reed at 600 S. Paulina. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. All identifying information will be removed and data will be coded by numbers not participant names.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The ClinicalTrials.gov Identifier is NCT05433415

What are the costs to participate in this study?

All costs for the required study group sessions will be paid by the National Institutes of Health.

Will you be paid for your participation in this study?
You will be paid a $20 gift card at each data collection point. There are three data collection points (baseline, 3 months after baseline and 6 months after baseline). The total possible payment is $60. If you do not finish this study, you will be paid for data collection you have completed. You will be paid immediately after completing the data collection.

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Reed at telephone number (773-231-7797).

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Reed, Principal Investigator at 773-231-7797 or email her at Monique_reed@rush.edu .

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Reed writing at the address on the first page. Dr. Reed may still use your information that was collected prior to your written notice.

Other Information

Parents please be aware that under the Protection of Pupils Right Act 20 U.S.C. Section 1232 (c)(1)(A), you have the right to review a copy of the questions asked of or materials that will be used with your students. If you would like to do so, you should contact Dr. Monique Reed at (773) 231-7797 or email Monique_reed@rush.edu to obtain a copy of the questions or materials."

SIGNATURE BY THE PARTICIPANT OR THE PARTICIPANT'S LEGAL REPRESENTATIVE:

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant	Signature of Participant	Date of Signature

Minor Assent	Date of Signature

Parent, Guardian or Legal Representative's Signature	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant [or the participant's legally authorized representative]. I further attest that all questions asked by the participant [or the participant's legal representative] were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature