Informed Consent Form

Dietary Guidelines: 3 Diets (DG3D) – Aim 1 Study

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Official Title	Ensuring the Cultural Relevance of Dietary Guidelines Diet Patterns Among African Americans: Increasing Dietary Quality and Reducing Type 2 Diabetes Risk
Brief Title	The Dietary Guidelines 3 Diets Study
NCT Number	NCT04981847
Principal Investigator	Gabrielle (Brie) Turner-McGrievy, PhD, MS, RD
Institution	University of South Carolina

UNIVERSITY OF SOUTH CAROLINA

CONSENT TO BE A RESEARCH SUBJECT

Title: Ensuring the cultural relevance of Dietary Guidelines diet patterns among African Americans: Increasing dietary quality and reducing type 2 diabetes risk

KEY INFORMATION ABOUT THIS RESEARCH STUDY:
You are invited to volunteer for a research study conducted by Principal Investigator, Brie Turner-McGrievy, PhD, MS, RD. I am a Professor in the Department of Health Promotion, Education, and Behavior at the University of South Carolina. The National Institutes of Health is sponsoring this research study. The purpose of this study is to examine the impact of three different diets on dietary quality and Type 2 Diabetes Mellitus (T2DM) risk factors among African Americans. This study is being done at the University of South Carolina's Columbia Campus and will involve approximately 63 volunteers.

We are conducting a randomized trial examining how three different dietary patterns [1) Healthy U.S.-style Eating Pattern (US), 2) Healthy Mediterranean-Style eating Pattern (Med), and 3) Healthy Vegetarian Eating Pattern (Veg)] impact dietary quality and Type 2 Diabetes Mellitus (T2DM) risk factors among African Americans (AAs). Our study will recruit AA adults (n=63) with overweight/obesity and ≥ three T2DM risk factors to participate. Potential benefits include weight loss and/or a decrease in T2DM risk factors. Potential risks, discomforts or potential harm include: participants may not lose weight or may gain weight; bruising at side of finger prick for blood sample collection.

PROCEDURES:
If you agree to participate in this study, you will do the following:

1. Attend orientation to learn about the study and sign this consent form. This will last approximately two hours.

2. Attend a clinical lab visit to complete a physical exam which will include the following assessments:
    a. Blood pressure
    b. Hemoglobin A1c (HbA1c) finger stick
    c. Inventory of current prescribed medications
    d. Height and weight
    e. Waist and hip circumference
3. Complete questionnaires online, by telephone or in-person, including three 24-hour diet recalls.
4. Be randomly assigned to either the 1) Healthy U.S.-Style Eating Pattern (US), 2) Healthy Mediterranean-Style Eating Pattern (Med), or 3) Healthy Vegetarian Eating Pattern (Veg). You will not have a choice over which diet you get and will

be assigned like a flip of a coin.

5. Attend a 1 ½ hour class, once a week, on the campus of the University of SC's Discovery building, for three months to learn about your assigned diet. Class will be offered in the evening.
   At these classes, you will learn how to follow the diet you are assigned (US, Med or Veg diet) based around healthy ways to prepare dishes. You will watch cooking demonstrations, participate in cooking, attend a grocery store tour, and learn how to eat healthier is social situations, as well as in restaurants. If you miss a class, it can be made up with an instructor or online.
6. Complete a weekly class feedback survey.

After 3 months:

1. Attend a clinical lab visit to complete the following assessments:
   a. Blood pressure
   b. Hemoglobin A1c (HbA1c) finger stick
   c. Inventory of current prescribed medications
   d. Height and weight
   e. Waist and hip circumference
2. Complete questionnaires as well as diet measurements.
3. Participate in a focus group at the end of the intervention to discuss experiences with each diet focus groups (~75-90 minutes; audio-recorded).

Timeline for Assessments

	Orientation	Clinic 1 (at start of study)	Clinic 2 (3 months)
Sign consent	X		
Blood pressure		X	X
HbA1c finger stick		X	X
Bring medications		X	X
Height, weight, and waist/hip circumference		X	X
Online questionnaires and diet recalls		X	X

DURATION:
Participation in the study involves about 16 visits over a period of 4 months. This includes attending an orientation session, attending your clinical lab assessment at baseline and 3 months, participating in weekly classes for 12 weeks, and participating in a focus group at the end of the study. Each study visit will last about 1 ½ hours and the clinical lab assessment visit will last about one hour. The online questionnaire will take approximately 20 minutes to complete (and you will complete

one at baseline and one at 3 months) and each dietary recall will take approximately 15 minutes to complete (you will complete 3 at baseline and 3 at 3 months).

RISKS/DISCOMFORTS:
Blood Draw: We will conduct a finger prick blood draw at each lab visit. The risks of drawing blood include temporary discomfort from the needle stick, bruising, and infection. Fainting could occur.

Randomization: You will be assigned to either the US, Med or Veg group by chance. We expect that participants in each group will see improvements in their health.

Loss of Confidentiality: There is the risk of a breach of confidentiality, despite the steps that will be taken to protect your identity. Specific safeguards to protect confidentiality are described in a separate section of this document.

BENEFITS:
You may experience improved health including weight loss, improvements in your blood pressure and cholesterol levels, as well as increased knowledge about diet and health. This research may help researchers understand the effects of changing your diet on your body weight and risk factors for T2DM, including high blood pressure.

RETURN OF CLINICALLY RELEVANT RESEARCH RESULTS:
After your 3-month assessment, you will receive a comparison report of your HgbA1c, weight, and diet changes (pulled from your dietary recalls) at baseline and 3 months.

COSTS:
There will be no direct cost to you for participating in this study other than ensuring transportation to attend study sessions.

PAYMENT TO PARTICIPANTS:
Participants will receive up to $50 (Visa gift card) for participating in this study. Participants will receive $30 for completing all baseline and 3-month assessments (clinical lab visit and all questionnaires) and $20 for participating in the focus group.

USC STUDENT PARTICIPATION:
Participation in this study is voluntary. You are free not to participate, or to stop participating at any time, for any reason without negative consequences. Your participation, non-participation, and/or withdrawal will not affect your grades or your relationship with your professors, college(s), or the University of South Carolina.

CONFIDENTIALITY OF RECORDS:
Any information that is obtained in connection with this study will remain confidential and will be disclosed only with your express written permission, unless required by law. You will be given a unique identifier number to protect your identify throughout

the study. Your information will be securely stored in locked files and on password protected computers, using unique identifier number. The results of the study may be published or presented at seminars, but the report will not include your name or your identifier number or other identifying information about you. Although we ask that all participants in the diet and health classes keep private what other class members say, we cannot promise that they will do so.

CLINICAL TRIAL REGISTRY DATABANK:
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.

VOLUNTARY PARTICIPATION:
Participation in this research study is voluntary. You are free not to participate, or to stop participating at any time, for any reason without negative consequences. If you do withdraw from this study, the information you have already provided will be kept in a confidential manner. If you wish to withdraw from the study, please call or email the principal investigator listed on this form.

REMOVAL FROM STUDY: The researchers may decide to remove you from the study without your approval or choice for the following reasons:

- You are unable to keep your appointments;
- You cannot give blood samples;
- You do not complete the questionnaires
- You are unwilling to accept your diet assignment or are unwilling or unable to change your diet; If you become pregnant.
- If the investigator believes that it is not in your best interest to continue in the study.

If this occurs, we will let you know in detail why you are being removed from the study.

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study, or a study related injury, I am to contact Dr. Brie Turner-McGrievy at 803-777-3932 or email brie@sc.edu.

Questions about your rights as a research subject are to be directed to, Lisa Johnson, Assistant Director, Office of Research Compliance, University of South Carolina, 1600 Hampton Street, Suite 414D, Columbia, SC 29208, phone: (803) 777-6670 or email: LisaJ@mailbox.sc.edu.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

Signature of Subject / Participant	Date
Signature of Qualified Person Obtaining Consent	Date