Consent Form

Hair Care Product Use Among Women of Color: A Northern Manhattan Intervention

Sponsored by Pilot Funding from the National Institute for Environmental Health Sciences

Key Information Summary

Your consent is being sought for research, and your participation is completely voluntary. This form explains why we are doing this study and what you will be asked to do if you choose to participate. It also describes the way we would like to use and share information about you.

We would like to obtain electronic consent for this study if in-person consent is not feasible. **May I have your verbal consent to email or text message you a link to the e-consent?** You will be able to follow along and provide electronic consent (e-consent).

- □ Yes, please send me the link to the e-consent.
- □ No, do not send me the link to the e-consent, now. I choose to complete the e-consent later.

- □ No, do not send me the link to the e-consent. I choose not to complete an e-consent as part of this study.

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If, and when, this study has an in-person component, may we contact you in the future? This will be the end of the consent process for this study. Thank you!

- o Yes
- o No

You should ask any questions you have about this form and about this research study as we go through this information. You do not have to participate if you do not want to.

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

Study Purpose

The purpose of this research is to further understand hair care product use and knowledge among women of color.

Study Procedures

If you volunteer to participate in this study, we will ask you to attend 1-2 group recorded sessions taking place on a video conferencing tool called Zoom. You will learn about the different chemicals in hair care products during the group sessions. We will also ask you to participate in at least two follow-up phone appointments. Each time, you will be asked to complete questionnaires and possibly provide a urine sample.

Study Materials

We would like to mail you study materials as well as email and/or text you materials you will need to participate in this study. Mailed study materials would include a urine collection kit with instructions. Electronic study materials would include a link to the electronic version of this consent form, questionnaires, biospecimen collection forms, and study reminders. **Please choose to provide consent or choose not to provide your consent to the following options:**

- □ I consent to having the study materials mailed to the address I will provide.
- □ I consent to having the study materials e-mailed to the address I will provide.
- □ I consent to having the study materials texted to the cell phone number I will provide.

I do not consent to having study materials mailed to me and/or electronically sent to me. I understand that this will make it difficult for me to participate in this study remotely.

If, and when, this study has an in-person component, may we contact you in the future? This will be the end of the consent process for this study. Thank you!

- o Yes
- o No

We would like to email and/or text and/or use Direct Message (DM) on **Instagram** and/or send **email** via Qualtrics to send reminders regarding materials to be completed for the study. **Please choose to provide consent or choose to not provide your consent to the following options:**

- □ I consent to having the study materials sent to the **Instagram** username I will provide. Insert your Instagram handle: _____
- □ I consent to having the study materials **e-mailed** to the address I will provide.
- □ I consent to having the study materials **texted to** the cell phone number I will provide.

I do not consent to having study materials mailed to me and/or electronically sent to me. I understand that this will make it difficult for me to participate in this study remotely.

If, and when, this study has an in-person component, may we contact you in the future? This will be the end of the consent process for this study. Thank you!

- o Yes
- o No

Duration of Participation
Participation duration**:** Group sessions will be between 1.5-2.5 hours and follow-up sessions will be 30 minutes each. These will take place over approximately 10 months.

Alternative Procedures
You have the choice not to participate in any part of this research study and can withdraw at any time without repercussions.

Study Procedure Summary
We will mail, email, and/or text you study materials in advance of your first group session.

If you volunteer to participate in this study, we will ask you to participate in 1-2 recorded group sessions on Zoom.

During the group session(s), we will provide you with an educational presentation and informational materials on chemical ingredients in personal hair care products and how you can reduce exposure to these chemicals.

We will also ask you to complete two follow-up sessions over the phone at the end of your third trimester and about 1-month postpartum. During these follow-up sessions and throughout the study, we will ask you to complete questionnaires, which will ask you basic questions about yourself, as well as your knowledge, attitudes, and opinions on the products you use. You can choose not to answer or to skip any of the questions.

We may ask you for a urine sample at session 1 and at each follow-up session. We will ask you to mail your urine sample in the provided pre-paid mailing kit back to us or we will collect the sample at the in-person group session (whichever is feasible).

Each phase of the study is voluntary, and you can withdraw at any time by contacting the Principal Investigator, Dr. Jasmine McDonald. See the Contact Information section for contact details.

More details on specific study procedures are as follows:

Recording of Group Sessions
The team at Columbia University Irving Medical Center (CUIMC) will record both audio and video during the group Zoom sessions. The recordings will be used for analysis by the research team and will not be used for commercial purposes. The recordings will include full facial features and your first name. We are including this identifiable information so that we can keep track of what each person says throughout the discussion.

You will have the option to turn off your camera on Zoom if you prefer not to share the image of your face, in which case you will be identified by the Zoom username you register with.

The transcription company, a registered vendor with Columbia University, will have access to the recording so that they can transcribe what is said during the discussion. The Confidentiality Section provides details on who will have access to your information and how we will protect your information.

Questionnaire Data
The data obtained from the questionnaires will be analyzed by research staff who are CUIMC IRB approved for this study. The data obtained may also be analyzed by study collaborators. These collaborators include Drs. Adana Llanos and Emily Barrett from Rutgers School of Public Health in New Jersey, and WE ACT for Environmental Justice in Harlem, New York. We will deidentify the data before it is sent to these collaborators, which means that we will remove your name and other identifying information from the data.

Biospecimen Data
Urine samples will be analyzed by Dr. Kurt Pennell, study collaborator and director of the 231 Engineering Research Center at Brown University in Rhode Island. CUIMC researchers will de-identify the samples by removing your name and any other personally identifiable information before the sample is sent to Brown University. The Confidentiality Section provides details on who will have access to your information and how we will protect your information.

Study Risks and Discomforts
There is a chance you may feel uncomfortable answering some of the questions on the questionnaires. You have the right to refuse to respond to any questions you do not wish to answer. The information you provide on the questionnaire will be kept entirely confidential. However, any time personal information is released, there is a possibility of your confidentiality being compromised. We have developed strict guidelines to safeguard the confidentiality of any information obtained during this study from you. The Confidentiality Section provides details on who will have access to your information and how we will protect your information.

Study benefits
You may or may not receive personal benefit from taking place in this study.

Costs
There is no financial cost to you for participating in this study.

Compensation
You will receive compensation for your time throughout this study through a Prepaid Registered Visa Debit Card. You will use this one visa card throughout the entire study. Components of your participation will result in certain amounts of money being placed on your visa card. We will place up to $40 on your visa card to compensate you for your time and participation at each visit. We will add $20 for completing all the questionnaires and $20 for receipt of the urine sample. The process for receiving the visa card, activating the visa card, and getting the money on the visa card is as follows:

1. Study staff will mail you one Registered Visa Debit Card to your postal address.
2. Before you can activate the visa card and before we can place money on the visa card, we need to know you have the visa card. Therefore, we will ask you, the participant, to confirm you have received the visa card in writing, through email or text.
3. Study Staff will then let you know when you can activate the visa card. It is important that you wait for our instructions before activating the visa card. It takes about 2-3 business days for the visa card to be active for use.
4. We will place money on your visa card throughout the study. It takes about 2-3 days for the money to appear on your visa card once we send the money.

Please do not discard the Visa Debit Card after its use. We will use the same visa card throughout the study. If you lose the visa card, please inform the study staff immediately. If you lose the visa card and there was money remaining on the card, you will also need to contact the bank's number on the back of the card.

If your session is in person, we will also provide up to $20 to cover the cost of travel to and from the session. Additionally, we are looking to acquire free hair product samples, but in case they are not available, we will provide everyone with $10 placed on your Visa Debit Card to purchase a phthalate-free product. We will also provide you with small gifts, such as tea packages.

Research Results
No individual results will be provided to participants.

Confidentiality
Any information obtained during this study will remain strictly confidential. Complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems, such as a stolen computer may occur, although highly unlikely: Please note the following process will be adhered to for ANY and ALL aspects of the study in which your research data is labeled with your unique code number. For this study your code numbers will include your study ID and your specimen ID:

Overall: The research file that links your name or any information that can identify you to the code number will be kept in a locked file cabinet, an encrypted data file, and/or CUIMC IRB approved and encrypted hard or shared drives. Questionnaires and biospecimens will be stored using your unique code number and not be directly linked to your name or any information that can identify you to the code number. Questionnaires, biospecimens, and recorded sessions will be kept in a locked file cabinet, an encrypted data file, and/or CUIMC IRB approved and encrypted shared drives. Only the principal investigator and study staff who have CUIMC IRB approval for this study will have access to these files. Your name or any of your information that can identify you will not be used in any reporting of the study results.

Questionnaires: The information you provide in the questionnaires will be assigned with your unique code number and not include your name or any information that can identify you.

Recorded Sessions (Transcription): In order to protect your privacy, the transcription company will only receive a recording of the session that includes the image of your face (if you choose to keep the camera on) and the name you provide when you register for the session (your zoom user name). This is so they can create a "script" of the conversations that takes place during the recorded group sessions and keep track of who said what. The transcription company will receive the recording through a secure file transfer system. Our contract with the transcription company will require that recordings be destroyed as soon as the script of the session is submitted to and approved by the CUIMC research team.

Study collaborators will only have access to the 'script' and not the recordings.

The image of your face and user name will be attached to your study ID. The files linking your image and user name to your study ID will be kept in an encrypted data file and/or a CUIMC IRB approved and encrypted hard or shared drive. Only CUIMC IRB approved research staff will have access to the files. Your image, name, or any of your information that can identify you will not be used in any reporting of the study results.

Biospecimen: The urine collection receptacles will have labels with a prepopulated code number (your specimen ID). Dr. Kurt Pennell, study collaborator and director of the 231 Engineering Research Center at Brown University and his team will analyze the biospecimens. Before sending your specimen to our collaborators, we will deidentify the specimen, meaning we will remove your name and any other personally identifiable information from the biospecimen before our collaborators at Brown receive them. Any unused samples will be destroyed by Brown University or mailed back to us at CUIMC.

Your biospecimens will not be used for whole genome sequencing in this study.

The following people and/or agencies will be able to look at, copy, use and share your research information as part of these organizations' responsibility to ensure the protection of human subjects in research:

- The principal investigator, Columbia University Medical Center and New York-Presbyterian Hospital study staff and other medical professionals who may be evaluating the study.

- Authorities from Columbia University and New York-Presbyterian Hospital, including the Institutional Review Board ('IRB'). An IRB is a committee organized to protect the rights and welfare of people involved in research.
- The Federal Office of Human Research Protections ('OHRP')

We will be using the Columbia University registered Visa Debit Card incentive system that is approved by the Columbia University Irving Medical Center IRB. Only for payment purposes will those facilitating this secure system have access to your personal information.

Future Use

We would like to store the data and biological samples that you consent to provide as part of this study for future research. The data and samples will be stored at CUIMC either with the researchers on this study or in a central CUIMC storage facility called a repository. With your permission, your data and samples will be stored at CUIMC indefinitely in identifiable form.

With your permission, your data and samples may be used by other Columbia researchers or researchers at other institutions for future research purposes. This means that your name and other identifying information will have been permanently removed from your data and samples or your data and samples will be coded and the researchers who will use them will not have access to the key that links the code to you. After such removal, the information or biospecimens could be used for future research studies without additional consent from you. But, if they are given to researchers who are not CUIMC researchers on this study, they will only be given in deidentified form or coded. This includes the collaborators from Rutgers University, and WE ACT for Environmental Justice.

Please choose to provide consent or choose not to provide your consent to the following options:

___ I agree to the storage of my data and samples at CUIMC in identifiable form after completion of this study. I understand that my data and samples will only be given to researchers in deidentified form or coded.

___ I agree to the use of my data and samples for future research and/or testing that may or may not be related to this study. I understand that my data and samples will only be given to researchers in deidentified form or coded.

Voluntary Participation

Participation in this research study is voluntary. You may refuse to participate or withdraw from the study at any time without being penalized. Signing this form does not waive any of your legal rights. You may choose to prevent further use of your data in future studies by requesting this in writing. Please see Contact Information of the Principal Investigator below.

Contact information

If you have any questions or concerns about this study or if any problems arise, please contact the Principal Investigator:

Dr. Jasmine McDonald, Principle Investigator
Columbia University Mailman School of Public Health
Department of Epidemiology
722 West 168 Street
Room 713
New York, NY 10032
Telephone: (212) 305-3586
jam2319@cumc.columbia.edu

If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact the Institutional Review Board listed below:

Institutional Review Board
Columbia University Medical Center
154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883

irboffice@columbia.edu

Statement of Consent
I understand that my participation is voluntary and that I can withdraw from the study at any time without repercussion. I have reviewed the above information and agree to enter this research study. Signing/E-Consenting this form does not waive any of my legal rights.

The research study has been explained to me. I agree to participate in the research study as described above. I confirm I have been informed that if I have any questions or concerns about the study or believe I have sustained injury as a result of participating, I can contact Dr. Jasmine McDonald, the Principal Investigator of the study. I confirm that Dr. McDonald's contact information has been provided so that I can review the matter and identify the medical resources which may be available to me, should the need arise.

By consenting, you grant permission for your information to be made available to: Columbia University, Columbia University's Institutional Review Board (IRB), and the Office of Human Research Protections (OHRP); as part of these organizations responsibility to ensure the protection of human subjects in research.

Your signature on this form grants the investigator named above permission to record you as described above during participation in the above-referenced study. The investigator will not use the recording(s) for any other reason than that/those stated in the consent form without your written permission.

I will receive an electronic or hard copy of this consent form for my records after completion.

Signature (if any portion of study in person):

_____
Participant Signature Date

Qualtrics e-Consent Process
Print Name
□ First Name
_____
□ Last Name
_____

Please sign your name below if you consent to the above

SIGN HERE
×
clear

Date
_____

Please enter a valid email address and mailing address to be sent a copy of the signed document
Email Address _____
Mailing Address _____