ClinicalTrials.gov Study Title: Condom Performance in a Longitudinal Enhanced Assessment of User Experiences (C-PLEASURE)

ClinicalTrials.gov Identifier: NCT02753842

Consent Form Date:
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Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: C-Pleasure: Condom – Performance in a Longitudinal Enhanced ASsessment of UseR Experiences

Principal Investigator: Patrick Sullivan, DVM, PhD
Emory University Department of Epidemiology

Study-Supporter: National Institute of Child Health and Human Development (NICHD)
National Institutes of Health

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.**

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?
The purpose of this study is to understand whether participant ratings of pleasure and preference are different for three condom types (fitted, thin, and standard). We are also looking at the clinical performance (breakage and slippage) of these condoms. We expect to enroll about 500 eligible participants in this trial.

What will I be asked to do?
Today: If you join the study today, we will first ask you some questions to see if you are eligible to participate in the follow-up study. You will be tested for HIV, and receive HIV counseling. If your HIV test is positive, we will call this result preliminary. We may ask you for more blood (about 2 teaspoons) to confirm the result of the finger prick test. If you have symptoms and are at risk of acute HIV, we may ask you for blood for more testing. If you are infected with HIV, we will call with follow-up questions and referral options for up to one year after your diagnosis.
If you are eligible to continue participating, you will also be asked to complete a survey on a computer. The survey will take about 30-45 minutes to complete. The survey will ask some questions about you and your background, your sexual partners, and your history of condom use. You will receive training in study participation, including the ways we want you to use study condoms and how to complete electronic study forms at home. If you have not already found your fitted condom size, you will be asked to do that within 2-5 days of the visit. You will then be given or mailed five condoms to use over the next two weeks.

In the two weeks after each study visit: You will be asked to complete a brief (1-5 min) online survey each day. This survey will ask about whether you have has sex and used a study condom. If you have not had sex using a study condom, there will be no more questions for that daily survey. If you have used a study condom, we will ask a few questions regarding the performance of the condom in terms of breakage, slippage, and pleasure. You will receive daily email or text message reminders with a link to complete the home survey.

Follow-up Sessions: You will be asked to come in for follow-up visits every two weeks for up to a total of six follow-up visits. At each follow-up visit, you will be asked to bring in any unused condoms, and return any condoms that broke in a secure bag that we will provide. Study staff will review your daily surveys with you. You will be asked questions about STI and acute HIV symptoms. If you have symptoms and are at risk of acute HIV, we may ask you for more blood for additional testing. You may complete a survey during the follow-up visit. This survey will last about 5 minutes. At some visits, you will be given more condoms to use. If at any time you wish to stop participating in study follow-up visits, please immediately notify study staff and they will arrange to have your study participation stopped.

Who owns my study information and samples?
If you join this study, you will be contributing study information. If you withdraw from the study, data that were already collected may be still be used for this study.

What are the possible risks and discomforts?
There are minor risks associated with this study.

You may find out that you are infected with HIV or may be infected with a STI. This might upset you. If you are infected with HIV, we will help you find a doctor. We will also provide you with additional lab tests to help you get into care. If you have symptoms of another STI, we will refer you to testing. If your rapid HIV test is preliminary positive or you have symptoms and are at risk of acute HIV, we will collect blood by putting a needle in a vein in your arm. There is a small chance that you may have a bruise where the needle went into your arm. You could develop an infection where the blood was drawn.

There may be side effects from using study condoms or lubricant, however all condoms and lubricant we will use are cleared by the USA FDA. If you do experience reactions or side effects to study products, you may be asked to have a picture taken of the reaction. This picture will not be entered as study data and will only be used by the study clinician for adverse event determination. As with any condom trial, there is a risk that the condom may break or slip. To minimize risk of condom failure, we will instruct you on proper condom use.

Some of the questions in the survey are personal. They may make you uncomfortable. We hope you will answer all questions to the best of your ability. For most questions, you can choose not to answer any question that makes you uncomfortable. We will keep information about your HIV testing and your responses to the survey questions. Although we will take steps to reduce the chance, there is a small chance that someone other than study staff might see your study information. More information about how we will protect your confidentiality is below.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?
This study is not designed to benefit you directly, except for learning your HIV status, learning more about HIV prevention and local services, and being linked to treatment and care if needed. This study is designed to learn more about the performance of condoms. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will receive $50 today regardless of your eligibility. You will get $35-50 for each completed follow-up visit, to compensate you for your time and effort. This amount depends on the number of daily home surveys you complete. If you complete at least ten home surveys, you will receive the full compensation of $50. If you do not finish the study, we will compensate you for the visits you have completed.

You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment.

What are my other options?

If you decide not to enter this study, you will still be given the option to receive a free HIV test today. Taking part in this study will not affect your ability to participate in future research studies.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents. We will do everything we can to keep others from learning about your participation in the research. To further help protect your privacy, the investigators have received a Certificate of Confidentiality.

The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Medical Record

Your study information will not be linked to any medical records.

Costs

There are no anticipated costs to you from being in this study, other than the cost of your transportation to the study site. If you get ill or injured from being in this study, Emory would arrange for you to have urgent health care. Emory has not set aside any funds to pay for urgent health care. Also, Emory has not set aside any funds to pay you if you become ill or injured from being in this study. The only exception to this policy is if it is proven that the negligence of an Emory employee directly caused your injury or illness. “Negligence” means the failure to follow a standard duty of care.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study in which you may choose to participate.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Your name, telephone number, email address, and mailing address.
- Dates.
- Laboratory test results.
- Body measurements.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, and Institutional Review Boards (IRBs). Study data will be shared with the United States Food and Drug Administration (FDA). The FDA will use the data to inform marketing claims for these condoms about pleasure and patient preference. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

If you have a positive test for HIV or an HIV viral load, state law requires us to report that positive test to the state health department for purposes of statistics and service planning. It is possible that the Health Department could contact you to offer referrals for care or help with getting your partners tested. These procedures are the same as if you were tested for HIV at a doctor's office or a clinic outside of this research study. It is possible in Georgia to be tested for HIV without providing your name. We can give you names of clinics that will test you for HIV without asking your name.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study.
- Emory may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The Principal Investigator and research staff will share your PHI with the FDA to inform marketing claims for these condoms about pleasure and patient preference.
- The National Institutes of Health (NIH) is the Supporter of the study. The NIH may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The NIH may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections and the Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must write to Dr. Patrick Sullivan, Emory Rollins School of Public Health, 1518 Clifton Road, Atlanta, GA 30322.

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact the Principal Investigator, Patrick Sullivan, at 404-727-2038 or patrick.sullivan@emory.edu:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study device, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

☐ Please check this box if you would like our research team to store your contact information for up to five years, so that we can contact you for future research studies. Deciding to participate in any future research is entirely voluntary, and checking this box is also entirely voluntary. If you check this box, you may later contact us at any time and ask to be removed from the contact list. If you do not check this box, we will not contact you again, and your contact information will be deleted from our study contact list at the end of the study period.

TO BE FILLED OUT BY STUDY TEAM ONLY

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Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**