INDIANA UNIVERSITY STUDY INFORMATION SHEET

Lorals Study, IRB Protocol #22596

Why is This Study Being Done?
The Lorals for Protection product (latex underwear) is FDA-cleared for protection from sexually transmitted infections. The purpose of the study is to explore both positive and negative user experiences of the product, assess any errors and problems, gather ideas for product improvement, and examine how use of Lorals is incorporated the usual behaviors, roles, and interpersonal dynamics during sexual activity with a partner.

Inclusion Criteria:
To participate in this study, individuals must meet the following criteria: be at least 18 years old, have a vulva, does not have an allergy to latex and/or personal lubricant, currently sexually active and report engaging in cunnilingus (can be any sexual orientation), willing to wear Lorals underwear and complete rating scales on the experience, and must be able to attend one in-person meeting with the researchers.

If you are interested in joining this study, please complete our Screening Questionnaire. If you are found eligible for the study and provide your email address, we may contact you from kisexsci@iu.edu for meeting coordination. Once you have arrived at the study site, the research personnel will review an informed consent form with you, ask if they have any questions, and make sure you understand the study procedures. You would then provide written consent by signing the consent form.

The study is being conducted by Cynthia Graham, Senior Scientist at the Kinsey Institute and Professor at IU Department of Gender Studies.

What Will Happen During the Study?
If you agree to participate, you will be asked to do the following:

- You will complete one study visit lasting about 45 minutes. During the visit, you will complete questions regarding basic demographic information and questions regarding your sexual background. You will then be provided with supplies of Lorals for Protection (2 packs, each containing 4 Lorals) and Uber Lube, as well as instructions for use, and asked to use the product during partnered sex for a period of 4 weeks (aiming for 6-8 occasions).

- For the next 4 weeks, you will be asked to use Lorals for Protection each time you have a sexual encounter. After each encounter, you will be asked to complete a

brief online questionnaire regarding your use of the product. The questionnaire will take approximately 5 minutes to complete.

- After 4 weeks, you will be asked to complete the post-study questionnaire regarding your experience of using Lorals, which will take approximately 15 minutes.

Your participation in the study will last about 4 weeks.

What are the Risks of Taking Part in the Study?
There is very low potential risk, and this would primarily relate to discomfort or allergic reactions to the Lorals underwear material or lube samples. If you experience any type of allergic reaction or physical discomfort, please notify a study team member and discontinue use. You may also feel uncomfortable answering various survey questions. You can choose to not answer any question that makes you uncomfortable. There is also a risk that someone outside the study team could get access to your research information. All participant information will be kept confidential, stored on password-protected computers and accessible only by the research team.

Who Will Pay for my Treatment if I am Injured?
If you have an injury or illness as a result of participating in the study, you will be responsible for seeking medical care and for the expenses associated with any care received. Any costs not covered by your medical insurance will be your responsibility. We don't have money set aside to pay for these types of injuries. However, signing our informed consent form won't take away any of your legal rights if you are injured.

What Are the Benefits of Taking Part in the Study?
We don't think you will have any personal benefits from taking part in this study, but we hope to learn things that will help other people in the future.

Will I be Paid for Participating?
You will be compensated a total of $50 for their involvement in this study. An initial payment of $20 will be provided after the first visit to acknowledge your time and effort. Upon successful completion of all study requirements, including the post-study questionnaire, you will receive the remaining $30. Compensation will be distributed in the form of gift cards, ensuring that you are rewarded promptly and conveniently for your valuable contribution to our research. You will be paid individually at each step.

How Will My Information be Used?
The following individuals and organizations may receive or use your identifiable information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- State and Federal government agencies as permitted by law [including but not limited to:
    - The United States Food and Drug Administration (FDA)

Information collected for this study may be used for other research studies or shared with other researchers who are conducting their own research studies. This may include sharing with researchers outside Indiana University and sharing with private companies. It may also include making the information available in public and private databases of research data so that other researchers can use the information to answer research questions.

If we share your information in this way, we will remove information that could identify you, such as your name and contact information, before any information is shared. Since identifying information will be removed, we will not ask for your additional consent for this sharing.

A description of this clinical trial will be available on 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 this website at any time.

How Will My Information be Protected?
We will do our best to keep your personal information private, but we cannot promise complete confidentiality. We won't share any information that we think could be used to identify you in publications about this study. However, your personal information may be shared outside the research study as described above and/or if required by law.

Who Should I call With a Question or Problems?
For questions about the study, contact the research team at kisexsci@iu.edu. For research-related injury, contact the researcher, Dr. Cynthia Graham at 812-855-3910 or cygraham@indiana.edu. For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

What if I Do Not Want to Participate or Change my Mind?
After reviewing this document and having your questions answered, you may decide to participate in the study. Or, you may choose not to participate in the study. This decision

is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your relationship with Indiana University.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, please contact a study team member.