INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Women, Immunity and Sexual Health (WISH)

You are invited to participate in a research study of women’s health across the immune cycle. You were selected as a possible subject because you indicated interest in the study and are a healthy woman who is or is not having sex regularly. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

The study is being conducted by Drs. Tierney Lorenz and Julia Heiman of the Department of Psychological and Brain Sciences and the Kinsey Institute.

STUDY PURPOSE

The purpose of this study is to measure changes in the immune system in women at different points in their menstrual cycle. We are also looking at whether or not sexual activity influences women’s immune systems. We are also looking at how hormones, parts of the nervous system, mood, diet and exercise influence women’s immune systems at different points in their menstrual cycle.

NUMBER OF PEOPLE TAKING PART IN THE STUDY:

If you agree to participate, you will be one of 40 women who will be participating in this research. We are recruiting two equal groups of women: up to 20 women who are not sexually active with a partner, and up to 20 women who are regularly sexually active with a partner.

PROCEDURES FOR THE STUDY:

If you agree to be in the study, you would be followed over the course of one menstrual cycle – for most women that is about one month. You would visit the lab twice, and complete some procedures at home two other times. In all, it will take about 3 hours over four weeks.

Lab visits are scheduled at the start and middle of your menstrual cycle, and always in the afternoons. Each lab visit will take about an hour. The lab is in the Psychological and Brain Sciences building on IU campus.

In the first lab visit, you will take a pregnancy test. This will involve providing a urine sample in a cup in private. Your test will be read confidentially by the researcher, and then destroyed.

We will measure your height, weight, and percent body fat using a floor scale.

You will have your heart rate recorded. That will involve lying still for 5 minutes with a heart rate and breathing monitor strap around your chest.

You will fill out some surveys about your physical and health, menstrual cycle, sexuality, contraceptive use, relationships, and stress. You will also be asked about your physical activity, sleep patterns, and diet over the last week.

You will give a saliva sample by spitting into a tube.
You will give a small blood sample (three small tubes totaling 30 ml, or about 5 teaspoons each time you come in). Blood will be collected using a small gauge needle from a vein in your arm. We use sterilized equipment that is one-use only. The needles we use are about one third the width of a needle used for a blood donation at the blood bank, and the amount of blood we take is about 5% of what you would give in a blood donation.

If you come in on a weekday, the blood sample will be taken at the IU Student Health Center, so the researcher will walk you there at the end of your session. If it is on a weekend or a holiday, the blood sample will be taken in the Sexual Psychophysiology Lab in the Psychology Building. Either way, the person drawing your blood will be an experienced technician with special training to minimize discomfort and risk during blood collection. We will use methods that are standard medical procedures to obtain blood for tests.

One week after your lab session, we will send you a link to an online questionnaire to fill out at home. It will take you about 20 minutes to complete this questionnaire.

We will also give you a tube to complete another saliva sample at home. You will freeze this saliva sample as soon as you finish it, and either bring it with you to your next lab session, or arrange to have someone from our lab to pick it up.

You will also be given four test strips to test for ovulation. They are very similar to a pregnancy test: you will urinate into a cup and then dip the strip in. You will put each strip in a plastic bag and bring them with you to the lab. You will do these tests at home two days before and two days after your second lab session.

If you are sexually active: At least once a week during the study you will find a time in which you can attempt vaginal intercourse with a partner using your normal form of contraception. For each time you have sex, you will fill out an online confidential survey that will take about 5 minutes to complete.

About two weeks after your first lab session, you will return to the lab. You will complete the same procedures as before – a urine test for pregnancy and ovulation, a recording of your heart rate, measurement of your weight and body fat, a saliva and blood sample, and a questionnaire.

Three weeks into the study you will complete another survey and saliva sample at home. Again, you will freeze the saliva sample and either drop it off at the lab or have us pick it up.

Finally, about four weeks after your first lab session, you will either come into the lab to drop off your last saliva sample and ovulation tests, or have these picked up from you. You will also tell us the first day of your next period via email.

In total, you will give two blood samples – one at the first lab visit, and one at the second lab visit, for a total of 60 ml (about 3 tablespoons). You will give four saliva samples – two during lab visits, and two at home.
Here is a summary of all of the study procedures:

### If you are not sexually active:

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 7</th>
<th>Day 14</th>
<th>Day 21</th>
<th>Day 28</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In the lab</strong>&lt;br&gt;Pregnancy test&lt;br&gt;Height/weight&lt;br&gt;Heart rate recording&lt;br&gt;Saliva sample&lt;br&gt;Blood sample&lt;br&gt;Surveys</td>
<td><strong>At home</strong>&lt;br&gt;Saliva sample&lt;br&gt;Surveys</td>
<td><strong>In the lab</strong>&lt;br&gt;Ovulation test&lt;br&gt;Height/weight&lt;br&gt;Heart rate recording&lt;br&gt;Saliva sample&lt;br&gt;Blood sample&lt;br&gt;Surveys&lt;br&gt;Drop off saliva sample and ovulation tests</td>
<td><strong>At home</strong>&lt;br&gt;Saliva sample&lt;br&gt;Surveys</td>
<td><strong>At home or in lab</strong>&lt;br&gt;Drop off saliva sample and ovulation tests&lt;br&gt;Confirm start date of next period</td>
</tr>
</tbody>
</table>

### If you are sexually active:

<table>
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<tbody>
<tr>
<td><strong>At home</strong>&lt;br&gt;Sex with partner&lt;br&gt;Brief survey</td>
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### RISKS OF TAKING PART IN THE STUDY:

While in the study, the risks and/or possible discomforts are:

- **Blood draw can be mildly uncomfortable for some people.** It is possible that you may bruise at the site of the needle stick. According to the World Health Organization (WHO), about 2-3% of people notice a small bruise after blood draw. You may have a fainting reaction to the needle stick or blood draw; although uncomfortable this is not medically harmful. Also, there is the possibility of infection whenever the skin is punctured; however the risk during standard blood draw procedures is fairly low (according to the WHO, about 1 in 1000).

- **Answering questions about your sexuality may be embarrassing for some people.** You are free to skip any question you do not wish to answer, and none of your answers will be connected to your name or identifying information in any way. If you are distressed after filling out the surveys, you are welcome to speak with one of the head researchers (Drs. Tierney Lorenz and Julia Heiman), both of whom are clinical psychologists with training in counseling women in sexuality issues.

- **It is possible that you may discover you are pregnant during the first lab session.** If this happens we will remove you from the study, and you will be encouraged to follow-up with your own primary care physician.
We will test your blood and saliva samples for hormone levels and measures of how your immune system works. Please note that we are not using tests that are used to diagnose health conditions. Also, your blood and saliva samples will be labeled with your study ID number and not your name. That means that we are not able to tell you anything about the results from your blood and saliva tests.

**BENEFITS OF TAKING PART IN THE STUDY:**

If you wish, at each lab session, you can be given personalized information about:

- Your body fat percentage, which is a measure of the ratio of fat and muscle in your body.
- Your resting heart rate variability (HRV), which is an index of your heart health that is often used to track athletic fitness.

The findings from this study could help women and their doctors make better decisions about how to protect themselves from getting sick.

**ALTERNATIVES TO TAKING PART IN THE STUDY:**

You can choose not to participate in this study.

**CONFIDENTIALITY**

We will make our best effort to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your data will be identified with only a code number, never your name or any other identifying information.

Your personal information may be disclosed if required by law. These circumstances include (but are not limited to) inspection of the study and study data by organizations that provide quality assurance and/or research participant protection such as the Indiana University Institutional Review Board or its designees.

If the study research is published, you will not be personally identified in those reports. At most, a summary of the data from all participants will be reported.

**COSTS**

We do not anticipate the study procedures will incur any cost to you other than the cost of transportation to the lab for study sessions. If you drive to study appointments, you will have your parking validated in an IU parking lot.

**PAYMENT**

You will receive payment for taking part in this study.

If you are a community participant, you will receive up to $30 in compensation for your time. You will receive $10 at the first lab visit and $20 at the second lab visit.

If you are a psychology student participating for course credit, you will receive up to 4 hours of course credit. You will be given 1 hour of credit when you complete the phone screening, 1 hour when you
complete the first lab session, and 2 hours when you complete the second lab session. If you are participating for course credit you will not receive financial compensation for participating.

If you withdraw from the study without completing, you will be entitled to compensation commensurate with your level of participation (i.e., you will not receive compensation for study procedures you did not complete).

Also, if you are withdrawn from the study by the researchers (as described above) you will be entitled to compensation for the study procedures you completed up to the point that you were withdrawn.

**COMPENSATION FOR INJURY**

In the unlikely event of an injury resulting from your participation in this research, you will be responsible for any necessary medical treatment and subsequent medical expenses. Costs not covered by your health care insurer will be your responsibility. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

**CONTACTS FOR QUESTIONS OR PROBLEMS**

For questions about the study or a research-related injury, contact the researcher Dr. Tierney Lorenz at 812-856-9036. If you cannot reach the researcher during regular business hours (i.e. 8:00AM-5:00PM), please call the IU Human Subjects Office at (812) 856-4242 or (800) 696-2949. You can also email the lab at immunitylab@gmail.com at any time.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (812) 856-4242 or (800) 696-2949.

**VOLUNTARY NATURE OF STUDY**

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not affect your current or future relations with Indiana University or the Kinsey Institute.

There are a few circumstances where the researchers may withdraw you from the study, even if you wish to participate further. These include:

- If you get sick during the month you are participating.
- If you are found to be pregnant at the first study session.
- If you do not respond to our attempts to contact you for more than 2 weeks.
- If you are in the “not sexually active” group but you have sex during the month you are participating.
- If you are unwilling or unable to give blood or saliva samples at either lab session.
SUBJECT’S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject’s Printed Name:______________________________

Subject’s Signature:__________________________ Date:________________

Printed Name of Person Obtaining Consent:________________

Signature of Person Obtaining Consent:__________________________ Date:________________

For IRB Office Use ONLY
IRB Approval Date: Oct 9, 2013
Expiration Date: Oct 8, 2015