

**UNIVERSITY OF CALIFORNIA, IRVINE**  
**CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT**

***fMRI Investigation of Sex Hormone Influences on Emotion and Cognitive Function***

You are being asked to participate in a research study. Participation in this study is completely voluntary. Please read the information below and ask questions about anything that you do not understand before deciding if you want to participate. A researcher listed below will be available to answer your questions.

**RESEARCH TEAM**

**Lead Researcher:**

Larry Cahill, Professor  
Department: Neurobiology and Behavior  
Center for the Neurobiology of Learning and Memory  
Telephone number and e-mail address:  
(949) 824-1937 lfcahill@uci.edu

**Other Researchers:**

Nicole Ertman  
Belinda Pletzer

**Study Location(s):**

University of California, Irvine

**PURPOSE OF STUDY**

The purpose of this research study is to further our understanding of how activity in the brain can be affected by different hormones. You have been asked to participate in a research project studying brain using magnetic resonance imaging (MRI). We will be looking at how connections between different brain regions change over the course of the menstrual cycle, and also how they change when women use birth control pills. We will also be looking at how areas of the brain that respond to emotion and cognition change as hormones do.

**SUBJECTS**

***Inclusion Requirements***

You are eligible to participate in this study if you are over 18 years of age, have normal menstrual cycles, and can speak English. You must be right handed.

***Exclusion Requirements***

You may not be eligible to participate in this study if you have any metal implants in your body, if you are taking certain medications, or if you have neurological, psychological, or endocrine disorders. If you are or think that you may be pregnant, you are not eligible for this MRI study.

***Number of Participants and Time Commitment***

This study will include approximately 120 subjects and will involve approximately 3 hours of your time. The tests will have a total duration of no more than 90 minutes per session. Experiments require two sessions. We may contact you with follow-up questions after the sessions are complete.

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Approved by IRB on: 04/20/12

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## PROCEDURES

The following procedures will occur:

1. You will fill out several questionnaires, which are standardized psychological assessments, about your recent activities, experiences, and mood.
2. You will lie still in the MRI machine for up 45-60 minutes.
3. You will watch a slideshow of images while in the MRI machine and make some judgments about the pictures you see. Some of these pictures may be unpleasant or disturbing (e.g., an image of a mutilated body part).
4. We will take several saliva samples throughout the experiment.
5. You will return to our laboratory for a second and final appointment.
6. We will ask you to do some cognitive tests.
7. You will view another slideshow and make more judgments about the images.
8. We may ask you to use a standardized, take-home urine analysis test. This is used to identify your exact menstrual cycle phase.
9. We may re-contact you within 1 and 4 weeks of your second and final appointment to ask you more questions about your menstrual cycles since experimenting. This also gives us more precision regarding your phase at the time of the experiment.

## RISKS AND DISCOMFORTS

Participation in this study may involve some discomforts:

1. You may experience physical discomfort from lying still inside the scanner.
2. When in use, the MRI machine can be loud at times. You will be giving earplugs and headphones to reduce the noise, but some people still find it uncomfortable.
3. Some people report headaches, dizziness, or tingling sensations while in the scanner. These are rare and not dangerous, and will stop when you leave the machine.
4. Because the MRI is a small, enclosed space, some people experience claustrophobia or anxiety. If severe claustrophobia has been a problem for you in the past, you should not participate in this experiment.
5. Some of the images you view may be very unpleasant or disturbing to look at. However, viewing them is very unlikely to cause any significant harm.

Please note: No short-term ill effects have as yet been reported in studies utilizing Magnetic Resonance Imaging (MRI). There is also at present no evidence of longer-term risks for a MRI of this type, however, these potential risks remain under evaluation at this time. The effects of MRI on pregnant women and children under the age of 2 have not as yet been fully studied.

## BENEFITS

### ***Subject Benefits***

You will not directly benefit from participation in this study.

### ***Benefits to Others or Society***

The investigators may learn more about how hormones can influence emotion and brain function, and thus how to better treat disorders related to emotion.

## COMPENSATION, COSTS AND REIMBURSEMENT

### ***Compensation for Participation***

You will receive \$60 for completion of the experiment, prorated to \$40 should you be able to finish only the first session.



## **WITHDRAWAL OR TERMINATION FROM THE STUDY AND CONSEQUENCES**

You are free to withdraw from this study at any time. **If you decide to withdraw from this study you should notify the research team immediately.** The research team may also end your participation in this study if you do not follow instructions, miss scheduled visits, or if your safety and welfare are at risk.

## **CONFIDENTIALITY**

### ***Subject Identifiable Data***

All identifiable information that will be collected about you will be removed and replaced with a code. A list linking the code and your identifiable information will be kept separate from the research data.

### ***Data Storage***

All research data will be maintained in a secure location at UCI. Only authorized individuals will have access to it. All research data will be stored electronically on a secure network with password protection.

### ***Data Access***

The research team, authorized UCI personnel, the study sponsor, and regulatory entities such as the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare. Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Research records provided to authorized, non-UCI entities will not contain identifiable information about you. Publications and/or presentations that result from this study will not include identifiable information about you.

### ***Data Retention***

The researchers intend to keep the research data in a repository indefinitely.

## **OTHER CONSIDERATIONS**

### ***Use of Specimens***

Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the University of California, Irvine (UCI). Once you provide the specimens you will not have access to them. The specimen(s) will be discarded or destroyed once they have been used for the purposes described.

### ***Incidental Findings***

There is a risk of an unexpected finding from your MRI. The results will be shared with you and if necessary, you will be referred to your primary care physician or other specialist for additional consultation.

## **IF YOU HAVE QUESTIONS**

If you have any comments, concerns, or questions regarding the conduct of this research please contact the research team listed at the top of this form.

If you are unable to reach a member of the research team listed at the top of the form and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact UCI's Office of Research by phone, (949) 824-6068 or (949) 824-2125, by e-mail at [IRB@rgs.uci.edu](mailto:IRB@rgs.uci.edu) or in person at 5171 California Ave., Suite 150, Irvine, CA 92697-7600.

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**VOLUNTARY PARTICIPATION STATEMENT**

You should not sign this form unless you have read it and been given a copy of it to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with UCI or your quality of care at the UCI Medical Center. Your signature below indicates that you have read the information in this consent form and have had a chance to ask any questions that you have about the study.

*I agree to participate in the study.*

\_\_\_\_\_  
**Subject Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Printed Name of Subject**

\_\_\_\_\_  
**Researcher Signature**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Printed Name of Researcher**

