Informed Consent

Body and Social Behavior

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: September 5, 2023
IRB Study # 22-1024
Title of Study: Body and Social Behavior Study
Principal Investigator: Dr. Keely Muscatell
Principal Investigator Department: Psychology and Neuroscience
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Funding Source: National Science Foundation

The purpose of this research study is to understand how the immune system influences responses to negative and positive social experiences. The full purpose of the study will be withheld until the debriefing period. You will come in to complete a 30-minute survey and task before receiving the influenza vaccine. You will be randomly assigned either to receive the influenza vaccine or a sham vaccine. Twenty-four hours after receiving the vaccine, you will come into the lab for your post-vaccine session. At this session, which will occur in the morning, you will complete a brief survey, some tasks, and have two videorecorded conversations: one with a pre-selected friend and another with a random stranger. You will also have a blood draw at each of your two sessions. Incentives are described later in the consent form.

You may feel some discomfort from the venipuncture blood draws or from answering questions about yourself. However, you may terminate your involvement in the study at any time. There are no direct benefits associated with participating in this study.

If you are interested in learning more about this study, continue reading below.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to understand how the immune system influences responses to negative and positive social experiences. The full purpose of the study will be withheld until the debriefing period.

Are there any reasons you should not be in this study?

You should not be in this study if you are younger than 18 or older than 35, are not currently a student at UNC-CH, have already received the annual influenza vaccine or had influenza this season, report current illness, use of tobacco products, use of immune-altering medications (e.g., beta-blockers), use of mood-altering medications (e.g., antidepressants) if using medication for less than three months, allergy to eggs, current or history of any major medical condition (e.g., diabetes, asthma), have had Guillain-Barre Syndrome (GBS), are allergic to the influenza vaccine or ingredients present in the vaccine, report current Covid-19 infection within ten days leading up to your session or current upper respiratory symptoms in the five days leading up to your session, or weigh less than 110 pounds. You will not be included if you have had any type of adverse reaction to a blood draw (i.e., to needles, sight of blood, etc.).

You will also need to identify that you have a same-gender friend who is willing to accompany you to the post-vaccine study session to complete part of the study procedures.

The study involves tasks that will be audio and video recorded. You should not be part of this study if you are not okay with being video and audio recorded.

How many people will take part in this study?

There will be approximately 300 people in this research study.

How long will your part in this study last?

This study will take approximately 3-3.5 hours to complete. Prior to the start of the study, you will be contacted over email and phone. Emailing will be for scheduling purposes. You will be consented via Zoom and texted for study reminders. You will complete a questionnaire and task (30 minutes) and, after, you will be given the influenza or sham vaccine and get your blood drawn #1 (30 minutes). The post-vaccine component of this study will include tasks, questionnaires, and conversations (100 minutes), blood draw #2 (15 minutes), and debriefing (5 minutes). All study parts will take place over the course of 2 consecutive days.

What will happen if you take part in the study?

This study will take place in person and begin at the Clinical and Translational Research Center (CTRC, located on the UNC Medical Campus in Chapel Hill).

The study will begin in the morning when come to the CTRC, where you will complete the initial baseline survey and complete a short task. Then, you'll have your blood drawn by a trained phlebotomist and will be randomly assigned (like flipping a coin) to receive either the influenza vaccine or the sham vaccine. The next morning and twenty-four hours after receiving the vaccine, you will come to the lab (Howell Hall, located on the UNC campus) for your post-vaccine session. First, you will complete a set of questionnaires answering questions regarding your affect, social behaviors, and demographic information. You will get your photograph taken. After completing the questionnaire, you will have your blood drawn (done by a trained phlebotomist). You will also complete the following tasks:

1) Decision Making Task – You will complete 90 trials of this two-part task. In the first part of this task, you will play a bargaining game in which, on each round, you must figure out how to divide a pot of money ($9, $10, or $11) between yourself and another person. If you accept the offer, then both people get the proposed split of money. If you reject the offer, then neither person gets any money. In the second part of the task, you are instructed to indicate how much of the subsequent stake you would like to offer to future players.

2) Sociogram Task – In this task you will be mapping your social network.

3) Social Interaction Tasks – You will have brief (10-15 minute) conversations with a friend and separately, a stranger. Conversations will be videorecorded. During the social interaction task you will wear a chest strap that will record your heart rate.

After completing the study tasks, you will be debriefed in person by study staff. You will be told if you received the influenza vaccine or the placebo vaccine. The blood specimen will be used to assess your immune response to the influenza vaccine.

Audio and/or Video Recordings

Audio and video recordings will be used by the research team to evaluate your non-verbal cues and behavior during the social interaction task. All recordings will be stored on a secure password-protected computer located within our laboratory space. They will not be shared with any other personnel beyond the research team.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study beyond receiving the influenza vaccine which may contribute to your health.

What are the possible risks or discomforts involved from being in this study?

The risks of completing the tasks in this study are not greater than those ordinarily encountered in daily life. Answering detailed questionnaires and questions may make you feel uncomfortable, however you may choose not to complete a task or answer any question at no penalty. You may also terminate your participation at any point with no penalty to allay any discomfort. All identifying information will be kept completely separate from your responses, so that your responses will remain anonymous.

Additionally, we do not expect the risk of emotional distress or embarrassment during the social interaction task to be any greater than what participants might experience in everyday life, as they engage in normal social interactions with people you know and don't know.

You may experience discomfort from the insertion of the venipuncture needle for the blood draws. Some participants may experience light-headedness, or they may faint. Our phlebotomists are trained to handle this situation. Phlebotomists are also trained in emergency protocol and will ensure that you are seated and comfortable.

When receiving the flu vaccine, possible discomforts or risks may occur. According to clinical trials of the vaccine, fainting can occur in association with administration of injectable vaccines. Procedures will be in place to prevent falling or injury. Additionally, a CTRC staff member trained in emergency protocol will administer the vaccine and assist if an immediate reaction arises. Further, in clinical trials with adults, the most common solicited local adverse reaction was pain although there were a few other adverse reactions reported. Find the injection and systemic adverse reactions below:

Injection Site Adverse Reactions:

- Common (>25-50%) and Mild: Pain
- Infrequent (>1-10%) and Mild: Erythema
- Rare (<1%) and Mild: Swelling, Induration, Ecchymosis

Systemic Adverse Reactions

- Likely (>10-25%) and Mild: Myalgia, Headache, and Malaise.
- Infrequent (>1-10%) and Mild: Shivering

We acknowledge the potential risk for breach of confidentiality; however, routine measures will be taken to reduce this risk (e.g. entering responses into secure online questionnaire; all data and files stored on password protected computers, identifying information such as emails and phone numbers deleted at the end of the study).

How will information about you be protected?

Individual participants will not be identified in any report or publication about this study. We may use de-identified data from this study in future research without additional consent. Personal information will not be linked your survey responses in any way. Your research data will be stored under a research number. The linkage file connecting your name to this number will be stored on a password protected computer drive only accessible by study personnel Video recorded images will be retained but only linked to this unique number and not to your name in any way.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

Will I receive any clinical results?

You will not receive any clinical results by participating in this study.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped. If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal

will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?
You will receive:

- $25 for completing the initial survey, blood draw, and vaccine administration
- $50 for completing post-vaccine session
- **Thus, you will receive $75 for completing the full study.**

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by the National Science Foundation. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the study email listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

By signing below, you are indicating that you understand your participation is voluntary, that your responses will be kept anonymous, and that you are at least 18 years of age.

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent