**Lincoln University of Pennsylvania**

**(Insert Department Name and Address)**

|  |
| --- |
| INFORMED CONSENT FOR NON-MEDICAL RESEARCH |

(Note: PLEASE USE SECOND PERSON, SINGLE-SIDED, SINGLE-SPACED. DELETE INSTRUCTIONS IN BOLD PRIOR TO SUBMITTING THIS DOCUMENT)

* **This template is NOT for studies utilizing the Cognitive Neuroscience Imaging Center.**
* **Be consistent throughout the document, use simple language and be concise.**
* **If the study involves using multiple consent forms for different populations, subtitle the consent with that population’s name; for example: Teachers, Parents, Caregiver, etc.**
* **Use the pronoun “you” consistently throughout (except for the “Signature of Research Participant” on the last page.**
* **The consent document should be revised to be consistent with your application, please remove the instructions/examples as appropriate.**

**(INSERT TITLE OF THE STUDY)**

You are invited to participate in a research study conducted by **(insert names and degrees of principal investigator (including faculty advisor)** at the Lincoln University; because you are **(insert eligibility criteria).** This study is funded by **(insert funding agency here/remove as applicable).** Your participation is voluntary. You should read the information below, and ask questions about anything you do not understand, before deciding whether to participate. Please take as much time as you need to read the consent form. You may also decide to discuss participation with your family or friends. If you decide to participate, you will be asked to sign this form. You will be given a copy of this form.

**PURPOSE OF THE STUDY**

**(State what the study is designed to assess or establish. Technical or complicated language should be avoided. Participants should be able to easily understand the purpose of the study and that it is research.)**

**STUDY PROCEDURES**

If you volunteer to participate in this study, you will be asked to **(Describe the procedures in the order they will be administered or experienced using simple language, short sentences and short paragraphs. If several procedures will be used, the use of subheadings may help to organize this section and increase readability. If scientific terms need to be used, they should be defined and explained. If experimental procedures will be used, they should be identified as such. If survey or questionnaire instrument(s) are used, briefly describe the types of questions asked. If applicable to the study, clearly state participants will be photographed and/or audio/video-recorded. Clarify if the participant can still participate in this research study if they do not wish to be audio/video-recorded or photographed.)**

**(If applicable, specify the participant’s assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location where the procedures will be take place, etc. For research involving randomization, specify the randomization procedure, for example, “you will be assigned randomly, much like tossing a coin, into…...)**

**POTENTIAL RISKS AND DISCOMFORTS**

**(Describe any reasonable foreseeable risks, discomforts, inconveniences, including physiological risks/discomforts; describe any psychological, social, legal or financial risks to the participant, and how these will be minimized. If there are no anticipated risks, state so.)**

**POTENTIAL BENEFITS TO PARTICIPANTS AND/OR TO SOCIETY**

**(Describe direct benefits from participating in the study. Also, state the anticipated benefit to society. If there are no anticipated benefits to the participant, state so. Note that as this is a research study, the benefits are contingent upon the results. The investigator can state only that benefits are anticipated, not that they will occur. If there are no direct benefits to participants, there should be anticipated benefits to society.)**

**PAYMENT/COMPENSATION FOR PARTICIPATION**

**(State whether the participant will receive payment/compensation or any other form of compensation, e.g. small gift, course credit, etc. If not, state clearly, “You will not be paid for participating in this research study” or remove the section. If participants receive payment, describe amount, when payment is scheduled, and pro-rated schedule should the participant decide to withdraw or is withdrawn by the investigator. If participants are reimbursed for expenses such as parking, bus/taxi, travel companion/assistant, etc., list payment.)**

**POTENTIAL CONFLICTS OF INTEREST OF THE INVESTIGATOR**

**(A "Conflict of Interest (COI)" is a situation in which financial or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgment in proposing, conducting, supervising or reporting research. If there appears to be a conflict of interest (COI) or there is a COI, include this section. Delete this section if there are no conflicts of interest.)**

1. **The investigator must disclose all financial or other personal considerations that compromise, or have the appearance of compromising, the investigator’s professional judgment in proposing, conducting, supervising, or reporting research. Conflicts include financial as well as non-financial interests. Conflicts include financial interests (stocks, stock options, or other ownership interests, whether traded publicly or not) in a research sponsor or licensee; management roles in a research sponsor, licensee, or other company having an economic interest in the outcome of the research; and using students to perform services in which an investigator maintains an ownership interest or management role.**
2. **In disclosing your proprietary interest and research interest in the informed consent, you may do so in general terms, in a manner consistent with IRB requirements. At a minimum, you must disclose the nature of the interest, such as a paid consultant, a lecturer, a board member, an equity ownership, or a management or supervisory role in the sponsoring company. Such conflicts should also be disclosed to the Vice President of Academic Affairs for resolution. The proposed informed consent language must be reviewed by the IRB. For more information go to: Lincoln University Office of Compliance Step by Step Guide to Conflict of Interest Disclosure:** [**http://www.lincoln.edu/hr-board-trustees-policies**](http://www.lincoln.edu/hr-board-trustees-policies)

**Example 1: If there may be commercial product development in the future, the following statement can be used: The Lincoln University or the biotechnology company \_\_\_\_\_\_ (insert company name) may use your \_\_\_\_\_\_ (insert type of samples) for other research studies. Those studies may develop products that can be sold. If they make money from these products, you will not receive any money.**

**Example 2: If you have a financial interest in the sponsoring company, the following statement should be used.**

**The investigator has a financial interest in the company sponsoring this study. (Briefly describe your financial interest.) The nature of this financial interest and the design of the study have been approved and allowed by the institutional committees.**

**CONFIDENTIALITY**

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. The members of the research team, the funding agency and the Lincoln University’s IRB may access the data.The IRB reviews and monitors research studies to protect the rights and welfare of research subjects. **(remove references to funding agency if not applicable)**

The data will be stored **(state where and how the research data will be stored). [If applicable to the study, describe the participant’s right to review/edit the audio/video-recordings or transcripts, who will have access (including transcribers), if the audio/video-recordings will be used for educational purposes, describe how personal identities will be shielded/disguised and, if/when the audio/video-recordings will be erased (approximately). If the audio/video-recordings will be maintained indefinitely, state how confidentiality will be maintained. If information will be released to any other party for any reason, state the person/agency to which the information will be furnished, the nature of the information, and the purpose of the disclosure. Give a brief description of how personal information, research data, and related records will be coded, stored, etc., to prevent access by unauthorized personnel (list the personnel who have access).**

**[Indicate how long the data will be kept. Please note that data must be kept for a minimum of three years after the completion of the study. The data may be kept indefinitely.]**

**CERTIFICATE OF CONFIDENTIALITY**

**(If a Certificate of Confidentiality is issued (or anticipated to be issued), please use the following language, otherwise remove)**

Any identifiable information obtained in connection with this study will remain confidential, except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care). A Certificate of Confidentiality has been obtained from the Federal Government for this study to help protect your privacy. This certificate means that the researchers can resist the release of information about your participation to people who are not connected with the study, including courts. The Certificate of Confidentiality will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others.

When the results of the research are published or discussed in conferences, no identifiable information will be used.

**PARTICIPATION AND WITHDRAWAL**

Your participation is voluntary. Your refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. **(If appropriate, describe the anticipated circumstances under which participation may be terminated by the investigator without regard to the participant’s consent.)**

**ALTERNATIVES TO PARTICIPATION**

**(Please describe and explain the procedures that will be employed to provide alternate yet equal activities for those who wish not to participate.)**

**Example: If you joined the student subject pool, your alternative may be to participate in another study or to write a paper, please contact the Subject Pool Coordinator for further information.**

**EMERGENCY CARE AND COMPENSATION FOR INJURY (For greater than minimal risk studies, include the “Emergency Care and Compensation” section which provides evening/emergency phone numbers.)**

If you are injured as a direct result of research procedures you will receive medical treatment; however, you or your insurance will be responsible for the cost. The University of Southern California does not provide any monetary compensation for injury.

**INVESTIGATOR’S CONTACT INFORMATION**

If you have any questions or concerns about the research, please feel free to contact **(identify research personnel: Principal Investigator, Faculty Sponsor (if student is the Co-P.I.), and Co-Investigator(s). Include day phone numbers, email addresses, and school/business addresses for all listed individuals. (DO NOT INCLUDE HOME ADDRESSES FOR YOUR PERSONAL SAFETY).**

**RIGHTS OF RESEARCH PARTICIPANT – IRB CONTACT INFORMATION**

If you have questions, concerns, or complaints about your rights as a research participant or the research in general and are unable to contact the research team, or if you want to talk to someone independent of the research team, please contact the Lincoln University, IRB Committee, 1570 Baltimore Pike, Lincoln University, PA 19352 – 09999 (484) 365 8000 or [www.lincoln.edu](http://www.lincoln.edu)

|  |
| --- |
| **SIGNATURE OF RESEARCH PARTICIPANT** |

I have read the information provided above. I have been given a chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

**AUDIO/VIDEO/PHOTOGRAPHS (If this is not applicable to your study and/or if participants do not have a choice of being audio/video-recorded or photographed, delete this section.)**

□ *I agree to be audio/video-recorded /photographed* **(remove the media not being used)**

□ *I do not want to be audio/video-recorded /photographed* **(remove the media not being used)**

Name of Participant

Signature of Participant Date

|  |
| --- |
| SIGNATURE OF INVESTIGATOR |

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date