**INSTRUCTIONS TO INVESTIGATORS**

This template is for use with Expedited or Full Board Review research projects. ***Delete the RED text before submitting this form to the IRB.***

**Guidelines for completing this consent template:**

* Student researchers must include their Faculty Sponsor contact information.
* Use simplified language that is understandable to your subjects and avoid technical terminology, acronyms, scientific jargon, and abbreviations.
* Avoid using first person language from the perspective of the participant (e.g, “I understand…” or “I agree to…”).
* Delete all instructions in ***RED*** text in the template and make the font and color of text the same throughout before submitting for review.
* Proofread your consent document for grammar and spelling errors prior to attaching it to your IRBNet package.
* Enter the version date of the consent & page numbers in the header before submitting for review.
* Be sure to include the generic DU logo in the heading or your specific department logo.

**Consent to Participate in Research**

|  |
| --- |
| **Study Title:** *if the official title is technical and difficult to understand, a simplified non-technical title should be used in addition to the official title*  **IRBNet #:** |
| **Principal Investigator:** *name and credentials*  **Faculty Sponsor:** *if student investigator, insert faculty sponsor’s name and credentials*  **Study Site:** *Location where study will take place (i.e., DU department or lab, school district, community center, etc.)*  **Sponsor/Funding source:** *if no funding involved, delete* |

**You are being asked to participate in a research study.** Your participation in this research study is voluntary and you do not have to participate. This document contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

The purpose of this form is to provide you information that may affect your decision as to whether or not you may want to participate in this research study. The person performing the research will describe the study to you and answer all of your questions. Please read the information below and ask any questions you might have before deciding whether or not to give your permission to take part. If you decide to be involved in this study, this form will be used to record your permission.

***NOTE:*** *If this research is part of a classroom activity, state the following:*

This research study will take place during regular classroom activities; however, if you do not want to participate, an alternate activity will be available. *[Describe the alternate activity*]. If the study involves a classroom setting, state that their grades will be not affected by the study. If the study is in a clinical setting, state that the study will not affect their health care.

Simply state the reason a person has been asked to participate (e.g., “because you are a teacher who teaches math to elementary school children”.

**Purpose**

If you participate in this research study, you will be invited to *[provide a brief background and describe the purpose of the activity in lay-language. Do not use professional jargon, acronyms or abbreviations without clearly explaining the abbreviations]*.

Provide a brief summary of the project, that is concise and focused, and that will most likely assist a prospective subject to understand the research and choose to participate. This summary should include:

* The purpose and expected duration (*include the commitment of time for each activity, the total amount of time involved, and how long the study will last*)
* Requirements of the study (*describe questionnaires, surveys, and interviews and provide examples of the most personal and sensitive questions you will ask*)
* State that subject may refuse to answer any question or item in any test, inventory, questionnaire, or interview.
* Other alternatives to participating, if appropriate. For studies involving interventions (educational, social, medical, or other) include description of alternative procedures or activities that are available if a subject is not to be in the study.

**If educational records will be accessed:**

* Specify the records that may be disclosed;
* State the purpose of the disclosure; and
* Identify the party or class of parties to whom the disclosure may be made.

**If the project involves a Functional MRI (fMRI) Procedure**

This study uses functional magnetic resonance imaging (fMRI) to look at your brain. Functional magnetic resonance imaging is a brain scan that shows changes in blood flow in your brain.

If you agree to participate, you will be asked to complete an MRI Screening Sheet -- the screening sheet asks questions that allow us to determine whether you can safely participate in this study.

An fMRI scan is taken in a large machine that is shaped like a tunnel. This scan does not use x-rays. Instead, the fMRI scanner uses strong magnet and radio waves, like those used in an AM/FM radio, to make pictures of your body.

You will be asked to lie still on a platform that will be slid into the center of the tunnel. A plastic coil will be placed around your head and foam pads will be placed to limit your head movement during the study. At different points during the scan, you may be asked to perform different tasks (see below).

You will hear “hammering”, clicking, or squealing noises during the scan. You will be given earplugs or headphones to reduce the noise. During the scan, the fMRI staff is able to hear you and talk to you. You will be able to hear the staff. Also, an alarm button will be placed next to your hand – you can alert the fMRI staff by squeezing the alarm button.

If you feel uncomfortable in the scanner for any reason, please let the fMRI staff know and we will stop the experiment.

The fMRI scan will take about { } minutes.

**Risks or Discomforts**

There are no expected risks to you as a result of participating in this study. *Do not state that there are no risks or that risk “should be” minimal.*

***OR***

Potential risks, stress and/or discomforts of participation may include (*include information on the psycho-social and physical risks, including side effects, stress, discomforts, breach of confidentiality, or the invasion of privacy that might results from each procedure.)*

**If you will make recordings (e.g., audio/visual) of subjects,** *indicate if you will keep the records indefinitely, will share them with other researchers, or use them in presentations or publications, and explain whether subjects will be given an opportunity to review the recordings or delete any portions.*

***For studies that involve psychological risk and/or emotional risk*** *(many of the studies that are done by GSPP faculty/students do not involve physical risk, but rather the possibility of psychological and/or emotional risk from participation): The principles are similar to those that involve physical risk. Participants should be informed of the risk. They should be given the names and telephone numbers of agencies that may alleviate their mental health concerns, such as a crisis hotline*.

**If the project involves Native Americans:**

If you are Native American and agree to participate in this study, there may be risks associated with the research that impact your community. Risks may include legal, financial, social, or physical harm. Information may be published that conflicts with your communities’ culture, traditions, mythologies, or spiritual beliefs.

**If an fMRI is a research procedure**

**Risks of fMRI**

While there are minimal risks from fMRI as it will be used in this study, participation may involve some discomfort. It may bother you to be placed in a tight space (claustrophobia), to lie still on your back (back pain), or to hear the noise made by the magnet during the scan. You will be given earplugs or headphones to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan.

Some people have reported sensations during the fMRI scan, such as "tingling" or "twitching." This is caused by changes in the magnetic field that can stimulate nerves in your body -- the sensations will usually stop soon after the scan is completed. If you have these sensations and are uncomfortable, you can tell the MRI staff, and they will stop the scan.

You may not be able to have this scan if you have any metal in your body, such as aneurysm clips in the brain, heart pacemakers or defibrillators, and cochlear (inner ear) implants. Also, you may not be able to have this scan if you have iron-based tattoos, or if you have pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye). If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs.

If you use a transdermal patch (medicated patches applied to the skin), you may need to take it off before having the fMRI scan. Tell the researchers and the staff at the fMRI facility if you are using a transdermal patch.

The magnetic field in the MRI is very strong and unsecured metallic objects can be pulled in at high speed and become very dangerous. Thus, you should pay attention to the metallic screening procedures and safety measures.

Regarding pregnancy:  There is no current evidence that an MRI scan is harmful to a fetus.  However, as a precautionary measure, if you are pregnant you should not participate in this study.  Should you be concerned about the possibility that you might be pregnant before participating in the experiment, we will have a pregnancy testing kit that you can administer to yourself in private; you will not be required to reveal the results.

Please be aware that this fMRI scan is designed for research purposes. We do not plan to have the fMRI images of your brain reviewed by a radiologist or physician for the purpose of identifying any health issues or risks for disease. If the research staff has concerns about your MRI, they will consult a specialist or contact you, but this is NOT a medical scan and the researchers are not trained to look for medical abnormalities.

**Benefits**

The benefits which may reasonably be expected to result from this study are *(describe any benefits; if none state as such)*. We cannot and do not guarantee or promise that you will receive any benefits from this study. *(If applicable)* Your decision whether or not to participate in this study will not affect your *(choose as appropriate): employment; medical care; grades in school.*

*[Describe the expected benefits to individual subjects and/or society. State if subjects will not benefit from being in this study.* ***Reimbursement/compensation is NOT considered a benefit****.]*

**Source of Funding**

***This section is required only if there is funding for the research***.

The study team and/or the University of Denver is receiving [*financial support, OR describe other type of support from [insert sponsor’s name]*.

**Financial Interest**

*This section is required when any investigator has a Financial Conflict of Interest. If no one has a Financial Conflict of Interest, this section should be omitted.*

*[Investigator name]* has a financial or other relationship with *[company name].* The University of Denver (DU) developed a Conflict Management Plan to reduce the possible effects of this relationship on this study and your participation.

**Confidentiality of Information**

***NOTE:*** *One risk of participating in any research is a loss of privacy. There is no legal privilege between investigator and subjects as there is between physician and patient or counselor and client. Thus, do not give or imply a guarantee of “complete” or “strictest” confidentiality.*

*State whether data will be confidential (linked to identifiers) OR anonymous (no links). If you think it is important for your specific study to eventually destroy identifiers (or links to identifiers), state something like*, “The link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law.” *State who or what other agencies (sponsors, other researchers, etc.) will have access to identifiable data. Do not state that research data will not be released to subjects, unless you have a contractual obligation with a sponsor or other group to prevent release of data. However, it is acceptable to state that there are no plans to release the data to subjects, or to not mention this issue at all.* ***Do not make statements to the effect that only the research team will have access to the data.***

**Limits to confidentiality**

*[****NOTE****: If the project involves situations that may reasonably elicit a response indicating the existence of child abuse/neglect, suicide ideation, or threatened violence against another specific person, that information must be reported, and the following statement must be included in the consent form.]*

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, including, but not limited to child or elder abuse/neglect, suicide ideation, or threats against others, we must report that to the authorities as required by law.

**Online Survey Studies ONLY:** **The following language is recommended as appropriate for studies where data are collected through online systems such as Qualtrics, RedCap, and mTurk.**

Before you begin, please note that the data you provide may be collected and used by *[insert online system]* as per its privacy agreement. This research is only for U.S. residents over the age of 18. Please be mindful to respond in private and through a secured Internet connection for your privacy. Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties.

{Describe the way you will maintain the confidentiality of records that identify the subject. Use words to the following effect, if appropriate:} Your name will not be used in any report. Identifiable research data will be encrypted and password protected.

{If you will be coding the data:} Your responses will be assigned a code number. The list connecting your name to this code will be kept in an encrypted and password protected file. Only the research team will have access to the file. When the study is completed and the data have been analyzed, the list will be destroyed.

{If you are using an audio or video recording, or photographs in the study, describe if and when such materials will be destroyed}: With your permission, I would like to audiotape this interview so that I can make an accurate transcript. Once I have made the transcript, I will erase the recordings. Your name will not be in the transcript or my notes.

{For a focus group:} You will not be identified in any report or publication of this study. Even though we will tell all participants in the study that the comments made during the focus group should be kept confidential, it is possible that participants may repeat comments outside the group.

{If the study will be anonymous, use words to the following effect:} The information that you give in the study will be anonymous. Your name will not be collected or linked to your answers.

{If it is possible to deduce the participant’s identity through their responses, state the following:} Because of the nature of the data, it may be possible to deduce your identity; however, there will be no attempt to do so and your data will be reported in a way that will not identify you.

{If the information will be shared:} Information that may identify you may be used for future research or shared with another researcher for future research studies without additional consent. [Explain]

{OR}

Information that identifies you will only be used for future research or shared with another researcher after obtaining your consent. [Explain]

{OR} Information collected about you will not be used or shared for future research studies.

**For SONA/Psychology Research Participation (PRP) System Studies**: The following information should be included for studies utilizing SONA/PRP.

Your name and identifying information will not be connected in any way to your responses in this study. The online system will grant you credit when you submit your responses by separately submitting your Identity Code to the system while your responses are sent to a different database for retrieval by the researcher.

{Required} The information that you provide in the study will be handled confidentially. However, there may be circumstances where this information must be released or shared as required by law. Representatives from the University of Denver may also review the research records for monitoring purposes.

**For all studies in which links between subjects’ identities and the data will be kept, add**:

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

**If you are obtaining a federal Certificate of Confidentiality, insert the following language:**

**Certification of Confidentiality**

**For possible discovery of illegal activities** – because research records do not have the same legal privilege as medical records, subjects are placed at risk when they are asked about possible illegal drug use, residency status or other illegal activities. For such cases, you may wish to obtain a Certificate of Confidentiality from NIH, which can help protect identifiable research information from forced disclosure. Certifications will be given regardless of whether or not the research is federally funded.

**Whether or not a Certificate is obtained, warn prospective subjects as follows:**

Participation in research may cause a loss of privacy. In this study, you will be asked about *[insert possible illegal activity*]. The researchers will keep information confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, research records have been subpoenaed by a court.

We have a Certificate of Confidentiality from the federal *[insert the name of the institution that issued the Certificate, such as the National Institutes of Health].* This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can’t use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

* A member of the federal government who needs it in order to audit or evaluate the research;
* Individuals at the University of Denver, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
* The federal Food and Drug Administration (FDA), if required by the FDA;
* [*Insert or modify as appropriate*] authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

**ClinicalTrials.gov Registration**

*The FDA issued a final rule requiring that consent forms for applicable drug and device clinical trials include a specific statement that clinical trial data will be entered online into ClinicalTrials.gov.*

*The following mandatory language only needs to be entered if the study meets the FDA’s definition of clinical trial. The language must appear verbatim in consent forms for all clinical trials approved on or after March 7, 2012.*

“A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

**Use of your information for future research** [*One of the following statements is required if any identifiable private information or biospecimens/samples are collected*:}

Your information collected for this project will NOT be used or shared for future research, even if we remove the identifiable information like your name or date of birth.

OR

All identifiable information (e.g., your name, date of birth) will be removed from the information or samples collected in this project. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent

**Data Sharing**

*We strongly recommend that you include this section in your consent, to inform participants that you may share de-identified data you collect from them. Certain sponsors now require researchers to make available their de-identified data to the research community, as do a growing number of journals in a variety of disciplines. If you choose not to include the following language and later wish to share de-identified data, you may not be able to do so without re-contacting participants to obtain consent.*

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information (e.g., your name, date of birth) that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information or samples we share. Despite these measures, we cannot guarantee anonymity of your personal data.

**Incentives to participate**

*Describe any payments to subjects (cash, gift cards) including any prorated amounts, class credit, entering into a drawing, or service.*

*Explain when subject will be paid (e.g., immediately or in 6 – 8 weeks). If appropriate, include a payment schedule.*

**If it is possible or likely that a subject will earn $600 or more in subject payments during the calendar year, the University is required to report subject payments of $600 or more as miscellaneous income to the IRB. The following statement is required:**

The Shared Services Center at the University of Denver will be provided with your information, including your Social Security Number, in order to issue payment for your study participation. Study payments are considered taxable income and reportable to the Internal Revenue Service (IRS). An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

**Study Costs**

Your will be expected to pay for [*description of any costs that might be incurred by participants during the study (e.g., your own transportation, parking, childcare, etc.)* if needed. *If this does not apply, delete this section.*

**Consent to video / audio recording / photography solely for purposes of this research**

This study involves video/audio recording, and/or photography. If you do not agree to be recorded, you (CAN STILL/CANNOT) take part in the study*. [If this does not apply, delete this section.]*

\_\_\_\_\_ YES, I agree to be video/audio recorded/photographed.

\_\_\_\_\_ NO, I do not agree to be video/audio recorded/photographed.

**Optional Sub-Study**

This project involves optional participation in a sub-study. I understand that it is my choice whether or not to take part in the sub-study. I understand that if my ability to consent or assent for myself changes, either I or my Legal Representative may be asked to re-consent prior to my continued participation in this study. *[If this does not apply, delete this section.]*

\_\_\_\_\_\_ YES, I agree to take part in the optional sub-study.

\_\_\_\_\_ NO, I do not agree to take part in the optional sub-study.

**Consent for Accessing Education Records**

Education records used by this research project are education records as defined and protected by Family Educational Rights and Privacy Act (FERPA). FERPA is a federal law that protects the privacy of student education records. Your consent gives the researcher permission to access the records identified above for research purposes. *[If this does not apply, delete this section.]*

\_\_\_\_ **YES**, I give permission to the researcher to access my education records for this research project.

\_\_\_\_ **NO**, I do not give permission to the researcher to access my education records for this research project.

**Compensation for Injury**

*[If appropriate: This clause is typically required for research involving more than minimal risk to participants. If in doubt, consult with the IRB office.]*

If you are injured because of participation in this study, you should call the study principal investigator immediately (if it is a medical emergency, first call 911). Study contact numbers are listed on page one of this consent form. If you require medical care, go to your local or primary care hospital. In an emergency, the researchers will dial 911. The University has no plan to pay for medical treatment for a research-related injury. You will be responsible for any expenses related to transportation or medical treatment.

**Questions**

For questions, concerns, or complaints about the study you may contact*insert Principal Investigator’s name, credentials, email and phone number. Include faculty sponsor’s contact information if student research.*

If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the University of Denver (DU) Institutional Review Board to speak to someone independent of the research team at 303-871-2121 or email at IRBAdmin@du.edu.

# For Researcher Only: Written signatures are required as determined by the IRB. For many studies involving focus groups, observations, and on-line surveys it may be necessary to obtain an implied consent (consent without written documentation) often used in internet research signature from participants. Please submit Appendix A as part of your IRBNet package to request approval for administering consent without obtaining written documentation.

# Use this signature line if you will be obtaining written consent.

# Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Printed name of subject** |  | **Signature of subject** |  | **Date** |

**Use this section below only if signed consent will NOT be obtained and a waiver of written documentation of consent will be requested through the submission of Appendix A.**

**Please take all the time you need to read through this document and decide whether you would like to participate in this research study**.

If you decide to participate, your completion of the research procedures indicates your consent. Please keep this form for your records.