

Recommended Consent and Information Sheet Language

Below you will find IRB recommended language that should be included in your information sheet, consent, parent/legal guardian permission, or assent documents, if your research includes the particular activity, risk, or design element. Some of the language is already included in the templates posted on the Office of Research Services website.

- If your research involves recruiting individuals at their place of work, such as teachers at a school or workers at a company, the “***Can I decide not to participate?***” section should include the statement, “Your decision whether or not to participate will not affect your relationship with [insert name of place of work] or your job standing.”
- If your research involves students (such as elementary, middle school, high school, or college students) the assent (if under 18) or consent (if 18 or older) “***Can I decide not to participate?***” section should include the statement, “Your decision whether or not to participate will not affect your relationship with [insert names of school(s)] or your grades.” The parental permission document for children under 18 should include the statement, “Your decision whether or not to allow your child to participate will not affect you or your child’s relationship with [insert name of school(s)] or your child’s grades.”
- If your research will be conducted in a Chicago Public School, the “***What will I be asked to do if I agree to participate in this study?***” section of the parental permission document must include this statement,

Parents please be aware that under the Protection of Pupil Rights Act. 20 U.S.C. Section 1232 (c) (1) (A), you have the right to review a copy of the questions asked of or materials that will be used with your students. If you would like to do so, you should contact [insert contact name] at [insert phone number (XXX) XXX-XXXX] to obtain a copy of the questions or materials.

There are additional consent document requirements based upon the guidance issued by the Chicago Public School system. These can be reviewed at: http://research.cps.k12.il.us/export/sites/default/accountweb/Requests/CPS_ResearchGuidelines.pdf and the guidance document on our web site called, “Guidance for Conducting Research with School Children.”

- If your research involves using health information from entities outside of DePaul Universities health providing units, the following language should be included in the ‘What will you be asked to do...’ section of the consent document.

Participating in this research includes allowing the researchers to obtain some health information about you. If you agree to let the [PI or DePaul Research Team] use your health information for the research, [\[insert names or groups of health care units or health care providers from which you will be obtaining protected health information for the research, for example your private physician,](#)

your health care providers at X facility.] will provide us with your health information from its/their records. Health information that will be used in the research study includes [insert a specific and meaningful description of information to be used]. Our purpose for using your health information is [a description/purpose for why we are using and disclosing the participant's health information].

A federal law called the "HIPAA Privacy Rule" requires us not to use your personal medical information for research without your permission. In order to obtain this permission from you, we will ask you to sign a separate document called an authorization form.

- If your research involves blood draw, the following statement should be included in the risk section, "Drawing your blood may cause pain or discomfort, bruising, bleeding, and rarely infection and fainting."
- If the research includes an MRI or fMRI, the following language should be in the risk section. Special consideration should be taken for the second paragraph.

You may not be able to have an MRI if you have the following: implanted medical devices such as aneurysm clips in the brain, heart pacemakers and cochlear (inner ear) implants, iron-based tattoos, pieces of metal close to or in an important organ (such as the eye). Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the MRI scanner or may be pulled away from the body in the MRI room. Also, metal can sometimes cause poor pictures if it is close to the part being scanned. For these reasons, you will be asked to remove these objects before entering the MRI scanner. Additionally, you will hear "hammering" noises while the scanner is preparing for scanning and taking the pictures. You will be provided with earplugs to reduce the noise. You may also feel some vibration during the hammering noise and some slight movement of the table during the examination. You may also experience claustrophobia (anxiety about being in a closed space) while you are inside of the MRI machine.

In this study, the MRI [fMRI] scan is being conducted for research purposes only. However, in the event that an abnormality is detected, you will be notified and encouraged to consult your physician.

- If the research includes testing for HIV or other conditions that carry mandatory state or federal reporting requirements, the risk section should include information informing the participants of the risks related to testing. For example:

As part of the research you will be tested for HIV. If test results should indicate that you are infected with the virus which causes AIDS, the study staff will promptly notify you of the results and refer you to appropriate medical and/or public health providers for confirmation of test results and counseling. You will be counseled before and after HIV testing and your test

result will be given to you only in person. If the initial HIV test is positive, a second confirmation test may be requested and if the second test is positive, this would require mandatory reporting of the positive test result to the State of Illinois. Accidental loss of confidentiality of a positive HIV status may cause psychological stress, discrimination from other people, problems with insurability or employability, or other unknown inconveniences. All possible precautions will be taken to prevent this loss of confidentiality. It may be helpful to you to know if you are HIV positive so that you may seek appropriate medical care.

- If your research involves video recording of participants, the consent should contain language that requests permission to make the video recording and a separate signature line for the participant to provide consent for this procedure. One of the options below should be chosen based upon the intended use of the video

Personal Release for Filming [to be used when the video will be used only for the specific research protocol]

1. I authorize DePaul University to take and use video and audio recordings of me in connection with the research study. The video and audio recordings will be destroyed after the research study is completed.

Personal Release for Filming [to be used when the video may be used for purposes outside of the research project]

2. I authorize DePaul University to take and use video and audio recordings of me in connection with the research study. I also authorize DePaul University to use the video and audio recordings for other purposes, such as presenting research at a conference or creating a documentary film. I understand that DePaul University will own the video and audio recordings of me and that I will not be given any financial compensation, other than as provided for in this informed consent, if the video or audio recordings are used in a documentary or for other purposes.

- If your research involves focus groups, you need to take extra precautions to prevent a breach of confidentiality (e.g., spend additional time informing participants about maintaining confidentiality, having participants sign a brief contract to indicate they won't share group information outside the group). In addition, the risk section should include the following statement indicating that complete confidentiality cannot be promised.

“We cannot promise complete confidentiality, because everyone in the focus group will hear what you have said and it is possible that they may repeat something you said to someone outside the group.”

- If your research involves the recruitment of subjects and data collection from Amazon MTURK, you should include the following information:

“Since you are enrolling in this research study through the Amazon Mechanical Turk (MTurk) site, we need to let you know that information gathered through Amazon MTurk is not completely anonymous. Any work performed on Amazon MTurk can potentially be linked to information about you on your Amazon public profile page, depending on the settings you have for your Amazon profile. Any linking of data by MTurk to your ID is outside of the control of the researcher for this study. We will not be accessing any identifiable information about you that you may have put on your Amazon public profile page. We will store your MTurk worker ID separately from the other information you provide to us. Amazon Mechanical Turk has privacy policies of its own outlined for you in Amazon’s privacy agreement. If you have concerns about how your information will be used by Amazon, you should consult them directly.”