

**Informed Consent Form Template Instructions for Completing the Form**

The Informed Consent Form Template has been made available to provide guidance and suggested language that may be used to inform participants about the research study, the requirements for participation, and the participants’ rights and responsibilities.

Instructions for using the template:

1. Leave all text that is not highlighted as-is
2. Follow the instructions in all areas that are highlighted in grey. Once you have completed the instructions, delete them from the document and remove highlighting.
3. Follow the formatting that exists in the template and type in the information that pertains to your study
4. Remove this instruction sheet from the final document

IMPORTANT - Please review the following as you prepare the consent form:

* You should select a font that is easy to read and a font size no smaller than 12 point.
* The consent document must be written using lay language, at an 8th grade reading level (similar to the level used by popular magazines and newspapers) that is appropriate for the participant population. It is to be written in the second person (e.g., *you* are invited to participate, *your child* will be assigned, etc.). Microsoft Word has a tool to assess readability. The form should be written as if the investigator and participant are engaged in conversation.
* The use of bulleted or numbered lists and/or tables may be helpful to explain study procedures, timelines, inclusion/exclusion criteria, etc…
* All pages must leave 1 inch margins on all sides..
* Consent form pages must be numbered and should follow the following format “page X of X.” When amending the consent form include the revision date in the footer.

Unless otherwise noted, all sections of the consent form (formatted as shown with proper headings) are required. The format of the template is appropriate for most research studies. If you feel that the format of the consent template would not be appropriate for your study, please explain why this is the case in the IRB-1 protocol application at the time of submission and submit an alternative version.

Research participants should be provided with a copy of the informed consent form for their records.

If you have questions concerning use of the template or need assistance preparing the consent form, please contact the Institutional Review Board staff at 312-369-8795 or IRB@colum.edu.



**Informed Consent Form**

Consent Form for Participation in a Research Study

**Title of Research Project:** Click here to insert project title

**Principal Investigator:** Click here to insert name, credentials and contact information

**Faculty Advisor:**  Click here to insert advisor’s name, credentials and contact information

**Chair of Thesis Committee:** Click and enter “Not Applicable” or insert chair’s name, credentials and contact information

**INTRODUCTION**

You are invited to participate in a research study to Click here to insert details. This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. You are encouraged to think this over. You are also encouraged to ask questions now and at any time. If you decide to participate, you will be asked to sign this form and it will be a record of your agreement to participate. This process is called ‘informed consent.’ You will receive a copy of this form for your records.

You are being asked to participate because Click here to insert details

# PURPOSE OF THE STUDY

The purpose of this research study is Click here to insert details in one or two sentences. Describe why you are conducting the study. Provide participants with a clear and accurate statement of the purpose and objectives of the research. Use lay terms.

**PROCEDURES**

If you agree to participate in this study, you will be asked to do the following:

* [Click here to insert details.] Using this bullet point format, describe the procedures to be used in the study in sequential order. If participants will be screened, describe screening procedures and major inclusion/exclusion criteria.
* [Click here to insert details.] If the research involves questionnaires, surveys or interviews, describe the type of questions that will be asked or the topics covered.
* [Click here to insert details.] Describe where the research will be conducted, when the research will be conducted and how much time (per session and in total) will be required of the participant and whether or not the participant will be contacted in the future.
* [Click here to insert details] Describe procedures to audio and/or videotape.

**POSSIBLE RISKS OR DISCOMFORTS**

The risk(s) in this study is(are):

* [Click here to insert details.] Inform the participant of any risks (e.g. physical, emotional, social) that may occur as a result of the study procedures. Each procedure should be identified and then the associated risks described. Identify immediate and latent risks and list them in appropriate order from most likely to least likely to occur. Identify steps taken to minimize risks. Indicate if there may be unforeseen risks.
* [Click here to insert details.] Inform the participant of any inconveniences (e.g. the amount of time required to complete procedures, length of time participants may be required to sit or stand) as a result of study procedures.
* [Click here to insert details.] If there are no known risks to the study, insert the following statement: I(We) believe there are no known risks associated with this research study other than the possible inconvenience of the time it takes to participate in the study.

**POSSIBLE BENEFITS**

The possible benefits of being in this study include:

* [Click here to insert details.] Describe any direct benefits to the participant that may be reasonably expected as a result of the research. Describe benefits expected to accrue to the population the participant represents or to society in general (e.g. advancement of knowledge). DO NOT include payments for participation or other incentives and gifts as a benefit of participation.
* [Click here to insert details.] If participants are not expected to directly benefit then use the following: You may not directly benefit from this study; however, I(we) hope that your participation in the study may…

**CONFIDENTIALITY**

Confidentiality means that the investigator will keep the names and other identifying information of the research participants private. The investigator will change the names and identifying information of research participants when writing about them or when talking about them with others, such as the investigator’s supervisors.

* [Click here to insert details.] Explain procedures to protect participant’s privacy and the confidentiality of study records and, if applicable, of audio or videotapes. If the study involves use of the internet, e-mail or electronic record keeping, describe procedures to ensure confidentiality of the electronic data (e.g. stand-alone servers, firewalls, etc..). State how long study records will be kept, where they will be kept, and who will have access to them. If participants are audio and/or videotaped, describe who will transcribe or view the recordings. Please note: personal study notes may be kept indefinitely as long as the data has been stripped of all identifiable information and described as such in the consent form.
* [Click here to insert details.] If study data is to be released, describe the person or agency to whom information will be furnished, the nature of the information to be furnished, the purpose of the disclosure and whether the participant’s name will be used. This is particularly important for certain vulnerable populations including employees (management access to study data), students (faculty access to study data).
* [Click here to insert details.] Describe any situations in which confidentiality cannot be guaranteed (such as reporting requirements for child abuse and neglect.

The following procedures will be used to protect the confidentiality of your information:

1. The researcher(s) will keep all study records locked in a secure location.
2. Any audio and videotapes will be destroyed after insert period records to be kept year(s).
3. All electronic files containing personal information will be password protected.
4. Information about you that will be shared with others will be unnamed to help protect your identity.
5. No one else besides the investigator will have access to the original data.
6. At the end of this study, the researchers may publish their findings. You will not be identified in any publications or presentations.

**RIGHTS**

Being a research participant in this study is voluntary. You may choose to withdraw from the study at any time without penalty. You may also refuse to participate at any time without penalty.

Thoughtfully consider your decision to participate in this research study. We will be happy to answer any question(s) you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the principal investigator, [Click here to insert PI’s name and phone number] or the faculty advisor, [Click here to insert faculty advisor’s name and phone number if applicable]. If you have any questions concerning your rights as a research subject, you may contact the Columbia College Chicago Institutional Review Board (IRB) staff at IRB@colum.edu.

**COST OR COMMITMENT**

* [Click here to insert details.] Describe any cash payment, gifts, raffle prizes, etc… to participants and the method by which compensation will be paid. Include conditions for partial payment or no payment for early termination. If compensation will be paid in stages, list amount for each stage and the total amount that could be earned for completion of the study.
* [Click here to insert details.] Describe any costs participants may incur (e.g. parking fees).
* [Click here to insert details.] Describe the exact nature of the time commitment.

**COMPENSATION FOR ILLNESS AND INJURY**

If you agree to participate in this study, your consent in this document does not waive any of your legal rights. However, in the event of harm arising from this study, neither Columbia College Chicago nor the researchers are able to give you money, insurance, coverage, free medical care or any other compensation injury that occurs as a result of the study. For this reason, please consider the stated risks of the study carefully.

**PARTICIPANT STATEMENT**

This study has been explained to me. I volunteer to take part in this research. I have had opportunity to ask questions. If I have questions later about the research or my rights as a research participant, I can ask one of the contacts listed above. I understand that I may withdraw from the study or refuse to participate at any time without penalty. I will receive a copy of this consent form.

All signature lines may not be needed for all studies – delete those that are not required for your study

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Participant/Parent/ Print Name: Date:

Guardian Signature:

Relationship (only if not participant): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Assent of Minor Signature: Print Name: Date:

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Principal Investigator’s Print Name: Date

Signature