**INFORMED CONSENT DOCUMENT TEMPLATE**

IC 701-B 01/21/2019

**THE UNIVERSITY of NORTH DAKOTA**

**INSTRUCTIONS FOR WRITING AN INFORMED CONSENT DOCUMENT**

**INSTRUCTIONS:**

* This consent document template is recommended for non-medical studies because it contains all required elements of consent.
* The highlighted text throughout this document offers suggestions and guidance. It should be deleted and replaced with information specific to your study and then un-highlighted. All other text on the document should remain.

**CONSENT DOCUMENT INSTRUCTIONS:**

* Consent documents should be written in the second person (e.g., “You are invited to participate”). Use of the first person (e.g., “I understand that…”) can be interpreted as suggestive and can constitute coercive influence over a subject.
* The consent form should be written at about an eighth grade reading level. Clearly define complicated terms and put technical jargon in lay terms.

**CONSENT DOCUMENT FORMAT:**

* To facilitate the IRB review process, the sample format below is recommended for consent forms.
* Prepare the entire document in 12 point type, with no blank pages or large blank spaces/paragraphs.
* ***Do not change the margins on the document.*** They are set to allow room for the IRB approval stamp.
* Multiple page consent documents should contain page numbers and a place for the subject to initial each page.

**CONCISE SUMMARY FOR ANY CONSENT FORM OVER 6 PAGES:**

If your consent is more than 6 pages, provide a brief explanation 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 presentation of information is to be short, and can summarize information explained later in greater detail. This summary should include:

* The purpose and expected duration
* Major requirements of the study
* The most important risks and/or benefits
* Other alternatives to participating, if appropriate
* Time commitment

**ASSISTANCE**

* If you have questions about or need assistance with writing an informed consent please call the Institutional Review Board office at 701 777-4279 or UND.irb@UND.edu.

**The University of North Dakota**

**Child Assent & Parent/Guardian Consent to Participate in Research**

**Project Title:**

**Principal Investigator:**

**Phone/Email Address:** *Use a UND number. If researcher is a student, do not list a phone number; only list UND email address.*

**Department:**

**Research Advisor:** *[If researcher is a student, medical resident, or post-doc, list the name of the faculty member serving as advisor over the study.]*

**Research Advisor**

**Phone/Email Address:**

**Potential Child/Teen Participants:** This form also serves as an assent form. That means that if you choose to take part in this research study, you would sign this form to confirm your choice. Your parent or guardian would also need to give their permission and sign this form for you to join the study.

**Parents/Guardians:** You have the option of having your child or teen join a research study. This is a parental permission form. It provides a summary of the information the research team will discuss with you. If you decide that your child can take part in this study, you would sign this form to confirm your decision. If you sign this form, you will receive a signed copy for your records.

The word **“you”** in this form refers to your child/teen.

**What should I know about this research?**

* Someone will explain this research to you.
* Taking part in this research is voluntary. Whether you take part is up to you.
* If you don’t take part, it won’t be held against you.
* You can take part now and later drop out, and it won’t be held against you
* If you don’t understand, ask questions.
* Ask all the questions you want before you decide.

**How long will I be in this research?**

We expect that your taking part in this research will last \_\_\_\_\_ (hours, days, weeks, months, years, or until a certain event.)

**Why is this research being done?**

The purpose of this research is to \_\_\_\_\_. (Explain in no more than a few sentences the main purposes of the research.)

**What happens to me if I agree to take part in this research?**

If you decide to take part in this research study, you will \_\_\_\_\_. (Describe the procedures/process in simple terms and in chronological order. Identify and explain any procedures that are experimental. Explain tasks, surveys, interviews or procedures; describe the assignment to control or experimental groups, length of time for participation, frequency of procedures, location etc. If the study involves surveys or questionnaires, include a statement that the subject is free to skip any questions that he/she would prefer not to answer. If the study involves audio, video, digital recordings or photographs, explain that here.)

**Could being in this research hurt me?**

The most important risks or discomforts that you may expect from taking part in this research include \_\_\_\_\_. (In simple language, explain the risks and discomforts that are most likely to occur in connection with the research. Risks may include psychology, emotional, physical, legal, privacy issues, etc. Depending on the type of study, some risks may be described as things that could the subject “uncomfortable” – such as fatigue or embarrassment. If there are no known risks, state that there are “no foreseeable risks” to participating.)

**Will being in this research benefit me?**

The most important benefits that you may expect from taking part in this research include \_\_\_\_\_. (In simple language, explain the reasonably expected benefits to subjects. If there are no benefits, state: It is not expected that you will personally benefit from this research.)

Possible benefits to others include \_\_\_\_\_. (In simple language, explain the reasonably expected benefits to others. Normally for minimal risk studies, benefits to others are future knowledge gained from the research.)

**How many people will participate in this research?**

Approximately [number] people will take part in this study at the University of North Dakota. (Add a sentence if study will be done at other sites and how many total subjects are expected to be enrolled.)

**What other choices do I have besides taking part in this research?**

Instead of being in this research, your choices may include \_\_\_\_\_. [If the research involves a group of subjects (such as students in a classroom or this project being done as extra credit), describe and explain the procedures that will be employed to provide alternative, yet equal activities/extra credit for those who do not wish to participate. Example: If you choose not to participate in this study, you may earn extra credit in your course in other ways. Please ask your instructor, who will provide you with comparable assignments that you may choose to complete (e.g. writing assignments, participation in other research experiments etc.). If there are no alternatives, this section can be omitted.]

**Will it cost me money to take part in this research?**

You (will/will not) have any costs for being in this research study. (Describe any costs to the subject. Be sure to include any travel/parking costs that the subject may be accountable for.)

**Will I be paid for taking part in this research?**

You (will/will not) be paid for being in this research study. [Describe the monetary compensation. If subjects must provide SSN and address to receive payment, please indicate. If compensation is pro-rated when a subject withdraws prior to completing the study, explain how it is pro-rated. If there is non-monetary compensation (e.g. extra credit, gift certificate, drawing) please describe.]

**Who is funding this research?**

The University of North Dakota and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study. [OR Name of agency/organization/company] is funding this research study. This means that [insert UND or other area] is receiving payments from [name] to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or an increase in salary from [name] for conducting this study.]

**What happens to information collected for this research?**

Your private information may be shared with individuals and organizations that conduct or watch over this research, including:

• The research sponsor (if applicable)

• People who work with the research sponsor (if applicable)

• Government agencies (if applicable: such as the Food and Drug Administration)

• The Institutional Review Board (IRB) that reviewed this research

• (List others with whom private information will be shared. If researcher is a student, medical resident, or post-doc, list the research advisor.)

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

(Choose one of these statements: 1) Data or specimens collected in this research might be de-identified and used for future research or distributed to another investigator for future research without your consent. OR 2) Data or specimens collected in this research will not be used or distributed for future research studies, even if identifiers are removed.)

(If the researcher is a mandatory reporter:You should know, however, that there are some circumstances in which we may have to show your information to other people. For example the law may require us to show your information to a court or to tell authorities if we believe you have abused a child, or you pose a danger to yourself or someone else.)

(If activities are to be audio, video, or digitally recorded, describe the subject's right to review/edit the recordings, who will have access, if they will be used for educational purpose, and when they will be erased.)

**Could being in this research hurt me? (**If study involves more than minimal risk, if not, delete this section.)

***[The following statement must be included in the consent form if the research involves more than minimal risk:]*** In the event that this research activity results in an injury, treatment will be available including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.) No funds have been set aside to compensate you in the event of injury. Also, the study staff cannot be responsible if you knowingly and willingly disregard the directions they give you. ***[Disclose any additional costs of the research procedures with estimated amounts.]***

 **What if I agree to be in the research and then change my mind?**

If you decide to leave the study early, we ask that you (Describe the procedures the subject may need to follow, such as calling the study coordinator, coming in for a close out visit. Describe any consequences of the subject’s withdrawal.)

(If appropriate add: You will be informed by the research investigator[s] of this study of any significant new findings that develop during the study which may influence your willingness to continue to participate in the study.)

(If appropriate add: Specify any circumstances of early withdrawal from the study without participant’s approval, such a deteriorating health or other conditions that might make continued participation harmful.)

**Who can answer my questions about this research?**

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at 701.777.4279 or UND.irb@UND.edu if:

* You have questions, concerns, or complaints that are not being answered by the research team.
* You are not getting answers from the research team.
* You cannot reach the research team.
* You want to talk to someone else about the research.
* You have questions about your rights as a research subject.
* You may also visit the UND IRB website for more information about being a research subject: <http://und.edu/research/resources/human-subjects/research-participants.html>

Assent of Child Participant:

Your signature documents your assent to take part in this study. You will receive a copy of this form.

Child’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Signature of Child Date

Consent of Parent/Guardian:

Your signature documents your consent for your child to take part in this study. You will receive a copy of this form.

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Name of Parent/Guardian Date

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Signature of Parent/Guardian Date

I have discussed the above points with the subject or, where appropriate, with the subject’s legally authorized representative.

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Signature of Person Who Obtained Consent Date