**Dinè College**

**Instructions for Informed Consent Form**

The purpose of this form is to provide basic information about your study, about your subjects’/participants’ (hereafter referred to as participants) role in the study, about your participants’ rights, and about confidentiality. It is designed to be read by adult participants of all backgrounds and should be written in simple, non-technical terms. Please address potential participants directly, with second-person (e.g., “you will be…”) language throughout.

Please replace the bracketed text after each question with your own text. In the final version and before printing, please ensure that you’ve used consistent fonts, formatting, and colors.

Coding Key

* **Red font:** Instructions pertaining to required and optional statements.
* **Blue non-italicized font:** Text that should be replaced with your information.
* **Green font:** Suggested language to be used if applicable.
* **Black font:** Required headings and required language.

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**Adult Informed Consent**

**ABOUT THIS STUDY**

**Title of Research Study:**[Title as it appears on IRB Application]

**This study is being conducted by:**[Name and contact information of primary researcher(s). If applicable, include advisor name and contact information and/or sponsor/funding agency]

**What is the purpose of the study?**[Describe the purpose of the study at a 6th – 8th grade reading level. This purpose should be consistent with the purpose outlined in the protocol. When appropriate, this statement should include not only the immediate purpose of the study, but also any larger, ultimate purpose.]

**ABOUT YOUR ROLE**

**Why are you being asked to take part in this research study?**

[Describe in simple terms why this person might qualify for the research study. What is it about the individual that makes them of interest to the research team – the inclusion criteria? Is there anything that would exclude them from participating – exclusion criteria (e.g., age restrictions, pregnancy, health restrictions, etc.). When appropriate, also include the approximate number of participants in the study.]

**What will you be asked to do? *or* What Information will be collected about you?**

[Describe the procedures chronologically using simple language, short sentences, and short paragraphs (less than 6 sentences). The use of subheadings may help to organize this section and increase readability for more complicated studies.]

**Where is the study going to take place, and how long will it take?**

[Describe where the study will take place and the amount of participant time the research will take.]

**ABOUT THE RISKS AND BENEFITS**

**What are the risks and discomforts?**

[Describe any known risks or discomforts that may result from participating in the research. List the most likely and/or most severe first. Common risks in social/behavioral research include loss of confidentiality and emotional, psychological distress and or social implications.]

* *It may be appropriate to include the following sentence:* “It is not possible to identify all potential risks in research procedures, but the researcher(s) have taken reasonable safeguards to minimize any known risks to the participant”
* *If embryo, fetus, or potential pregnancy is involved, add:* “or embryo or fetus if the participant is or may become pregnant.”
* *If applicable, add this statement:*“If new findings develop during the course of this research which may change your willingness to participate, we will tell you about these findings.”
* *For any research activity involving consumption of food or application of chemicals or other products to the skin (e.g., cosmetic research), include the following:* “If you are known to have a sensitivity to any food or food ingredient, or have had violent allergic reactions to drugs, chemicals, or food ingredients, you should not take part in this study.”

**What are the benefits to you?**

[If direct participant benefits can reasonably be anticipated as a result of participating in the study, then describe these benefits.]

*Conclude with the following standard clause:* “However, you may not get any benefit from being in this research study.”

*If direct participant benefits are not expected, then use the following standard clause:* “You are not expected to get any benefit from being in this research study.”

**What are the benefits to other people?**

[State the possible benefits to society in terms of advancement of knowledge, and/or ultimate possible benefits to persons in the prospective participant’s position.]

**ABOUT YOUR RIGHTS**

**Do you have to take part in the study?**

[Include text you feel appropriate.] *You must include the following voluntary participation clause:* “Your participation in this research is your choice. If you decide to participate in the study, you may change your mind and stop participating at any time without penalty or loss of benefits to which you are already entitled.”

**What will it cost me to participate?**

[Include only if applicable - A clear statement must be made about any costs for participation in the study AND, if applicable, who bears the responsibility for any treatment or medical costs that arise as a result of participation.]

**What are the alternatives to being in this research study?**

[In reasonable detail, describe any alternatives participants may have available, or state, “Instead of being in this research study, you can choose not to participate.”]

**ABOUT YOUR PRIVACY**

**Who will see the information that you give?**

[Describe whether or not records will be kept confidential. If records will not be confidential, describe how records will be presented, and if they will be archived for the public.]

*Possible language includes:* “We will keep private all research records that identify you. Your information will be combined with information from other people taking part in the study. When we write about the study, we will write about the combined information that we have gathered. We may publish the results of the study; however, we will keep your name and other identifying information private.”

* *IF THE STUDY IS ANONYMOUS, include the following statement:* “This study is anonymous. That means that no one, not even members of the research team, will know that the information you give comes from you.”
* *IF THE STUDY IS NOT ANONYMOUS, include a statement such as the following. Also, be sure to describe any coding that will be used, and describe the manner in which the linkage between the participant’s identity and their data will be disconnected:*  “We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. For example, your name will be kept separate from your research records and these two things will be stored in different places under lock and key.”
* *IF APPLICABLE, include the following statement:* “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”
* *IF APPLICABLE, include the following statement:* “…or to tell authorities if we believe you have abused a child, or you pose a danger to yourself or someone else.”

FOR CLINICAL TRIALS:

* *If your project involves the investigation of a drug (Phase I-IV), non-approved use of a drug or substance, or investigation of a medical device or substance that is subject to FDA regulations, you must add the following statement:*  “Representatives of the United States Department of Health and Human Services or the United States Food and Drug Administration may inspect your [insert “medical records” or “research records” as appropriate] to assess the results of this [insert “drug treatment” “medical device therapy” or “research” as appropriate.]”

**Is it possible that I might be asked to leave the study before it has ended?
[Include this section only if applicable.]**

[Describe in lay terms any reason why a participant may be removed from the study. For example, you might state “If you fail to show up to all sessions you may be removed from the study.”]

**Will I receive any compensation for taking part in this study?**
[**Include this section only if applicable.]**

[Describe any compensation the participant will receive. Examples include payment for the time commitment, extra or course credit, gift cards, and small gifts. If a raffle will be held for a prize, include the likelihood/probability of winning that prize.]

[NOTE: The nature and amount of compensation must not constitute undue inducement to participate, i.e., the compensation alone should not serve as sufficient inducement for the participant to volunteer. If participants are students being offered extra credit for participation, the amount/nature of the extra credit must not be unduly influential, and an alternative method, equal in time and effort, to earn extra credit must be offered.]

**What happens if I am injured because of this research?**
**[Include this section only if more than minimal risk, or otherwise applicable]**

“If you receive an injury in the course of taking part in the research, you should contact at the following phone number . Treatment for the injury will be available including first aid, emergency treatment and follow-up care as needed. Payment for this treatment must be provided by you and your third party payer (such as health insurance or Medicare). This does not mean that you are releasing or waiving any legal right you might have against the researcher or DC as a result of your participation in this research.”

**What if you have questions?**

“Before you decide whether to accept this invitation to take part in the research study, please ask any questions that might come to mind now. Later, if you have any questions about the study, you can contact the researcher, at .”

**What are your rights as a research participant?**

“You have rights as a participant in research. If you have questions about your rights or complaints about this research [*may add*, “or to report a research-related injury*” if applicable*], you may talk to the researcher or contact the DC Office for Academic Affairs:

* Telephone: TBI
* Email: TBI
* Mail: TBI



**Adult Informed Consent Signature Form**

Please initial beside each of the following with which you agree. If you have questions or do not agree with one of the statements, please ask the researcher. You will be given a copy of this consent form to keep.

1. I have read the informed consent form and had my questions answered.
2. I understand what I will be asked to do in order to participate in the study.
3. I understand that all of the information I provide will be confidential.
4. I may leave the study at any time without penalty.
5. I understand the risks and benefits of this study.
6. I agree to participate in the study.

Your signature Date

Your printed name

Signature of researcher explaining study Date

Printed name of researcher explaining study