**Informed Consent**

## Title of Study

This study is being conducted by (*Name, status, and contact information of primary researcher(s). If study is being conducted by a graduate student, the PI (advisor) should also be listed here.)*

### Key Information about this study

This consent form is designed to inform you about the study in which you are being asked to participate. Following is a brief summary about the study; however, you can find more detailed information later on in the form.

- *List key pieces of information designed to assist the participant in deciding whether or not they would like to participate in the study.*
- *This information should include:*
    - *Any relevant inclusion or exclusion criteria,*
    - *Risks/Benefits,*
    - *Time commitment,*
    - *Compensation,*
    - *Privacy concerns.*
- *This section is designed to be a concise and focused presentation of key information that is mostly likely to assist in understanding the reasons why one might or might not want to participate in research.*

You are being asked to participate in this study because (*Describe, at a 6$^{th}$-8$^{th}$ grade reading level, the purpose of the study.)*

As a participant in this study, you will (*Describe in simple and concise terms what participants will be asked to do and/or what information will be collected about them during the course of the study. Avoid technical language and acronyms whenever possible. This section can be broken out into several short paragraphs, presented with bullet points, and/or contain diagrams or figures.*)

This study will take place (*indicate where or how the study will occur; for example, the study will require participant to complete an online survey, or participate in an interview held at his/her place of business, etc.*) and should take you about (*total time commitment*) to complete.

As a participant in this study, (*Describe any anticipated risks that may result from the research (physical, psychological/emotional, financial, privacy/confidentiality related, stigmatizing or reputational risk, or legal (criminal or civil) liability. The most likely or the most critical should be listed first, followed by risks which are less likely or less critical.*

*It may be appropriate to include a statement that, "It is not possible to identify all potential risks in research; however, reasonable safeguards have been taken to minimize known risks. If new findings develop during the course of the research which may change your willingness to participate, we will tell you about these findings."*

*If the research involves consumption of food, or the application of chemicals or other products to the skin, please include the following, "If you are known to have a sensitivity to any food or food ingredient, or have had a violent allergic reaction to drugs, chemicals, or food ingredients you should not take part in this study.)*

Individual benefits of this study will include **(***If the participant will directly benefit from the research, include a description of the potential benefits here. For example, You will receive access to XYZ by participating in this research. Compensation--monetary or other compensation--should NOT be described in this section.)* Additionally, societal benefits (*Describe the expected societal benefits, or the expected scientific advances.)*

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. *(Provide explanation of how to discontinue participation. For example, you may discontinue your participation by not submitting the survey, or by notifying the researcher you no longer wish to participate. Reminder "at any time" is not always possible, so specifically note if there is a final point for the participant to withdraw from the study)*

You will not incur any costs for participating in this study. (**If the participant will be responsible for any costs associated with the research, describe these in this section. This section can be deleted if it is not applicable.)*

*If there are alternative treatments, ways to earn extra/course credit, etc. these should be described here. You may also state, "Instead of being in this research, you may choose not to participate."*

Your (*identifiable information or biospecimens)* will be collected during the course of the research. (*Describe who will have access to this information/biospecimens, how they will be protected, how research results will be presented, and if they will be available to anyone outside the research team at any time.)*

*Research collecting identifiable private information and/or identifiable biospecimens **must** state that:*

- *Collected samples/data may be given to another investigator for future research without additional consent, OR*

- *Collected samples/data will not be used or distributed for future research, even if de-identified.*

*When applicable, describe whether clinically relevant research results will be given to the participant, and under what conditions*

*If biospecimens (even after they are de-identified) will be used for commercial profit, this must be disclosed to participants, including whether or not that profit will be shared.*

*In addition, describe whether the research will or might include whole genome or exome sequencing.*

In the event of (*When applicable, describe any reason for which a participant may be removed from the study)* you will be removed from this study.

(*If applicable*) If you are injured during the course of this study, you should contact the *(principal investigator at your 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 Medicaid). This does not mean that you are releasing or waiving any legal right you might have against the researcher or Minot State University as a result of your participation in this research.

Before you decide whether you'd like to participate in this study, please ask any questions that come to mind now. Later, if you have questions about the study, you can contact *(name of principal investigator, phone number, email address* or *co-investigator, phone number, email address.)*

You have rights as a research participant. All research with human participants is reviewed by a committee called the Institutional Review Board (IRB*)* which works to protect your rights and welfare. If you have questions about your rights, an unresolved question, a concern or complaint about this research you may contact the IRB chair at irbchair@minotstateu.edu.

**Documentation of Informed Consent:**

You are freely making a decision whether to be in this research study. Signing this form means that

1. you have read and understood this consent form
2. you have had your questions answered, and
3. you have decided to be in the study.

You will be given a copy of this consent form to keep.

| | |
|---|---|
| Your signature | Date |
| Your printed name | Date |
| Signature of researcher explaining study | Date |
| Printed name of researcher explaining study | |

*DELETE this page if not applicable:*

*If study 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, following statement is required, "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.)*

*IF APPLICABLE, add the statement: A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by US 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 website at any time.*

[*The Certificate of Confidentiality section below is required for all NIH funded research, and any other research with a Certificate of Confidentiality. Delete if not applicable.]*

**Certificate of Confidentiality [include if applicable]**

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2. you have consented to the disclosure, including for your medical treatment; or
3. the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.