**Informed Consent**

**Research Study Title**

**INSTRUCTIONS: Delete anything in RED before submitting it to the IRB office with your application.**

**The language should be modified as appropriate for your study. Provide relevant information in the sections below, replace directions/guidance with information specific to your study. Some sections may not apply to your research (i.e. biospecimen collection or A/V recording), delete sections that do not apply to your research. Make sure all aspects of the consent are directly addressed to the participant (use “you” not “participants”).**

I am/we are asking you to participate in a research study titled “TITLE”. I/We will describe this study to you and answer any of your questions. This study is being led by Name of PI, Department at Dordt University. (If PI is a student)The faculty advisor for this study isName, Department at Dordt University.

**What the study is about**

The purpose of this research is to….

Provide a clear, concise explanation in lay language of the purposes of the research, including prominent use of the term "research." (Note: the IRB can allow modifications to this element if the study requires deception. In such cases, a debriefing statement is expected to be used to inform participants at an appropriate time after their involvement in the study.)

**What we will ask you to do**

I/We will ask you to…

Explain in simple, non-scientific language what will happen to the participant or what s/he will be asked to do in the study. Describe the participant’s time commitment for each component. All procedures listed in the IRB application and funding proposal should be described, and any experimental procedures (interventions, manipulations, treatments) specifically noted.

**Risks and discomforts**

**If there are no known risks: I/We do not anticipate any risks from participating in this research beyond that of everyday life.**

**If there are possible risks, in simple, non-scientific language, describe any reasonably foreseeable risks or discomforts. Risks may include**

**Emotional risks (e.g., feelings of sadness or anxiety)**

**Legal risks (e.g., possibility of discovering activities that may require reporting to authorities, possibility of being arrested)**

**Physical risks (e.g., nausea, muscle aches, rashes, infection, discomfort)**

**Social or economic risks (e.g., loss of confidentiality; effect on financial standing, employability, or insurability)**

**For any risks listed beyond that of every day life, specify who to contact if these risks occur. For Dordt undergraduate participants, you could say, “**Although this study involves minimal risk, participants may experience slight discomfort when reflecting on personal opinions or experiences during the surveys. However, the questions are not intended to probe sensitive topics, and participants can skip any question they do not wish to answer. If you experience more than slight discomfort, you may contact Student Health and Counseling (counseling@dordt.edu) about speaking to a counselor.”

**Benefits**

**Student research and any research without direct participant benefits should open with the statement: There are no direct participant benefits.**

**If you believe there are direct participant benefits, please describe them here and in your proposal.**

**Describe probable benefits of participation. Be sure to distinguish between a direct benefit (e.g., therapeutic or intervention research) and possible, specific, indirect benefits.**

**Note: Compensation, financial incentives, l**earning about how experiments are conducted, receiving a gift, or earning extra credit for being a research participant **are not “benefits” and should not be listed here.**

**Compensation for participation**

If participants will not receive any compensation: There will be no compensation for participating.

If you have arranged with some professors for students to receive extra credit: You may receive extra credit at the discretion of your instructor for participating in this study. If this is not something that your instructor provides, you will not receive any compensation for participation.

If you are providing some other form of compensation describe the compensation fully and how it is earned here, including what happens if they withdraw early from the study.

**Audio/Video recording**

**If audio and/or video recording devices will be used, explain why these are needed and what will be done with them upon completion of the research (kept indefinitely, archived after transcription, destroyed after X years). Explain how privacy of recordings will be maintained including in storage and in transcription.**

**If using a signed consent AND if the recording is optional for participation, provide a separate signature line for the participant to be audio/video recorded: Please sign below if you are willing to have this interview recorded (specify audio or video). You may still participate in this study if you are not willing to have the interview recorded.**

* **I do not want to have this interview recorded.**
* **I am willing to have this interview recorded:**

**Signed:**

**Date:**

**If you will take photographs or make audio, video, or other recordings that you want to use for activities beyond research analysis (publications, presentations, other promotional purposes), include a section that:**

**Informs the participant that you are making a [type(s) of media used] recording in which the person’s name, likeness, image, and/or voice will be included;**

**Asks the participant to grant you the right** to make, use and publish recordings in whole or in part in media forms now known (such as film, slides, and digital audio) or developed in the future. This includes the right to edit or duplicate any images/recordings;

**Explains the limitations on reproduction, distribution, performance, or display of images/recordings;**

**Explains that the participant does not have rights to inspect or approve the finished product or printed/published matter that uses the images/recordings or versions of the images/recordings; and**

**Explains that the participant will not receive any financial compensation for commercial and/or non-commercial (as appropriate) uses of the images/recordings.**

**The same signature line above may be used for this performance release information.**

**Information about use of your biospecimens**

**If you are collecting biospecimens: Specimens collected from you for this study and/or information derived from your specimens *will/may/will not* be used to generate commercial profit. You will/will not share in any commercial value or other compensation from products developed using these specimens.**

**If clinically-relevant research results may be generated: You *will/will not* receive any clinically relevant results discovered about you and/or the general subject population.**

**If your study may involve whole genome sequencing: This research *may/will* include whole genome sequencing.**

**Privacy/Confidentiality/Data security**

Explain briefly, and in lay terms,how you will protect the participant’s privacy and/or confidentiality. Address:

If data is collected anonymously or not

If, how, when, by whom identified data will be de-identified

Whether de-identification will occur with identifiers

Where will material be kept, how is the space secured, who will have access, when will it be destroyed for

Physical data

Computer files of data

Signed consent forms

How identified and de-identified data will be kept separate securely

If using an online survey, include the following statement: Please note that the survey(s) [is/are] being collected online on [name of survey company: e.g. Microsoft Forms, Survey Monkey, Google Forms], a company not affiliated with Dordt and with its own privacy and security policies that you can find at its website. We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.

**If research involves e-mail communication, include the following statement:** Please note that email communication is neither private nor secure. Though [I am/we are] taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

**Sharing de-identified data collected in this research**

Certain sponsors now require researchers to make available their de-identified data to the research community, as do a growing number of journals. If you choose not to include the following language and later wish to share de-identified data, you may not be able to do so without re-contacting participants to obtain consent.

If you may share data without identifiers: De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

**Future use of identifiable data or specimens collected in this research**

**If you are collecting identifiable specimens or not deidentifying data, include one of the following:**

**Your information will not be used or distributed for future research studies.**

**OR**

**Identifiers might be removed and the de-identified information used for future research without additional consent.**

**OR**

**Identifiable information might be used for future research after obtaining your consent.**

**Taking part is voluntary**

Your participation is voluntary, you may refuse to participate before the study begins, discontinue at any time, or skip any questions/procedures that may make you feel uncomfortable, with no penalty to you, and no effect on the compensation earned before withdrawing, or your academic standing, record, or relationship with Dordt University or other organization or service that may be involved with the research.

If completing all research materials (e.g., answering all survey or interview questions; meeting a minimal requirement of entries in a weekly/monthly log) is required for participation: You must answer all survey or interview questions/ meeting a minimal requirement of entries in a weekly/monthly log to participate in this research. If you are uncomfortable with these conditions, you can choose not to participate.

**Follow up studies**

**If** you will or might approach participants for a follow up study: I/We may contact you again to request your participation in a follow up study. As always, your participation will be voluntary and we will ask for your explicit consent to participate in any of follow-up studies.

Explicit consent may not be necessary. Here is suggested language if you choose to ask for specific consent:

May I/we contact you again to request your participation in a follow up study? Yes/No

**If you have questions**

The main researcher conducting this study is [principal investigator’s name], a [professor, graduate/undergraduate student, etc.] at Dordt University. [If you are collecting data directly] Please ask any questions you have now. If you have questions later, you may contact [principal investigator’s name] at [email address] or at [phone number], [If student researcher] or my faculty advisor for this study, [name], at [email] or at [phone number]. If you have any questions or concerns regarding your rights as a participant in this study, please contact the IRB at irb@dordt.edu.

Indicate how participants will be given a copy of this form for their records. Examples:

Please ask the researcher now for a copy of this form, if you would like one for your records.

**OR**

This document was attached to the recruiting email you received from the researcher, if you would like a copy for your records.

**Statement of consent**

For online or remote studies include one (or similar but appropriate to your design) of the following

Please click “I consent to participate in this study” below as an indication of your consent to participate in the study.

**OR**

Submission of your responses is an indication of your consent to participate in the study.

**For signed, written consent. (**Signed consentcannot be used if you tell participants that your study is anonymous.)

I have read the above information, and have received answers to any questions I asked. I consent to participate in the study.

Your Signature Date

Your Name (printed)

Signature of person obtaining consent Date

Printed name of person obtaining consent

This consent form will be kept by the researcher (where) for five years beyond the end of the study.