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**Institutional Review Board for the Protection of Human Subjects**

**Form A—Statement of Informed Consent For Adult Participants**

***Instructions to Investigator(s): Adapt this template to your project deleting all blue instructions and text. If a section with blue instructions is not applicable to your project, delete.***

**Title of Study:**

**Study Investigator(s):**

**Contact information:**

**Faculty Sponsor** *(include if applicable)*

**Contact information:**

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| --- |
| **KEY INFORMATION:**   * You are being asked to be in a research study of [insert general statement about study]. As with all research studies, participation is voluntary.  The purpose of this study is [explain research question and purpose in clear, concise language to help participant fully understand research].  * A maximum of [number] people will take part in this study. The results will be used for [describe what the results will be used for, including a master’s thesis or other course requirement, if applicable]. * If you agree to take part in this study, you will be involved in this study for [insert length of time (hours, days, week(s), month(s), or year(s)), number of sessions, duration of participant involvement, and estimated amount of time (in hours or minutes) spent participating. Include whether you intend to collect follow-up information and when this will be done. For example: “Follow-up information will be collected six months after last study visit.” * Briefly describe what will happen to the participant if they decide to participate, including the activities they will be asked to engage in, how long they will take, where the research will take place, and how often they will be asked to perform the research tasks. Note that you will provide more detail in the body of the consent form. * Inform the participant of the major risks or discomforts (e.g. physical, emotional, social) as a result of study procedures. Inform the participant of any inconveniences (e.g. the amount of time required to complete procedures, abstention from food, length of time participants may be required to sit or stand) as a result of study procedures. If there are no known risks, then use the following suggested statement in this section: “We believe there are no known risks associated with this research.” * 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, health benefits to others). DO NOT include payments for participation or other incentives and gifts as a benefit of participation. If participants are not expected to directly benefit, then use the following suggested statement in this section: “You may not directly benefit from this research; however, we hope that your participation in the study may… (Describe societal benefits).” If no benefits, state that here]. * [Describe alternative procedures or course of treatment, if any.] |

**INTRODUCTION**

You are being asked to be in a research study of [insert general statement about study]. This study is being conducted at [study location]. This study is being conducted by: [Name of PI] in the [academic department] at Whitworth University.

You were selected as a possible participant because [explain how subject was identified].

Please read this consent form and ask any questions you have before agreeing to be in the study.

**PROCEDURES:**

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

[Describe *in detail* what will happen to the subject if they decide to participate. Include a step-by-step description of the activities participants will be asked to engage in, how long they will take, where the research will take place, and how often they will be asked to perform the research tasks. If the procedures are simple and/or only happen one time, this section may be quite short.

The subject needs to know what will happen to them at each study visit. All study procedures need to be described, but do not include procedures and treatments that are established practice and not part of the study. All procedures should be described in the simplest wording possible. If terminology is used, a description should be included. Bullet points, charts or tables are encouraged to increase readability of complicated procedures.

List all study visits separately, in chronological order and note what procedures are to be expected. If multiple visits or sessions will be held, provide a timeline with a detailed description of each visit or session.

If applicable, include a distinct section that describes all the possible subject groups and study interventions. Tell the subjects how they will be assigned to an intervention group. If it is random assignment, it can be described with wording such as “by chance,” “flipping a coin,” “pulling numbers from a hat,” etc. If applicable, state the ratio (or odds) of possible intervention assignments: “You have a 1 in 2 chance of receiving” or “The odds that you will be in group A or group B are 1:1”.

If audio- or videotaping will be used, the subject must be informed of taping and given the choice to agree to the recording at end of form. Subjects must be informed of whether they can opt out of the recording and still participate in the study. If taping is required for participation, this must be clearly stated, both here and in the signature at the end of the study.]

**COMPENSATION/INCENTIVES:**

You will/will not receive compensation. [Describe compensation. Include payment or other compensation information here, if applicable, including when disbursement will occur and conditions of payment. For example, if monetary benefits will be pro-rated due to early withdrawal, explain that.]

*To participate in this study you will need to pay for:*

**CONFIDENTIALITY:**

The records of this study will be kept private and your confidentiality will be protected. In any sort of report the researcher(s) might publish, no identifying information will be included. [If research methods include a focus group, add: Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others. If applicable, add: The only exception to maintaining confidentiality would be if you indicate that there is immediate and serious danger to the health or physical safety of yourself or others. In that case, a professional may have to be contacted. We would always talk to you about this first.]

Research records will be stored securely and only the researcher(s) will have access to the records. All data will be kept [describe where records will be kept, such as a locked filing cabinet in the researcher’s office or on a password-protected laptop] by the investigator(s). All study records, including approved IRB documents, tapes, transcripts, and consent forms, will be destroyed by shredding and/or deleting after [specify number of 3 or more] years. If audio-recordings are made, they will be erased as soon as they are transcribed. [If any recordings will be made, explain who will have access, if they will be used for educational purposes, and when they will be erased. If this is not relevant to your study, delete this last section]

[If you wish to use identifying information in a publication or presentation, including photographs, audio or video recordings, include the following, as appropriate:[

I/We will protect the confidentiality of your research records by [explain]. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**. [OR]** [Describe limitations to confidentiality, if any.]

It is possible that other people may need to see the information we collect about you. These people may include (Example: those who work for Whitworth University, a co-investigator at another institution, a government office that is responsible for making sure the research is done safely and properly).

If you are a mandatory abuse reporter and it seems likely that you will encounter reportable events as part of the study, insert the following otherwise delete it] “If you tell us something that make us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.”

I/We will/will not keep your research data to use for [future research or other purpose]. Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project. **[OR]** Your name and other information that can directly identify you will be deleted from the research data collected as part of the project.

**VOLUNTARY NATURE OF THE STUDY:**

Participation in this study is voluntary and requires your informed consent. Your decision whether or not to participate will not affect your current or future relations with Whitworth University or with [name any other cooperating institutions, such as a school or agency] . If you decide to participate, you are free to skip any question that is asked. You may also withdraw from this study at any time without penalty.

**CONTACTS AND QUESTIONS:**

The researchers(s) conducting this study: [name of researcher(s)]. If you have questions, **you are encouraged** to contact the researcher(s) at [location, phone number, e-mail address. If researcher is a student, including advisor’s name, title, telephone number and e-mail address as well.]

If you would like to talk to someone other than the researchers, please contact Whitworth University’s IRB compliance officer at (509) 777-3701.

**STATEMENT OF CONSENT:**

I am 18 years of age or older. I have read and understood the above information. I consent to participate in the study.

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Retain if applicable:*

*I agree to be audiotaped \_\_\_\_ Yes \_\_\_\_No If no, I understand that the researcher will [explain alternative to audio-taping, if any. If no alternative, state this clearly].*

*I agree to be videotaped \_\_\_\_Yes \_\_\_\_No If I do not wish to be videotaped, I will inform the researcher, who will instead [explain alternative to videotaping, if any. If no alternative, state this clearly].*

Signature of Investigator(s):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Please keep the second copy of this informed consent for your records.***

**ADDITIONAL CONSENT**

**INFORMATION THAT MAY BE ADDED AS APPLICABLE:**

*If your project could result in the subject being emotionally distressed add in the risk section and at the end. If the subjects are not Whitworth students substitute appropriate counseling information that would be accessible to the subjects.*

If the participation in this research study results in emotional distress

Please contact the Whitworth Counseling Center at 509.777.3701. For life threatening mental health emergencies call 911 and contact campus security at 509.777.4444.

*If your project could result in unexpected injury, add in the risk section:*

In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will however, be responsible for any charges for the emergency care. There is no commitment to provide any compensation for research-related injury. However, you have not released this institution from liability due to negligence.