## BRADLEY UNIVERSITY

**Information and Consent Form**

**Directions:** Include all bolded Headers in the consent form. The language contained in shaded boxes under the headers provides suggested guidance to be used as it applies to the proposed study. Use only language that is relevant to the current study. **OMIT** these directions on the consent form, and delete the material in the shaded boxes.

Study Title:

**Invitation to be part of a research study:**

You are invited to participate in a research study. In order to participate you must **[Inclusion Criteria]**. Taking part in this research project is voluntary.

**Key information regarding this study:**

For complex studies, this section (Key information regarding study) is required. However, for simpler studies (one that only require a page). Delete this section if not needed.

Informed consent must begin with a **concise and focused** presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. The 4 Key Elements are:

1. The purposes of the research, expected duration of the prospective subject’s participation, and procedures to be followed in the research
2. The reasonably foreseeable risks or discomforts to the prospective subject
3. The benefits to the prospective subject or others that may reasonably be expected from the research
4. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject

The purpose of this study is to **[briefly describe study]**. If you chose to participate you will be asked to **[do what, when, where, how]**. This will take approximately **[period of time, e.g., 10 minutes]**. Risks or discomforts from this research include **[briefly describe}**. The study will **[description of direct benefits to subjects or no benefits]**. Taking part in this research project is voluntary. You don’t have to participate and can stop at any time.

Please take the time to read this entire form and ask questions before deciding to participate in this research project.

**What is purpose of the Study?**

The purpose of the study is to **[describe the study purpose]**.

**What will happen if you take part in this study?**

If you agree to take part in this study, you will be asked to **[provide a detailed description of what the subject will be asked to do in chronological order (what, when, where, how)]**. We expect this to take about **[duration, number of interactions].**

If video or audio recordings are used, specifically state them, and how the recording will be treated, example: after the recording is transcribed, the recording will be permanently destroyed.

If using surveys or questionnaire or interviews, share with the participants the nature of the questions they will be asked.

If collecting demographic information, share the nature of that information and how it will be treated. Example: We will be asking for some general information about yourself such as [gender, race, ethnicity, etc. as appropriate to your study]. This information will be grouped to describe the sample and will not be specifically shared in relationship to your responses in this study.

If demographics are used as variables of interest, specifically state this. Example: You will be asked to share your sexual orientation in this survey as part of the research. However, your responses will not be linked to your identity when the data is shared.

**What are the risks of participating in the study?**

Some possible risks you might experience from this study are **[describe the specific risks and how these risks will be minimized. Risk can be physical, psychological, social or economic. Risks can also be a breach in confidentiality]**. **[OR]** We do not believe that there are any risk associated with this study.

**What are the benefits of participating in the study?**

Benefits you might receive from this study include **[describe benefits] [OR]** You probably will not benefit from this study.

**Are there any incentives for participating in the study?**

At the conclusion of the study you will receive **[Explain the amount or explain how they will receive whatever incentive. [OR]** There are not incentives offered for participating.

Include any payments that they will receive. Include when they will receive them.

If you are giving extra credit for a class, state the point value and when in the study it will be received. Also, state that alternate, non-research extra credit opportunities are available.

**What other options are there if you don’t participate in this study?**

This section is for studies that could treat or improve a condition or disease. Describe alternative treatments. **Delete this section if not appropriate to your study.**

**Possible text:**

Alternate treatments might be available. Discuss your options with your health care provider.

**How will your information be protected?**

We plan to publish the results of this study. To protect your privacy, we will not **[or will]** include any information that can directly identify you.

For example: Your name and any other information that can be used to identify you will be stored separately from the data collected for this research study. Your information will be stored in a locked office and computers used will be password protected.

**Also, describe any limitations to confidentiality if any.**

We will protect the confidentiality of your research record **[explain].**

If you wish to use identifying information in a publication or presentation—photos, audio recordings, video recordings, mention how these will be used. For example:

We will ask for separate written permission to use your name [or photo, or recording] in the research publication **[presentation]**.

**[OR]** We are collecting the data anonymously. There is no link between your name or other information that can directly identify you and the research record.

Other people may need to see this information. They include **[provide list]**

If you plan to register your project on ClinicalTrials.gov include the following: “A description of this study will be posted on http://ClinicalTrials.gov, and summary results of this study may be posted on this website at the conclusion of the research. No information that can identify you will be posted.”

**After the study, what will happen to the data collected?**

There are several options as to what will happen with the data once you study has ended. Please select the appropriate opinions that is appropriate to your study. Different disciplines have different requirements.

The information will be destroyed **[enter length of time]** after completion of the study.

**[OR]**

We will keep your research data to use for **[future research or other purpose**]. Your name and other information that can directly identify you will be deleted from the information collected as part of the project.

**[AND/OR]**

We may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you. [If data must or will be deposited in a public or other repository, briefly describe.]

**What are the costs?**

Potential sample text for repository:

Information collected as part of this study will be posted to the **[insert name of repository]** for future use by other researchers. This information will not contain any information that can directly identify you.

Clearly explain costs for participation as they apply to your study; describe any payment. Examples are:

There are no costs for participation in this study.

The \_\_\_\_\_\_\_\_\_ will be supplied by \_\_\_\_\_\_\_\_\_\_ free of charge. Any additional tests done solely for research purposes will be paid for by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Taking part in this study may lead to added costs for you or your insurance company. Please ask about any expected added costs or potential insurance problems.

In the case of injury or illness resulting from this study, emergency medical treatment is available and may be called at your (the participant’s) expense. No funds have been set aside to compensate you in the event of injury.

**Your participation in the study is voluntary**

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. You do not need to answer any question you do not want to answer. **[if appropriate]** If you withdraw before the study is completed **[provide details on disposition of data]**.**[if appropriate describe how participation in the study can be terminated by the PI] [If there are consequences for withdrawing before the study ends, describe them here].**

**Who should I call with questions or problems study?**

If you have any questions about this study, please contact the researcher in charge of this study: **[PI name, phone, email]**

**If the PI is a student, include the faculty advisor’s (or Co-PI’s) contact information also.**

**Who should I contact with questions about my rights as a research participant?**

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

Committee on the Use of Human Subjects in Research (CUHSR)

Bradley University

1501 W Bradley Avenue

Peoria, IL 61625

(309) 677-3877

**Where can I get more information?**

Additional information can be obtained from:

**[provide list including how to obtain the information]**

# Your informed consent

You are voluntarily making a decision to participate in this study. Your signature means

that you have read and understood the information presented and have decided to participate. Your signature also means that the information on this consent form has been fully explained to you and all your questions have been answered to your satisfaction. If you think of any additional questions during the study, you should contact the researcher(s).

I agree to participate in this study Date

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Signature of Participant **[if appropriate, or legally authorized representative]**

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Printed Name

**Or if using a waiver of documentation of informed consent [a waiver must be requested and approved by CHUSR] you can use the following:**

**Your informed consent**

By submitting the survey **[or** clicking the button **if online]** you are voluntarily making a decision to participate in this study. Your submission means that you have read and understood the information presented and have decided to participate. Your submission also means that the information on this consent form has been fully explained to you and all your questions have been answered to your satisfaction. If you think of any additional questions during the study, you should contact the researcher(s).

**The participant should be given a copy of the informed consent or offered a way of obtaining one.**

**Be aware that depending on the complexity, the risk or the subject population, there may be other required elements on the consent form.**