**Wartburg College IRB**

Protocol for Research with Human Subjects

 (revised 1/2019)

* Refer to instructions, sample forms, and templates on the Wartburg College IRB website: <https://info.wartburg.edu/Academics/Undergraduate-Research/Human-Subjects>.
* Complete all questions.
* Send a single electronic Microsoft Word file (form and any materials) to irb@wartburg.edu.
* Student principal investigators: Your completed form and materials must be submitted by the faculty/staff research advisor

**Name(s) of Principal Investigator(s):**

Click here to enter text.

**Faculty/Staff Research Advisor’s Name (if applicable):**

Click here to enter text.

**Title of Project:**

Click here to enter text.

**Type of Review Requested**

[ ]  Full [ ]  Expedited

**Project Type (Check one.)**

[ ]  Faculty research

[ ]  Student research (under faculty direction)

[ ]  Student class project (under faculty direction) List course number and class name Click here to enter text.

[ ] Other (please specify)

Click here to enter text.

**Principal investigator's e-mail address, college mailing address, and telephone number:**

Click here to enter text.

**Expected duration of the study (you must request a renewal if the study extends more than 1 year):**

Click here to enter text.

**Will the results of the study have the potential for dissemination (e.g. conference presentation, publication, RICE day presentation)?**

[ ]  Yes [ ]  No

**Funding source (if any):**

Click here to enter text.

*By signing below, I certify that I have carefully read/reviewed all information below. If this is a re-submission, any and all comments the committee requested have been respectfully addressed.*

**Electronically sign your full name and provide the date in the box below**.

**Signature(s) of Principal Investigator(s):**

Click here to enter text.

**Faculty Research Advisor’s signature (if PI is a student):**

Click here to enter text.

**PART A: PROJECT OVERVIEW**

Provide a brief (one to two sentence) statement regarding the purpose of the proposed research project.

Click here to enter text.

Provide a brief (200 words or fewer) overview of the study’s method/procedure.

Click here to enter text.

Provide a brief review of the background literature (including references) on which your study is based. Include only the most important references relevant to your study. Include in-text citations and your list of references. If your study includes demographic variables, or other details that may lead to identification of participants, include justification for including these variables. ***Limit this section to 500 words or fewer*** (including references). **Do not attach additional pages.**

Include full references in this section as well.

**PART B. METHODS/PROCEDURES**

**MEASURES**

**Check all that apply to your study. Include surveys/questionnaires/interview questions (including measures of demographic variables) at the end of the document for review. If you are using previously published measures/materials, include the reference to each component at the top of the page of the measure/materials.**

[ ]  bodily fluids [ ]  private data (e.g., GPAs)

[ ]  exercise [ ]  interview/focus group

[ ]  questionnaire/survey [ ]  publicly available data (e.g., personal websites)

[ ]  dietary supplements [ ]  internet/email data collection (e.g., survey monkey)

[ ]  observation [ ]  video/audio recording

[ ]  test (e.g., recall, reaction time) [ ]  physiological data (e.g., heart rate)

[ ]  other (specify below)

Click here to enter text.

**PROCEDURE**

**Provide a description of how the study will be conducted. The description should be presented in chronological order according to what participants will experience from the time they learn about and register for the study to debriefing. Include a copy of the informed consent document, copies of any stimulus materials (e.g., word lists, photos), and other materials (e.g., instructions, scripts, debriefing materials) at the end of the document for review.**

 **PART C. PARTICIPANTS & PARTICIPANT RECRUITMENT**

**1. Who are the participants?**

Click here to enter text.

**2. Will all participants be at least 18 years of age?**

[ ]  Yes [ ]  No

*\*\*If the research involves minors, include a copy of the letter to parents, and (if applicable) to the school principal at the end of this form. If the research involves* ***any*** *high school students (even those 18 years or older), parental consent and permission from the principal are required.*

**3. What is the minimum number of participants you will include?** Click here to enter text.

**4. How will participants be recruited? Check all that apply. Include text of recruitment e-mail messages, flyers, or postings at the end of this form.**

[ ]  Wartburg College classes

[ ]  Email recruitment through directors, coaches, etc. (attach communication)

[ ]  Flyers posted around campus (attach text)

[ ]  Juice announcement (attach text)

[ ]  Social media (attach text)

[ ]  Word of mouth/snowball sampling

[ ]  Posted on Sona system

[ ]  Other (explain below and attach any relevant materials at the end of the form)

Click here to enter text.

**5. Will informed consent be obtained? (Attach consent form to the end of this document)**

[ ]  No\*\*\* [ ]  Yes

\*\*If No, indicate reason below.

Click here to enter text.

**If yes, who will be giving informed consent?**

[ ]  Participant

[ ]  Parent/Guardian

If participants are minors, will assent also be obtained? (skip question if participants are not minors)

[ ]  No\*\* [ ]  Yes

\*\*If No, indicate the reason below

Click here to enter text.

**6. Will participants receive remuneration (cash, payment, credit, extra credit, etc.) for their participation?**

[ ]  No [ ]  Yes\*\*

\*\*If yes, list type:

Click here to enter text.

**7. Are you (or your research advisor, in the case of student principal investigators) in a position of authority over the participants (students in your class, advisees, or employees)?**

[ ]  No [ ]  Yes\*\*

 \*\*If yes, describe the position of authority and describe how you will guarantee that their participation is voluntary and that there will be no repercussions if individuals choose not to participate or choose to withdraw their participation from the study.

Click here to enter text.

**PART D. RISKS**

**1. Are there any anticipated risks of psychological or physical harm to participants in the study, beyond what they would experience in day to day life?** (According to the federal regulations at [**§46.102(i)**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102), minimal risk means that the probability **and** magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

[ ]  No [ ]  Yes\*\*

\*\*If Yes, describe briefly **a**) the risk, **b**) justification for the risk, and **c**) plans for mitigating the potential for harm.

[If exposing the participant to greater risk than what is expected in daily life, you must include in your debriefing procedure and materials additional resources (e.g., academic sources, counseling, health services, pathways, Spirituality & Campus Ministry, off-campus mental health resources).]

Click here to enter text.

**2. Will participants be deceived in any part of the study? This includes withholding information about the study's purpose and/or actively introducing misleading information about the study.**

[ ]  No [ ]  Yes\*\*

\*\*If Yes, **a**) describe the form of the deception, **b**) why it is needed, and **c**) procedures for debriefing the participants (including *when* participants will be debriefed regarding the deception).

Click here to enter text.

**PART E. ANONYMITY & CONFIDENTIALITY**

**ANONYMITY & CONFIDENTIALITY OF PARTICIPATION**

1. Can you ensure **anonymity** **of participation**? In other words, can you ensure that it is impossible to know whether an individual participated in the study or not?

[ ]  No (answer next question regarding **confidentiality** of participation)

[ ]  Yes (describe below and skip to Attachments Checklist)

Click here to enter text.

2. Can you ensure **confidentiality of participation**? In other words, can you ensure that the fact that an individual participated in the study remains private? Note: In some studies (e.g., studies in which participants meet in a group setting, focus groups), it is not possible to ensure confidentiality of participation.

[ ]  No (describe below the limits of confidentiality of participation and any steps you will take to maximize confidentiality of participation)

[ ]  Yes (describe below)

Click here to enter text.

**ANONYMITY & CONFIDENTIALITY OF DATA**

1. Can you ensure **anonymity of data**? That is, is it possible to ensure that the data are in no way connected to the participant? Note that stratifying data based on demographic variables (e.g., gender, race, major) could make participants identifiable. If your study has a small sample size, you might not be able to ensure anonymity of data.

[ ]  No (answer the next question regarding **confidentiality** of data)

[ ]  Yes (describe below and skip to Attachments Checklist)

Click here to enter text.

2. Can you ensure **confidentiality of data**? That is, is it possible to ensure that participants’ data remain private? Note: In some studies (e.g., focus groups), it is not possible to ensure confidentiality.

[ ]  No (describe below the limits to confidentiality of data and any steps you will take to maximize confidentiality of data)

[ ]  Yes (describe below, including where hard copies and electronic versions of data will be stored and who will have access to the data)

Click here to enter text.

**PART F. ATTACHMENTS CHECKLIST**

Use this checklist to ensure that any necessary materials are attached to the end of this document.

[ ] Letter to parent, principal, director, etc.

[ ] Text of recruiting e-mail, letter, flyers, etc.

[ ] Informed consent document (use the informed consent checklist and template)

[ ] Assent document (for participants who are minors)

[ ] Personal data being collected (e.g, demographics, etc.)

[ ] Questionnaires/surveys
[ ] Experimental materials

[ ] Debriefing document (use the debriefing template if using a debriefing form)

[ ] Other (specify below)

Click here to enter text.