Submission Type: Initial Date: 11-7-2021

IRB #: IRB-2021-39
Title: Test for IRB
Creation Date: 11-5-2021
Status: Unsubmitted
Principal Investigator:

Getting Started

About Cayuse IRB

Cayuse IRB is an interaction web application.. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. Therefore not all sections may appear. You do not have to finish the application in one sitting. All information can be saved.

For more information about the IRB Submission Process, IRB Tracking, and Cayuse IRB Tasks, please refer to the Cayuse IRB Procedures Manual.

Additional information has been added throughout the form for guidance and clarity.

For information related to the Western Michigan University policy please click on this link Human Subjects Research Protection and the Institutional Review Board Policy

Getting Started

Throughout the submission, you will be required to provide the following:

- Detailed Study Information
- Informed Consent Forms
- Study Recruitment Document
- Other Information

PRINCIPAL INVESTIGATOR

Refer to the Human Subjects Research Protection and the Institutional Review Board Policy to determine who is eligible to serve as the Principal Investigator (PI).

- **4.1.3.1. The following are eligible to serve as PI:**
  - 4.1.3.1.1. Tenured/tenure track faculty
  - 4.1.3.1.2. Faculty specialists
  - 4.1.3.1.3. Full time professional staff on permanent appointment with WMU that have appropriate credentials (less than full time permanent appointments are at the discretion of the WMU IRB)
  - 4.1.3.1.4. Research Scientist (at the discretion of the WMU IRB)
  - 4.1.3.1.5. Emeritus Faculty (with department appointment and at the discretion of the WMU IRB
- **4.1.3.2. The following are not eligible to serve as PI:**
  - 4.1.3.2.1. Students may not serve as the principal investigator on a human research study.
  - 4.1.3.2.2. Part-time faculty, adjuncts, research associates, visiting professors, and visiting scholars are not eligible to serve as the principal investigator; however, they may serve as a Co-Investigator on a human research study.

Western Michigan University Institutional Review Board (WMU IRB)

The Principal Investigator (PI) has ultimate responsibility for the conduct of the study, the ethical performance of the project, and the protection of the rights and welfare of the subjects who participate in the study as presented in the Belmont Report and 45 Code of Federal Regulations Part 46 (referred to as the Common Rule).

Submission of a research study protocol to the Western Michigan University Institutional

Review Board (WMU IRB) certifies that the Principal Investigator attests to the scientific merit of the study; to the competency of the investigator(s) to conduct the project; and that continued guidance will be provided as appropriate to ensure the protection of human participants and compliance with IRB requirements.

- You cannot begin data collection until a formal approval letter from the WMU IRB has been received.
- Study submissions are reviewed on a rolling basis.
- The WMU IRB Board meets, as needed throughout the year, to review studies that are greater than minimal risks and require review by the full committee.
- Your human subject research study cannot be approved until the require training in human subject research protections has been completed through CITI **(Group 1 Social & Behavioral Sciences Researchers**)

*required

I have read the information above and I am ready to begin my submission.

✓ Yes

Submission Information

*required

What type of activity is this submission for?

- ✓ Collection of New Research Data
- Secondary Data for Analysis Only
- Class Project
- Activities Without a Plan to Conduct Research (Evaluation, Case Report, or Quality Improvement Project)
- Other

What type of research are you conducting?

- ✓ Social-Behavioral Research
- Biomedical Research

*required

Principal Investigator

Refer to the Human Subjects Research Protection and the Institutional Review Board Policy to determine who is eligible to serve as the Principal Investigator (PI).

Students, part-time faculty, adjuncts, research associates, visiting professors, and visiting scholars are not eligible to serve as the principal investigator.

*required

Primary Contact

If this study is being conduct to fulfill a degree requirement, please add the student (dissertation, master's thesis, capstone, honors thesis, etc.) as a primary contact.

If a GA is working on this project, please add them here as a Primary Contact.

Multiple primary contacts may be added.
Name:
Organization:
Address:
Phone:
Email:

*required

Are you collaborating with one or more researchers at other institutions/organizations to conduct this study/ collect data?

Yes

No

Study Information

*required

What is your status at Western Michigan University?

- Faculty
- Student
- ✓ Staff
- Other

If you cannot find an individual in "Find People" please contact the WMU IRB at ovpr-hsirb@wmich.edu or Research Compliance at 269-387-8293.

Study Personnel

Note: If you cannot find a person in the people finder, please contact the WMU IRB Office at ovpr-hsirb@wmich.edu.

Co-Investigator

Other WMU Students

Provide name, email, and role in this research study.

Will Non-WMU Researchers work on this study?

- Yes
- No

*required

Study Site

Where is the physical location of your study?

Note: If you are collecting data virtually please select Western Michigan University.

Western Michigan University

External Site (non Western Michigan University)

Funding

*required

Is this study funded?

Yes

No

Study Dates

Please provide the study start and end dates.

Note:
The WMU IRB will approve your study for one year. To continue with this study, you must apply for an extension by submitting the Continuing Review.

*required

Start Date

*required

End Date

The WMU IRB will approve your study for one year. To continue with this study it must be reviewed and approved by the WMU IRB. Renewal/Post Approval Monitoring requires the Continuing Review submission prior to expiration.

Targeted Participant Pool

*required

Maximum number of subjects you will recruit

*required

Number of subjects you want to complete the study

*required

Number of subjects in the control group

If none, please indicate.

*required

Justification for number of subjects

*required

Gender

Female

Male

Both

Other

*required

Targeted Race/Ethnicity

- None/Not applicable
- African-American
- Alaskan Native
- American Indian
- Asian-American
- Caucasian
- Hispanic
- International/Non US Resident
- Multiracial
- Pacific Islander
- Other

*required

Ages

Select the age range of subjects that will be enrolled in this study. Check all that apply.

- 1 month to less than 12 years old (Office of Human Research Protection - Research with Children FAQs)
- 12 years old and less than 18 years old
- 18 years and older

*required

Targeted Participants in Special Consideration Categories *(Vulnerable Population)*

Please check the population(s) that will be enrolled. Check all that apply.

- Pregnant or lactating women
- Minors with Parental Consent
- Minors Who can Consent Themselves
- Prisoners
- Wards
- Cognitively Impaired Persons
- Military
- Blind Individuals
- Students
- Non-English-speaking individuals
- Institutionalized individuals
- Other
- None of the Above

Study Design

*required

Identify the type of review you believe your study should be reviewed as.

Exempt, Expedited, and Full Categories of Review require WMU IRB oversight through the life of the project.

Exempt

To qualify for review under the exempt Exempt Category of Review, the research must not be greater than minimal risk* and must fall into one or more of the exempt categories (https://www.hhs.gov/ohrp/regulations-and-policy/re...)

*Minimal risk is defined by the federal regulations as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Expedited

To qualify for review under the Expedited Category of Review, the research must not be greater than minimal risk and fall into at least one of the expedited categories defined by the federal regulations (https://www.hhs.gov/ohrp/regulations-and-policy/gu...)

*Minimal risk is defined by the federal regulations as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Full

Studies that involve greater than minimal risk require review at full board IRB meeting. The research requires approval from a majority of those members.

Full studies include where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk.

*required

Abstract

Briefly describe the purpose of the study, the rationale, and the major design/methodologies.

*required

Background and Purpose

Provide the purpose of the study, the rationale, and a review of previously conducted research with sufficient information to allow the reviewer(s) to consider how the research is novel, place the proposed research in the context of previous research conducted, and consider the importance of the future findings. If for thesis or dissertation, this section should not be the complete review of literature from thesis or dissertation document. Please write in a manner in which individuals from a different academic discipline than the proposed study can adequately consider the information presented.

Subject Recruitment

*required

Layout the recruitment section in a step-by-step fashion to describe how you will recruit subjects and include the following:

- The number of subject being recruited
- How potential subjects will be recruited (i.e. flyers, announcements in class, other methods of recruitment)
- How potential subjects will contact the investigator(s) to express interest in learning more about participating (i.e. e-mail, phone)
- How the investigator will respond to individuals expressing interest in the study.
- Investigators should provide justification for the stated inclusionary/exclusionary criteria.

For example, if a study is going to include only male subjects, an appropriate justification should be provided].

*required

Inclusion Criteria

List and describe the inclusion criteria for subjects (i.e., age, gender, health status, cognitive status, other criteria).

*required

Exclusion Criteria

List and describe the exclusion criteria.

*required

Recruitment Materials

Attach recruitment emails and/or scripts . If applicable, this includes flyers, announcements in class, social media post, etc.

*required

Will there be incentives/compensation given for participation?

Yes

No

*required

Informed Consent Process

Describe the process by which informed consent will be obtained. If the participant is a child or mentally challenged, explain how the parent(s)/guardian(s) will be contacted for consent and how the researcher will insure that the participant understands and assents to the research. In a step-by-step fashion to specifically describe all of the steps involved from a potential participant expressing interest in learning more about participation in the study to the individual signing the consent form and agreeing to participate.

Informed consent must be obtained prior to the collection of any data.

In all consent documents, in the first paragraph, a study summary is required. Provide a concise summary of essential study information that individuals would want to know in order to make an informed decision about participation (Required under 45 CFR 46). See templates found online at https://wmich.edu/research/forms

In addition, alternatives to this research must be listed; if none state (alternative is to not participate in this study).]

*required

Informed Consent Form

Attach all consent documents. If applicable, attached all assent documents.

Study Procedures

*required

Describe all study procedures.

*required

Describe the duration of study participation, the length and number of study visits, and the timetable for study completion.

*required

Describe the information to be gathered and the means for collecting and recording data.

If previously collected data is to be used, describe both the previous and proposed uses of these data.

*required

Study Instruments

Attach all instruments (i.e. personality scales, evaluation blanks, etc) to be used in the study.

*required

Survey, Questionnaire, or Interview

Will the study utilize surveys, questionnaires, or interviews?

Yes

No

*required

Participant Data, Specimens, and Records

Does this project involve the collection or use of materials (data or specimens) recorded in a manner that could identify the individuals who provided the materials, either directly or through identifiers linked to these individuals?

Yes

No

Potential Risks

*required

Describe immediate risks, long-term risks, rationale for the necessity of such risks, alternatives that were or will be considered, and why alternatives may not be feasible.

This section should describe the nature and likelihood of possible risks (i.e. physical, psychological, social, economic, time) as far as they are known. Risks include mild discomforts, inconveniences, and potential for disclosure of sensitive information.

If there are no known risks please indicate this.

Include all measures to be taken to protect subjects from possible risks and discomforts.

*required

Describe any potential legal, financial, social, or personal affects on subjects of accidental data disclosure.

*required

Potential Benefits

Describe the expected or potential benefits for subjects (if any), the discipline, and/or society that will arise from this study.

Indicate potential benefits specific to the research participant, longer term or more general benefits, and benefits to the knowledge base.

If participation in the research study will not directly benefit the research participation, please include a statement indicating this (e.g., There are no direct benefits to participants for participating in this research).

Note: *Incentives/compensation for participating in this study are not a benefit of the research (e.g., extra credit, gift card, etc.)*

*required

Will deception be used as a method of data gathering?

Yes

No

*required

Dissemination of Data

How will the information obtained from subjects be used?

(Explain how the results of the study will be disseminated (i.e. thesis, dissertation, research journals, conference presentations, inclusion in grants, etc.).]

*required

Confidentiality of Data

Describe precautions to ensure the privacy of subjects and confidentiality of information. Be explicit if data are sensitive.

Note: *Confidentiality refers to a condition in which the researcher knows the identity of a research subject, but takes steps to protect that identity from being discovered by others. ... Anonymity is* ***a condition in which the identity of individual*** *subjects is not known to researchers.*

Describe coding procedures for subject identification.

Include the method, location, and duration of data retention (Federal regulations require data to be maintained for at least three years, after the study closes).
Your professional society may require you to keep the data longer.
Describe where the data will be stored.
In most instances, data must be stored at Western Michigan University (in a locked file in the PI?s office or another secure location where only members of the study research team will have access).

*required

Future use of Data

Select one option below that best describes how data from this study may be used for future research and/or sharing of data with another institution. (Required under 45 CFR 46).

***Note**: If you are unsure which option to select or if you anticipate having to share your data due to granting agency/publisher requirements the second option is the best choice ?Your personal information collected during this study may be stored and used for future research. After information that could identify you has been removed, de-identified information collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you.?*

The information collected about you for this research will not be used by or distributed to investigators for other research.

Your personal information collected during this study may be stored and used for future research. After information that could identify you has been removed, de-identified information collected for this research may be used by or distributed to investigators for other research without obtaining additional informed consent from you.

Your personal information collected during this study may be stored and used for future research. Should another research study be conducted you will be contacted. Data collected as part of this study will not be used or distributed without your consent. *If the researcher(s) are unable to contact you for consent your data will not be used for another study.*

*required

Did you collect biospecimens?

Yes

No

*required

Do you or any investigator(s) participating in this study have a financial interest related to this research project?

Yes

No

Informed Consent Form

Recruitment Materials

Study Instruments

Attach all instruments (i.e. personality scales, questionnaires, evaluation blanks, etc) to be used in the study.