Human Subjects Research Review Form

MUSKINGUM UNIVERSITY

Please do not renumber or reorder questions on this form.
Unless specified, answer all questions to be considered for fu
if a question does not apply to your research label it "N/A".

Primary Investigator(s), Department Name, Email. (PI = Primary Investigator throughout this form.)

_____

_____

_____

Researcher's Status (Check One):
_____Undergraduate Student
_____Graduate Student
_____Faculty
_____Other (Explain):

Research Assistants: List anyone other than PI or Faculty Advisor(s) who will have contact with participants. The researcher is responsible to assure that all assistants are briefed on the ethical treatment of participants and the maintenance of confidentiality.

_____

_____

Faculty Advisor(s) (if PI is a student), Department Name, Email:

_____

_____

Title of Project: _____

Desired Start Date: Upon Approval _____ Other*: (month/date/year)_____
*If other, please state why below, e.g. grant deadline or class deadline so committee can prioritize if needed.

Expected End Date (month/date/year): _____
Note: Approval is only good for one (1) calendar year from date of approval.
After that year, the researcher must inform the committee in writing if the research is ongoing.

Or if longer than a year or needing a set amount of time: _____

Will this research be submitted to an external agency for funding? Yes*_____ No_____

*If yes, please list name of agency: _____

Does this project make use of any of the following special types of participants and/or locations?
Please mark an "X" on the appropriate line:
___Research with Children
___Research with Prisoners
___Research with Pregnant Women and Fetuses in Utero
___Research in Public Elementary and Secondary Schools
___International Research

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___Research in Veteran's Administration Hospitals
___Research Conducted with Clinical Populations in which HIPPA Applies (e.g. Medical, Psychiatrist)
___Internet Research
___Drug Research in Human Population (FDA Regulated)

Please attach to <u>this form</u> the following items, each as <u>a separate appendix</u> in this document.
See sample appendix on last page:

- Sample of the parental permission slip, child assent, or consent form.
- Copy of all materials to be used in the research. Any scripts or written materials used for recruitment of participants, debriefing.
- Signed letter of permission/cooperation from any participating agency, school, institution or organization or full emails with headers from the latter.

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RESEARCH DESCRIPTION
Please complete the following sections as briefly, completely and simply as possible.
Attach additional pages/appendices to this document as necessary or as requested.

1. **PURPOSE/BACKGROUND OF RESEARCH**
   This is a chance for you to give the reviewers a background in the area of interest and educate them so they can understand your project and provide a full review in as short of time as possible.

   a. **<u>Background</u>: What literature exists on this area of interest? What does the existing literature say about the topic & how does this project add to our knowledge of the phenomena of interest? Please include basic citations (author and year only) of existing literature.**
   (**NOTE:** This should not be a literature review; instead provide a background for the reviewers who may not be from your discipline to understand the project at hand.)

   b. **<u>Define Terms</u>: Because reviewers are not necessarily from the same discipline as the researcher, please define necessary terms and concepts to understand the protocol. For example what is known by psychology might not be known by communication, e.g. "helicopter parents", "snowball sampling".**

   c. **<u>Research Questions and/or Hypotheses:</u> Please list your research question(s) and any hypotheses you might have.**

2. **PARTICIPANT POPULATION**
   The goal of these questions is to ensure the project meets the standard of justice as mandated by the federal government. Clearly explain and justify the process by which participants are selected.

   a. **Approximate number of participants is: _____**

   b. **The age range of participants is:_____**

   c. **Gender of participants (Check one):**
   _____ Just females, please explain why below.
   _____ Just males, please explain why below.
   _____ Both genders.

   d. **Anyone who fits into the following categories? (Check all that apply):**
   _____ Children (under age 18)*
   _____ Prisoners*
   _____ Pregnant women*

_____ Persons with disabilities (mental, emotional, or physical)*
_____ Economically or educationally disadvantaged persons, please explain why below*
_____ None of the Above.

If you checked any of the categories with a * after it then you are using a special/vulnerable population (those listed on page 1 of this form).
Please explain the rationale for the involvement of special classes of participants:

e. Are any of the anticipated participants current Muskingum University students? (Check One):

_____ Yes, thus the use of the Muskingum University Counseling Services is appropriate on the consent form & "take away" form discussed later.

_____ No.

f. Will being under the age of 18 be a disqualifying characteristic for your participant(s)? (Check Those that Apply):

_____ Yes, if so: Will any data gathered from an individual under 18 be destroyed and not used in the study?

_____ Yes

_____ No. Please justify.

_____ No. Please justify.

g. Are there any specific characteristics that will qualify/disqualify someone from participating? (Check One):

_____ Yes. Provide the reason and how those individuals will be selected at recruitment and/or time of participation (e.g. only want females for the study). The key is to minimize any embarrassment for the participant(s) who are excluded.

_____ No.

3. RECRUITMENT AND SELECTION OF PARTICIPANTS

a. Describe how participants will be recruited and selected. Attach a copy of any recruitment materials such as advertisements, recruitment statement (e.g. posted on a board or sign-up sheet, flyers, and letters as an appendix to your submission).

b. If recruiting/obtaining participants from specific class(es) (e.g. during class time):
Please list the professor(s) and classes to be sampled.

Permission from Instructor(s) is Demonstrated by? (Check One):
_____ A copy of the emails – with header – sent from the instructor(s) Muskingum.edu

account. Attach each permission email as an appendix to this document.

_____ A statement that your department has provided to ACHS permitting permission for major students to survey their classes. (Check with Department Chair.)

_____ A signed form stating instructors agree to allow you to survey their classes. (Follow up by sending the form(s) to the chair of ACHS.)

c. Are you recruiting from an agency off Muskingum's campus? (Check One):

_____ Yes, please go to 3d.

_____ No, go to #4.

d. If recruiting from an agency such as a school, or other institution, please state where. Attach a copy of the responsible party's permission to recruit from their agency/institution as an appendix to this document. (Email is acceptable if from appropriate domain e.g. @xxx.edu/org not .com, and includes the header.)

4. RESEARCH PROCEDURES/METHODS

Provide a description of each procedure including:

a. Nature of activities in which the participants will be engaged. (This is a step-by-step process of what will be expected of participants from the beginning to when the research is complete.)

b. List all data gathering instruments. Include copies of questionnaires or interview questions as appendices to this document. Refer to appendices throughout your proposal.

c. Provide frequency and expected length of time involved in each activity and the overall length of participation.

d. Please describe the training of the researcher in the methods used to collect data or administering the treatment. Also, specifically state names of courses and/or training workshops taken about research methods.

5. RESEARCH LOCATION

a. Where will the research be conducted? (Check One):

_____ On Muskingum's campus. (List buildings and room numbers if known.)

_____ Off Muskingum's campus. (Provide specific address.)

b. Please name/describe the location(s) where the research will be conducted.

c. Does the location allow participants privacy and comfort to protect from any risks such as loss of confidentiality or stress? (e.g. No one can overhear what is being said, or in any other way make the participant(s) feel at risk or exposed.) (Check One):

_____ Yes.

_____ No. Please explain.

6. DECEPTION

a. Does the research involve deception (misleading participants or omitting information at any stage of the study or until the conclusion of the study)? (Check One):

_____ Yes. Provide rationale and describe debriefing procedures and include the specific debriefing statement as an appendix to this document.

_____ No.

7. INFORMED CONSENT

Please attach all consent and assent documents as separate appendices to this document.

a. Describe the process of obtaining and documenting consent from participants, including assent (permission) from children under age 18. If working with children, be sure the language used is age appropriate.

b. Are all the participants over the age of 18? (Check One):

_____ Yes, please explain below the procedure of obtaining consent. Please go to 7f.

_____ No.

c. If any participants are under the age of 18 do you have a procedure for obtaining parental consent? (Check One):

_____ Yes, please explain below the procedure of obtaining parental consent.

_____ No.

d. If any participants are under the age of 18 do you have a procedure for obtaining child assent? (How participants will grant you permission after parental consent.) (Check One):

_____ Yes, please explain below the procedure of obtaining child assent.

_____ No.

e. If any participants are under the age of 18 have you adapted the language to the appropriate form for the child's age? (Check One):

_____ Yes.

_____ No, please justify.

f. Will participants be given a copy of the informed consent or other "take away" which includes summary of study, contact information (e.g. for researcher and/or advisor, counseling services) for his/her records? (Check One):

_____ Yes.

_____ No, please justify.

g. Are participants informed of their right to skip any question that might make them uncomfortable in both the consent form and any data gathering instrument (e.g. survey, interview instructions)? (NOTE: This is required out of respect for the person/participant. When in place, this allows more questions about sensitive topics to be asked without being considered a risk since participants can skip the questions.) **(Check One):**

_____ Yes.

_____ No, please justify.

8. LOSS OF CONFIDENTIALITY

If at any point in the research participants supply their name (verbally or written), image, voice, or significant characteristics, this information might allow them to be identified and loss of confidentiality is a possible risk.

Address these risks below and describe how participants' privacy will be protected and confidentiality of data maintained:

a. What steps after the consent forms are signed will be taken to protect confidentiality? (It's suggested to remove consent forms from the survey/data collecting instruments as soon as possible and store separately (e.g. separate file) with no links to specific data lines/forms.)

b. In what specific secure location (e.g. room, office) will the consent forms, paper copies or other data be stored?

c. Who will have access to data and information?

d. Projected date of destruction of consent forms and other documentation. (Note: if identifying information has been removed from the data, the data may be kept indefinitely; the key is the destruction of anything that could link the data back to the participants.)

_____

e. Method of disposal of data and documentation?

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9. RISKS & BENEFITS FOR PARTICIPANTS

a. Are the risks (physical, psychological, social, or legal) greater than what might be experienced during everyday activities/life? (Check One):

_____ Yes, complete rest of question.

_____ No, complete only d & e.

b. Describe the potential risks and discomforts associated with each research procedure including any physical, psychological, social, or legal risks e.g. psychological distress (other than loss of confidentiality) and assess their likelihood and seriousness.

c. Describe procedures for protecting against or minimizing risks. Describe provisions for insuring necessary medical or professional intervention in the event of adverse effects on the participants. Be sure to address every risk/discomfort listed in Part b here.

d. Describe the potential benefits to participants as a result of their participation in this research. Describe any potential benefits to society that may be expected from this research.

e. If students are receiving class credit or extra credit is the instructor/professor offering alternatives to earn the credit? (Check One):

_____ Yes. Alternatives are offered.

_____ No. Extra credit offered but no alternatives offered. Please explain how participants are protected against feeling that they are being coerced or forced into participating.

_____ No. No extra credit offered for participation.

_____ Not applicable to the current study.

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INVESTIGATOR'S ASSURANCE STATEMENT

I have read Muskingum University's policy concerning research involving human participants and I agree to:

1. Accept responsibility for the ethical conduct of this research study,
2. Obtain approval from the Animal Care and Human Participants (ACHS) Committee prior to changing any procedures,
3. Report any complications, adverse reactions or unexpected effects on participants to the ACHS committee and/or Vice President for Academic Affairs as appropriate,
4. Submit an Application for Approval of Continuing Projects within one year, or sooner as specified in the approval letter, describing the current status of the project.

Principal Investigator(s)

_____

Name & Date

_____

Name & Date

_____

Name & Date

Faculty Review of Student Projects: I have reviewed and approved the procedures to be used in the project described in this application. I agree to meet with the investigator on a regular basis to monitor study progress and assure that the well-being of participants is adequately safeguarded.

Faculty Advisor(s):

_____

Name & Date

_____

Name & Date

Did you include all requested appendices below as separate entries that apply to your study:

· Recruitment Materials—Including copies of scripts, flyers, bulletin board posts.

· Written Materials Used During Study—Including copies of questionnaires, focus group questions, interview questions, debriefing statements.

· Consent Forms—Provide a copy of what you're supplying to participants to sign and/or take away from your study.

· Parental and Child Assent Forms—Including parental permission and child asset forms (for participants under the age of 18).

· Signed Forms of Permission—Including permission statements from professors and external agencies.

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Appendix A—Type Name of Appendix Here

Start a new page (Insert→Page Break) for other appendices with corresponding letters and title.