

Please do not renumber or reorder questions on this form.

Unless specified, answer all questions to be considered for

full review; even if a question does not apply to your research label it “N/A”.

Protocol # \_\_\_\_\_\_\_\_\_\_\_\_\_ (ACHS committee will complete this)

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:

\*If yes, include information regarding the IRB review process for funding.

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 (under the age of 18)

 Research with Pregnant Women and Fetuses in Utero

 Research with Prisoners

 Research in Public Elementary and Secondary Schools

 International Research

 Research in Veteran’s Administration Hospitals

 Research Conducted with Clinical Populations in which HIPAA Applies (e.g., Medical, Psychiatrist)

 Internet Research (as a research tool to distribute surveys, for example, and/or as the object of study to research online postings, for example)

 Drug Research in Human Population (FDA Regulated)

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Please attach to this form the following items, each as a separate labeled appendix in this document.

See sample appendix on last page:

Parental permission form, child assent, and/or Informed Consent form.

* Copy of all materials to be used in the research.
* Scripts or written materials used for recruitment of participants, debriefing, etc.
* Signed letter of permission/cooperation from any participating agency, school, institution or organization or full emails with headers and signatures 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.

* 1. Background: 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.

**Provide a background for the reviewers who may not be from your discipline to understand the project at hand.**

* 1. Define Terms: Reviewers are not necessarily from the same discipline as the researcher, therefore it is necessary to define terms and concepts to understand the protocol. Include what is not common knowledge (e.g., “helicopter parents”, “snowball sampling”).
	2. Research Questions and/or Hypotheses: Please list your research question(s) and any hypotheses you might have.

Research question(s):

Hypotheses:

1. 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.

1. Approximate number of participants is:
2. The minimum age or age range of participants is:
3. Gender of participants (Check one):

 All genders.

 Just a specific gender or genders. Please identify the gender(s) and explain why below.

1. Anyone who fits into the following categories? (Check all that apply):

 Children (under age 18)\*

 Pregnant women\*

 Prisoners\*

 Persons with disabilities (mental, emotional, or physical)\*

 Economically or educationally disadvantaged persons \*

 None of the Above.

If you checked any of the categories with a \* after it then you are using a special/vulnerable population (per 45 CFR 46.111(b)).

Please explain the rationale for the involvement of special classes of participants:

1. Are any of the anticipated participants current Muskingum University students? Check all that apply.

\_\_\_\_\_ Yes, thus the use of the Muskingum University Counseling Services may be appropriate on the Informed Consent, take away form, and/or debriefing.

\_\_\_\_\_ No, thus the use of another appropriate counseling services may be appropriate on the Informed Consent, take away form, and/or debriefing.

1. 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.

1. 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.

1. Recruitment and Selection of Participants
	1. 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).
	2. If recruiting 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.)

1. If recruiting participants via the Student Digest and/or other Muskingum University campus offices or groups, please list them below. Note, you may not recruit until your research protocol has been approved by the ACHS committee.
2. Are you recruiting from an agency off Muskingum’s campus? (Check One):

 Yes, please go to 3e.

 No, go to #4.

1. 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 professional domain and include the header and signature.)

1. Research Procedures/Methods

Provide a description of each procedure including:

* 1. 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.)
	2. List all data gathering instruments. Include copies of questionnaires or interview questions as appendices to this document. Refer to appendices throughout your proposal. Include an active link to the study if it is being conducted online.
1. **List** all materials participants will receive that are not data gathering instruments. This includes the informed consent and debriefing. Refer to labeled appendices throughout your proposal.
2. Provide frequency and expected length of time involved in each activity and the overall length of participation.
3. Please describe the training of the researcher in the methods used to collect data and administer the treatment. If interacting with vulnerable populations (see Part 2.d.), describe training related to that population. And, specifically state title and course number of courses, training workshops taken or qualifications directly related to research methods.
4. Research Location
	1. Where will the research be conducted? Check all that apply.

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

 Off Muskingum’s campus. (Provide specific address if known.)

\_\_\_\_\_\_\_ Online.

* 1. 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. Please explain.

 No. Please explain.

1. Deception
	1. 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.

1. Informed Consent

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

* 1. 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.
	2. Are all the participants over the age of 18? (Check One):

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

 No.

* 1. 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 and refer to labeled appendix.

 No. Please justify.

* 1. 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 and refer to labeled appendix.

 No. Please justify.

* 1. 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.

* 1. 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 their records? (Check One):

 Yes.

 No, please justify.

* 1. 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.

1. 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:

* 1. 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.)

* 1. In what specific secure location (e.g., room, office) will the consent forms, paper copies or other data be stored?
	2. Who will have access to data and information?
	3. 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.)

* 1. Method of disposal of data and documentation?
1. RISKS & BENEFITS FOR PARTICIPANTS
	1. 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.

* 1. 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.
	2. 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.
	3. 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.
	4. If students are receiving class credit or extra credit, the instructor/professor must offer alternatives to earn the credit. Have you verified this with the instructor/professor? (Check One):

 Yes. Alternative extra credit is 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 class credit or extra credit offered for participation.

 Not applicable to the current study.

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 Provost 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

Checklist of materials you may need to include in labeled appendices.

\_\_\_ 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.
* \_\_\_Debriefing – Provide a copy of the debriefing participants will be given.

Appendix A—Type Name of Appendix Here

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