Initial Application for Murray State University Institutional Review Board Review

PART A – To Be Completed for ALL CATEGORIES of Research

General Instructions

The Institutional Review Board (IRB) Application becomes the permanent record of the compliance of the investigator(s) with laws and regulations protecting the rights and welfare of human participants in research. Sufficient detail of the proposed protocol must be included to permit the Murray State University (MSU) IRB to render a decision about whether the safeguards in the research protocol protect the rights and welfare of human participants and benefits justify any risks. **Applications with insufficient detail will be returned to the applicant, without review.**

Student researchers must obtain faculty advisor/mentor approval prior to MSU IRB submission. Researchers must complete human subjects training prior to conducting research. Please check the MSU IRB website for further information. Consult the website or your research supervisor/advisor/mentor for more information on research protocols that may be considered exempt, qualify for expedited review, or require full standard MSU IRB review.

Additional information is available on the website on how to compile and submit your application. **Murray State IRB Website**

Identifying Information

1. **Title of proposed research study: (**All titles should be in standard mixed case, where the first letter of each word is capitalized and followed by lower case letters.)

Researcher's Assurance: I certify that the information provided in this application is complete and correct. I understand that as principal investigator (researcher), I have ultimate responsibility for the conduct of the study, adherence to ethical standards, and protection of the rights and welfare of human participants. I agree to: (1) conduct the study according to the approved protocol; (2) make no changes to the approved study without prior MSU IRB approval; (3) use the approved procedure and form(s) for obtaining informed consent; and, (4) promptly report any significant adverse events to the MSU IRB within five working days of occurrence.

Researcher's Name Date

Faculty Advisor/Sponsor's Assurance: By my approval by either electronic signature below and email with the application, the advisor/mentor certifies that the student or guest researcher has sufficient knowledge to conduct the study in keeping with the protection of human participants. Further, the advisor/mentor agrees to: (1) monitor study progress; (2) supervise the researcher in solving problems in the research as they arise; (3) ensure that the researcher promptly reports significant adverse events; (4) identifies an alternate advisor/mentor or sponsor in the event that the current is unavailable (on leave or sabbatical) and advises the MSU IRB in writing of such arrangements.

Advisor/Mentor/Supervisor/Sponsor Name Date

2. **Type of Application:**

☐ New Proposal

☐ Modified Protocol/Application Resubmission (Research Project No._____)

3. **Principal Researcher Position:**

- ☐ Professor/Faculty
- ☐ Doctoral Student — Anticipated Graduation
- ☐ Master's Student — Anticipated Graduation
- ☐ Undergraduate — Anticipated Graduation
- ☐ Other (write in MSU or external position):

4. **Principal Researcher's Affiliation:**

- ☐ College of Humanities and Fine Arts — Program/Major
- ☐ Arthur J. Bauernfeind college of Business — Program/Major
- ☐ College of Education and Human Services — Program/Major
- ☐ School of Nursing and Health Professionals — Program/Major
- ☐ Hutson School of Agriculture — Program/Major
- ☐ Jesse D. Jones College of Science, Engineering and Technology — Program/Major
- ☐ University Libraries — Program/Major
- ☐ CARE — Program/Major
- ☐ Other

6. **Principal Researcher's Contact Information:**

Name: E-mail Address:

Daytime Phone:

Research Assistants:

Name: E-mail Address:

Daytime Phone: Degree:

Name: E-mail Address:

Daytime Phone: Degree:

Name: E-mail Address:

Daytime Phone: Degree:

Name: E-mail Address:

Daytime Phone: Degree:

7. If the Student is the Principal Investigator, Enter the MSU Advisor/Mentor/Supervisor Contact Information; OR

If there is a External Researcher, Contact Information:

Name:	
Daytime Phone:	
External Researcher Institution:	
External Researcher MSU Contact:	

8. Check the category that applies to your research:

- ☐ MSU Doctoral Dissertation
- ☐ MSU Master's Thesis/Project
- ☐ MSU Undergraduate Research/Senior Project
- ☐ MSU Graduate Student Research Project (non-degree)
- ☐ MSU Faculty or Staff Professional/Academic Research MSU Institution or Program Research
- ☐ Outside Research by External MSU Researcher
- ☐ Program/Product Evaluation (DNP)

9. Briefly describe the purpose(s) of the study (Give as many details as possible for study purpose. Include research questions and key variables):

Protocol Methods/Procedures

10. Describe the maximum expected <u>sample size</u> and <u>characteristics</u> of the sample of human participants: (Please make sure to include all characteristics associated with population (e.g. age range, total number of participants, gender, inclusion or exclusion criteria, how you plan to gain access to the potential participants, etc.)

a. Please check any of the following **"vulnerable populations"** included in your sample (Proposing to study any of these populations may require full MSU IRB review completion of Part B questions):

- ☐ Children/Minors (if children are involved state age, legal parent/guardianship status) Persons with Intellectual or Developmental Disabilities
- ☐ Frail Older Adults
- ☐ Adults or Legal Guardians of individuals with Physical Disability or Mental Illness Adults with legal guardians
- ☐ People who are economically or educationally disadvantaged
- ☐ Prisoners
- ☐ Pregnant Women
- ☐ Undocumented individuals
- ☐ Others:

11. Describe how participants will be recruited or selected: (From what source(s), i.e., hospital, institution, school, class, shopping mall, etc.? Attach letters of permission from all participating organizations/off site locations on their official letterhead and/or IRB approval from the organization related to recruitment. Will you be naming the organization in the presentation/publication/dissemination of the findings? If so, seek out permission to use the organizational name. Attach any recruitment materials in final form, e.g., letters, postcards, flyers, for MSU IRB review and approval.)

12. Data will be collected by:

- ☐ Mail Survey/Questionnaire
- ☐ Telephone Survey/Interview
- ☐ In-person Interview
- ☐ In-person Questionnaire
- ☐ Observation
- ☐ Experimental Procedure – direct measure/self-report
- ☐ Standardized/Educational Test
- ☐ Archival or Secondary Data Source (abstracted/analyzed)
- ☐ Participant Observation
- ☐ Sound/Video Recording and Content Analysis
- ☐ Focus Group Interview
- ☐ Electronic Survey
- ☐ Other

13. What will you do with the human participants? (Describe in detail all the methods and procedures that involve human participants. This section should help the MSU IRB Committee understand from initial contact to completion of the research protocol what will happen to participants and is the most important part of your application. State the following in chronological order: 1) what the participants will be asked to do, 2) where the research will occur, 3) what measures will be used (e.g. test), 4) what data and information will be collected and how, 5) whether participants will be identified (further elaborated on in the confidentiality section), 6) whether participants will receive an incentive to participate and if so describe, and 7) how long it will take to complete the instrument and/or task (if multiple items, break down by item). Please add the survey program name if an electronic survey will be used and a PDF copy of the final version.

14. State when (approximate dates) and where the activities involving human participants will take place. (State when (approximate dates) and where the activities involving human participants will take place. The beginning date must be after approval by IRB. If location(s) require permission(s), please attach authorization letters. For on campus research use "MSU," otherwise state location. Will the research take place at a location off-campus (any MSU campus) that may require permissions? Examples could include, school districts, institutions of higher education, businesses, etc. This is different than recruitment locations.)

Start Date: End Date:

Locations:

15. List the validity of measures used, titles of any tests, questionnaires, or other instruments to be used that were developed by another person, along with the source where you obtained the material. Attach copies of all these materials and evidence of permission to use the material (i.e., purchase invoice, letter or e-mail from author or publisher, general permission on a website, PsycTests, Creative Commons license). If security or copyright prohibits attachment, explain. If none, state "No materials designed by another person are being used for this research."

16. List the validity of measures used, titles and attach copies of any surveys, tests, assessments, questionnaires, or interviews that <u>you</u> developed. If none, state "No specially designed materials are being used for this research."

17. Are incentives being offered to participants (Will you offer money. extra credit or other incentives for participants' time)?

☐ **NO**

☐ **YES** – What are the incentives?

18. What level of risk does this research present to the dignity, rights, health, welfare, or privacy of the participants? Consider and identify physical (more than the participant may encounter on a daily basis), psychological (involves a response to participation in a psychological way), social or group risk (when a participant belongs to a group, is employed, or is a student and their status is in jeopardy or impacted by participating or not in the research).

☐ No Risk to Participants (may require an Exempt to further IRB review) – Justify your rating below

☐ Minimal Risk to Participants (may require an Expedited IRB review) – Justify your rating below

☐ More than Minimal Risk to Participants (may require a Standard IRB review) – Explain and Specify Risks below (Complete Part B)

19. Describe the safeguards to protect against or to minimize ANY risk (For minimal or more than minimal):

a. If, as part of your management of risk, you are referring participants to an agency that is not a part of the Murray State University, please list the name of the agency here and if applicable attach a letter from that agency stating its qualifications and granting you permission to use its name. The MSU IRB requires a minimum of three referrals if you are referring participants to a non-MSU agency.

20. Describe any benefits to the participant(s) that may reasonably be expected from the research, including providing summary of research findings where appropriate, benefits to organizations, professionals, or others.

21. Briefly describe the procedures for protecting the confidentiality of participants both during the project and after the research is completed (include where you will keep and how you will dispose of signed consent forms, if applicable. Signed consent forms must be archived for 3 years after the conclusion of the study). Include any procedures for keeping data secure and the location of secured data. (a copy must be maintained on MSU's campus and accessible for the 3 year requirement)

22. Briefly describe the procedures you will use to obtain informed consent. Attach your proposed consent form(s) and include the text of oral explanations, if applicable, and any additional Informed Consent forms required by other participating organization(s). Explain if participants will be in a confidential location when provided with the consent, if you will go over the consent, and if they will have a chance to ask questions. Also, if collecting surveys in person, state if the consent and surveys will be collected separately so they cannot be re-associated. If Informed Consent is not required, please explain that in more detail here. Applications where consent may not be required can include:1) De-identified secondary data analysis, 2) Direct observation in public places, 3) Educational settings/standardized educational tests, 4) Public/elected officials. See MSU IRB Forms and Examples webpage for template and examples. (See MSU IRB web site for template and examples. Your program or College MSU IRB may also have samples.)

- ☐ Informed Consent and/or Informed Assent required
- ☐ No Informed Consent Required (provide justification why)
- ☐ Informed Consent obtained/Information Sheet at the beginning of telephone interview or online survey or research (attach copy of either oral or electronic versions of informed consent.)
- ☐ Request for Waiver of Informed Consent (review MSU IRB website for explanation of circumstances for this type of informed consent)

23. Will a form of debriefing be needed for this study protocol or for this population? If **sensitive issues** are raised in the research protocol, or if **deception is used**, describe the nature of any debriefing of subjects. (If not, state "No debriefing", and justify your decision.)

Checklist of Attachments for Part A (some may be optional for some applicants)

- ☐ Letter (or email) from agency granting permission to use their name.
- ☐ Letter (or email) of approval from participating organization on official letterhead or with official title.
- ☐ Copyrighted tests, questionnaires, etc… and include evidence of permission to use.
- ☐ All other specially designed or public domain tests, questionnaires, interview protocols, debriefing etc.
- ☐ Proposed consent (or assent) forms, including text of oral explanations/scripts
- ☐ Final format for online/electronic tests, questionnaires, etc. (link and PDF copy are required)
- ☐ Human Subjects Protections Certificate (NIH or CITI) for anyone engaged in the research

PART B
TO BE COMPLETED FOR STANDARD REVIEW CATEGORY APPLICATIONS OR REQUESTS FOR WAIVER OF INFORMED CONSENT ONLY

Standard Full MSU IRB Review Supplemental Questions

24. To your knowledge, are there any **laws or regulations relevant to the special nature of your population** (An example for this would be for research involving minors (USA <18 years) and the fact that they are required to have parental or legal guardian consent prior to participation along with their assent.)? If so, explain how your research design deals with these laws or regulations.

25. If the study includes participants from vulnerable populations describe how your protocol protects or accommodates their special vulnerabilities. Appropriate additional safeguards are necessary if potentially vulnerable subjects are to be involved in your research. Potentially vulnerable subjects include the elderly, prisoners, children, cognitively impaired people, people who are economically or educationally disadvantaged, pregnant women, neonates, or persons with impaired decisional capacity.
For further information and clarification contact the IRB department or refer to the NIH website on the guidelines for the use of human subjects at http://grants.nih.gov/grants/policy/hs/index.htm.

26. Briefly describe the training and experience that qualifies you to carry out the proposed research that involves more than a minimal risk to participants or includes vulnerable populations (Human subjects training (CITI or NIH Certification), certification in profession or field, experience from internship/practicum, etc.)

Request for Waiver of Informed Consent

The MSU IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to document informed consent, provided one of the following sets of conditions exists and is documented. The federal regulations do not allow a waiver of informed consent simply because the conditions of informed consent are difficult to carry out or because the conditions make it difficult to enroll subjects into the research. However, the MSU IRB may grant a waiver of informed consent under the following conditions:

1. The research involves no more than minimal risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants; and
3. The research could not practicably be carried out without the waiver or alteration, and whenever appropriate, the participants will be provided with additional pertinent information after participation.

27. Explain why the proposed research could not be practicably carried out without the proposed waiver or alteration of the informed consent form or procedure.

28. Describe any protocol for providing participants with additional pertinent information after their participation.

29. State any risks to participants caused by their participation in this research, and justify that the requested waiver or alteration to usual informed consent procedures will not adversely affect the rights or welfare of the participants.