Institutional Review Board Guidebook

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(a) Investigators do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's prospective scientific, educational, or applied value and that equally effective alternative procedures that do not use deception are not feasible.

(b) Investigators never deceive research participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences.

(c) Any other deception that is an integral feature of the design and conduct of an experiment must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research (See also the standard labeled "Providing Participants with Information about the Study").

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Applicability

These regulations apply to all research involving human subjects conducted under the auspices of a department, school, or research unit at Mississippi Valley State University, regardless of funding status. Research is defined by applicable Federal regulations [45 CR 46.102(d), Revised June 1991] as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge."

All research must be approved or declared exempt from further review by Mississippi Valley State University's Institutional Review Board (hereafter called the IRB). No studies, pilot or otherwise, involving human subjects can be conducted until IRB approval or exemption is obtained.

Class projects done solely for educational purposes within the confines of a classroom and not for research purposes need not to be reviewed by the IRB. However, the IRB is available for consultation regarding class projects should questions arise. If class projects involve the collection of data outside of the classroom, on-campus, or off-campus, then all IRB procedures must be followed.

Overview

The initial recommendation of whether a proposal may be exempt from further IRB review, qualifies for expedited IRB review, qualifies for expedited IRB review, or is subject to full IRB review is made by the Principal Investigator (PI), or the Faculty Advisor (FA), if the investigator is a student. The recommendation is made on the basis of federally specified criteria described in the Instructions for Preparing the Human Subjects Application Section of this manual.

The final determination of whether a proposal is exempt from further IRB review, qualifies for an expedited review, or is subject to full IRB review will be made by the IRB Chair. The PI or FA will be notified as soon as a proposal is determined to be exempt from further IRB review, and no further action will be required. Expedited proposals must be reviewed by one or more members of the IRB, who can either recommend its approval, modification, or request a full review. Full review requires consideration of the proposal by the IRB at one of its regular meetings. Notice of the IRB action will be sent to the PI.

Federal Legislation

By Federal Legislation signed into law on July 12, 1974, all behavioral or biomedical research involving human subjects conducted at or sponsored by an agency of the Federal government must be approved by an Institutional Review Board (IRB). The regulations governing IRBs are contained in the Code of Federal Regulations, 45 CFR 46, Revised June 18, 1991.

Each agency is required to file an "Assurance of Compliance with HHS Regulations for Protection of Human Research Subjects." A Single Project Assurance form must be obtained for each project funded by a federal agency prior to the conduct of research. The Assurance stipulates that all research involving human subjects at MVSU will be reviewed and approved by an IRB, whether federally sponsored or not.

IRB Membership and Scheduled Meetings

The composition of the IRB is governed by Federal regulations. Briefly, it must have at least five members of varying backgrounds and expertise, including at least one person not affiliated with the University and at least one person whose primary concerns are in a non-scientific area. The IRB must not be homogenous with respect to gender or profession.

- As of FY 2012, the MVSU IRB members are:

  Louis Hall, Ph. D. (Chair)
  Chair of Natural Sciences & Environmental Health
  Natural Sciences

  Ademola M. Omishakin, MPH, Ph.D.
  Professor of Natural Sciences & Environmental Health
  Natural Sciences
  Campus

  Julius O. Ikenga, Ph.D.
  Associate Professor of Natural Sciences & Environmental Health
  Natural Sciences
  Campus

  Samuel Melton, Jr.
  Interim Director of Sponsored Programs & Interim Director of Title III
  Office of Sponsored Programs/Title III
  Campus

  Stacy White, Ph.D.
  Associate Professor of Mathematics, Computer, Information Sciences
  Mathematics, Computer, Information Sciences
  Campus

Rickey Hill, Ph.D.
Professor of Social Science,
Social Science Department
Campus

Solomon Terfa, Ph.D.
Professor of Social Science
Social Science Department
Campus

Mohammad Hoque, Ph.D.
Associate Professor of Social Work
Social Work Department
Campus

Robert Hoagland, Ph.D.
Community Advocate

Luke Schissel, J.D.
Lawyer & Community Advocate

Meetings of the IRB will normally be scheduled upon receipt of a research proposal.

Definition of Terms

Assent –a child's affirmative agreement to participate in research

Cover Sheet – is a form completed by the principal investigator (PI) or faculty advisor (FA) in order to request a review of research using human subjects; a sample cover sheet is included in this manual

Department or Agency Head – the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated

Exempted from further IRB Review – the proposed research poses minimal risks to subjects, and satisfies other criteria listed in *Institutional Review Board Application Kit Section* of this manual.

Expedited IRB Review – a review of minimal risk, non-exempted research by at least one IRB Committee member

Full IRB Review – all members of the IRB will review the submitted research proposal at the next scheduled monthly meeting

Grant Proposal – a proposal for IRB review of research, for which a grant application is being submitted to a funding agency

Human Subject – a living individual about whom an investigator is conducting to research to obtain data through intervention or interaction with the individual, or uses identifiable private information, including the observation or recording of behavior

Informed Consent – the process whereby a subject agrees to participate in an experiment or study after achieving a full understanding of what is involved in the study

Intervention – includes physical, social, and behavioral procedures by which data are gathered and manipulations of the subject's environment for research purposes. Interaction includes communication or interpersonal contact between investigator and subject

IRB Approval – the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB, the institution, and federal requirements

Local Review Committee – a department, school or research committee with at least three members, which reviews research proposals before they are submitted to the MVSU IRB

Minimal Risk – 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

Progress Report/Annual Renewal – a form used to obtain annual approval of a continuing project and to provide information about completed projects

Proposal Form – a form submitted by the PI that provides specific information about the proposed research. A sample proposal form is included in this manual

Research – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge

Significant Protocol Change – refers to any change in the protocol that renders incorrect statements or descriptions of procedures that lead to the MVSU IRB approval or exemption currently in effect

Specific Project – any study involving human subjects that is in progress or about to be undertaken

CRITERIA FOR EXEMPTED, EXPEDITED, AND FULL IRB REVIEW

EXEMPTED FROM FURTHER IRB REVIEW
EXPEDITED IRB REVIEW
FULL IRB REVIEW

Proposals must be sent to the IRB for all research involving human subjects, regardless of the review status recommended by the principal investigator (PI) or faculty advisor (FA), if the investigator is a student, and regardless of the funding status.

Exempted From Further IRB Review (unless protocol changes)
Research is exempted from further IRB review if it entails no more than "minimal risk" (defined in the Appendix) and falls into one or more of the following categories:

[Title 45 Code of Federal Regulations 46.101(b), Revised June 18, 1991].

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on effectiveness of or the components among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to be subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed by public officials or candidates for public office; or (ii) federal statue(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs

or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency of the Food Safety and Inspection Service of the U. S. Department of Agriculture.

The IRB cannot exempt research with children that fall under category 2. Such studies may be exempted only if they involve (a) educational tests or (b) observation of public behavior when the investigator does not participate in the activities being observed.

It is the IRB's responsibility to ensure that researchers follow the guidelines established in 45 CFR 46, especially 46.116, General Requirements for Informed Consent (*see Informed Consent Section of this manual*). This applies to research considered to be exempt from further IRB review, as well as research given expedited and full reviews.

Therefore, before a proposal is determined to be exempt from further IRB review, the IRB may request additional information about the proposal, and/or may require changes in the consent form, subject recruitment methods, or other aspects of the procedure.

Even if the IRB requires changes in forms of clarification of other issues, this is not considered an expedited or full review. Research that falls under the exempt category will be exempted from further IRB review following necessary clarifications, and no other action will be needed on the part of the investigator unless there are changes in the research protocol. The benefit of an exemption is that neither annual renewal forms nor progress reports need to be submitted.

Expedited IRB Review

Non-exempted research is eligible for expedited IRB review if it involves no more than "minimal risk" and it falls in one or more of the following categories:

1. Collection of hair and nail clippings, in a non-disfiguring manner, deciduous teeth, and permanent teeth if patient care indicates a need for extraction.

2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

3. Recording of data from subjects 18 years of age or older using non-invasive procedures routinely employed in criminal practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity,

electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

6. Voice recordings made for research purposes such as investigations of speech defects.

7. Moderate exercise by healthy volunteers.

8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

11. Any other category specifically added to this list by HHS and published in the Federal Register.

Expedited programs are approved for a period of no more than one year. At the end of that period investigators will be asked to submit a progress report. Continuing projects must be reviewed by the IRB.

Full IRB Review
All other research must undergo full IRB review.

CRITERIA FOR APPROVAL

BY THE IRB

In order to approve research, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) by using procedures that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic, treatment or educational purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits (if any) to subjects, and to the importance of the knowledge that may reasonably be expected to result.

3. Subjects will be recruited in an honest, non-coercive, and equitable fashion.

4. Informed consent will be sought from each prospective subject and/or the subject's legally authorized representative.

5. Informed consent will be documented, except when specifically exempted by the IRB.

6. In cases of oral informed consent, a written statement that describes the study will be provided to participants.

7. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.

8. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

9. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, mentally disabled persons, or economically educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Additional precautions are sometimes indicated (and required by federal regulations) when some or all of the subjects are pregnant women.

INFORMED CONSENT

WRITTEN CONSENT
ORAL CONENT

Informed consent must be obtained from each subject who is legally, mentally, and physically able to provide it. The consent must be in written form and signed by the subject (or his/her legally authorized representative) unless the IRB finds either (1) the consent document is the only link between the subject and the research and the principal harm would come from a breach of confidentiality, or (2) there is no risk of harm to the subject, other than minimal risk and the study involves no procedures for which written consent is normally required outside of a research setting. For subjects not able to provide informed consent themselves, written informed consent must be obtained from others (e.g., parents, guardians). Under certain conditions, the IRB may waive the informed consent provision (See Title 45 of Code of Federal Regulations 46, 46.116(c), June 18, 1991, or contact the IRB Chair).

The IRB will not approve passive informed consent. Failure of a subject, or of his/her legally authorized representative, to express an unwillingness to participate, does not constitute consent to participate in the project.

Written Consent

If consent is written, a copy of the consent form should be included in the proposal. Essential elements of a written consent form are provided below. A written consent form should include the elements below and it should relate to a specific study. It should not be a "standard form". It must be written in simple language so as to be easily understood by persons with no medical or scientific background. A general rule is that potential subjects must be given all information that might reasonably be expected to influence their willingness to participate. The PI should provide two copies of the consent form; one for the subject, parent, or guardian to sign and return, and the other for him/her to keep. The Office for Protection from Research Risks has suggested that investigators avoid writing the consent forms in the first person language ("I understand that…"). However, the IRB will accept consent forms that are written in either the first person ("I") language or the second person ("You") language. A written consent form should include:

1. A simple, descriptive title of the research project;

2. Name and telephone number of the Principal Investigator (PI) or Faculty Advisor (FA), if the investigator is a student;

3. A statement that the study involves research;

4. An explanation of the group purpose of the research. If the research involves an experimental treatment for a problem or disorder, that treatment should be identified as well as any alternative treatments that might be advantages to the subject;

5. An explanation of the procedures to be followed;

6. A statement concerning the approximate number of subjects involved in the study.

7. A description of all discomforts and risks to be reasonably expected.

8. A description of benefits to subjects that can reasonably be expected. In addition, you may choose to describe the importance of the knowledge that may be reasonably expected.

9. A statement concerning the expected duration of the subject's participation, frequency of trips to the study site, etc.

10. A statement of any costs to the subjects, if there are any.

11. A statement, if applicable, about any monetary or other inducements for participation and how these will be prorated.

12. A statement describing how confidentiality will be maintained and who will have access to the data.

13. A statement that the subject is free to refuse to participate or to withdraw from the research activity at any time without penalty and without jeopardy.

14. A statement that the Principal Investigator or Faculty Advisor (include name) may be contacted (list phone number) if the subject has any further questions about the study.

15. A paragraph containing information about the IRB similar to the following:

    You may contact the Mississippi Valley State University (MVSU) Institutional Review Board at the following address and telephone number at any time during this study if you have questions or concerns about your rights as a research subject:

    Institutional Review Board
    Louis Hall, Ph.D., Chair
    Mississippi Valley State University
    Natural Sciences & Environmental Health
    Fielding L. Wright Building, Rm. 118
    Box 7254
    Itta Bena, MS 38941-1400
    (662) 254-3384

16. Signature of the subject indicating consent. (Signature of parents or legal guardians for subjects who cannot legally represent themselves).

17. When appropriate, a simply worded assent form for children who can read and write should be prepared for their signature. This is in addition to the consent form signed by the parent or guardian (See Children as Research Subjects Section for additional information about research with children).

18. For research involving greater than minimum risk to subjects, a statement specifying whether any compensation or medical treatments are available if injury occurs and where further information may be obtained.

Oral Consent

When consent is obtained orally, all the applicable elements of informed consent should be verbally explained to the subject before he or she agrees to participate. In addition, the IRB requires that a written document be given to participants in studies that involve oral informed consent. A copy of this document should be in the proposal. The document should provide a description of the study and also include the name and phone number of the PI and FA, and the phone number of the IRB. In some questionnaire studies, this written document may be included as a preface to the questionnaire.

CHILDREN AS RESEARCH SUBJECTS

CONSENT BY PARENTS OR GUARDIANS
CHILDREN'S ASSENT

According to document 45 CFR 46.406, children are permitted to be research subjects if:

1. there is no greater than minimal risk, or

2. an intervention or procedure hold out the prospect of direct benefit for the individual subject, or a monitoring procedure is likely to contribute to the subject's well-being, or

3. there is only a minor increase over minimal risk and the intervention or procedure is likely to yield generalized knowledge about the subject's disorder or condition, which is of vital importance for the understanding or amelioration of the subject's disorder or condition, and the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

Consent by Parents or Guardians

A. According to the federal regulations on the Protection of Subjects, for research falling under categories #1 and #2 above, the permission of one parent is sufficient.

B. Permission from both parents is required for category #3 above unless one parent is deceased, unknown, incompetent, or not reasonably available, or where only one parent has legal responsibility for the care and custody of the child.

C. The IRB requires parental consent to be written.

Children's Assent

In addition to parental permission, federal regulations, in most instances, require that a child who is sufficiently mature to comprehend his/her participation in the research project be offered the opportunity to give assent. Generally speaking, the federal government has interpreted this rule as requiring assent of children seven years of age or older, and encourages assent of younger children if there is reason to believe it would be meaningful. "Assent" means a child's affirmative agreement, be constructed as assent. Affirmative agreement is necessary. Under some circumstances written assent may be appropriate, but generally verbal assent will be sufficient. When a written form is used it should contain a simple explanation of the research project, including possible benefits, risks and safeguards. A copy of the assent form should be included in the proposal. There is no requirement of securing a child's assent if the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of research.

APPLICATION GUIDELINES AND SUBMISSION PROCEDURES

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Proposals must be submitted for all research on human subjects, where research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge" [45 CFR 46.102(d), Revised June 18, 1991] (Neither pilot nor regular subjects can be run until IRB approval or exemption by the IRB is received from the IRB Chair).

Types of IRB Review

All research involving human subjects must be reviewed by the IRB or be determined to be exempted from further review by the IRB. Research that is not exempt will either qualify for expedited review by one or more members of the IRB or will require full review by the IRB at a regularly scheduled meeting. Criteria for determining exemption, expedited, or full IRB review are provided in the *Criteria for Exempted, Expedited, and Full IRB Review Section of this manual*.

Initial determination of whether a proposal is exempt from further IRB review, qualifies for expedited review, or requires a full review is made by the Principal Investigator (PI) or Faculty Advisor (FA), if the investigator is a student, based on the Criteria for Exempted, Expedited, and Full IRB Review section of this manual. This final decision is made by the IRB Chair.

Ethical Principles

Regardless of the type of proposal or type of review, every researcher must read and agree to abide by the Standards for Research with Human Participants included in the Appendix of this manual, as well as other principles and standards endorsed by the individual's School/Department/Unit. The signatures on the proposal attest to the fact that all relevant personnel have read and agree to these standards.

Route of Submission

The PI or FA, if the investigator is a student, submits all proposals, whether for IRB approval or exemption, and all renewals, to the IRB at the Office of Institutional Research and Effectiveness, 445 Sutton Administration Building.

Conflict of Interest

Where any member of the IRB is personally involved in the research, that individual cannot participate in the review or approval of the research.

Types of Projects

The proposal categories for purposes of IRB review are new, Annual Renewal, and Protocol Change. Proposals may fall into either a "specific project" category or a "grant proposal" category.

1. Specific Project

    a. Definition:
    The category "specific project" is used for any study involving human subjects that is about to be undertaken. IRB approval of specific projects remains in effect for one year or until there are significant protocol changes, whichever occurs first. Researchers should submit a single proposal for each study, even if it involves similar protocols.

    b. Submission Procedures:
    The PI or FA prepares a Human Subjects Application, Consent Form Checklist, and an IRB Criteria Checklist and submits them to the IRB. Additional documents may be attached as necessary and as specified in the instructions.

2. Grant Proposal

    a. Definition:
    A proposal falls into the category if the investigator is submitting a grant application to a federal agency or other funding source for support of the proposed research. A grant proposal should be developed in sufficient detail that the research design, protocol, and procedures for safeguarding human subjects are fully specified.

    b. Submission Procedures:
    The PI or FA prepares a Human Subjects Application, Consent Form Checklist, and an IRB Criteria Checklist and submits them to the IRB. Please do not substitute grant applications or collaborative protocols in place of any required forms. When appropriate, portions of these documents may be used as supplementary materials. Additional documents may be attached as necessary and as specified in the instructions. For a grant proposal that is being sent to more than one agency, prepare a cover sheet listing all agencies on the form. Submit the cover sheet and the proposal form in the usual manner. If a proposal is subsequently sent to another agency not included on the original proposal, please send a note informing the IRB of this addition, using the original proposal number as a reference (i.e. a new cover sheet is not needed).

3. Significant Protocol Change

    a. Definition:

A significant protocol change refers to any change in the protocol that renders incorrect statements or descriptions of procedures that led to the IRB approval or exemption currently in effect.

b. Submission Procedures:
Prepare a new cover sheet and attach an explanation of changes. There is no need to attach a copy of the original proposal. Materials should be submitted to the IRB.

4. Progress Report/Annual Renewal/Completed Project

a. Definition:
Annual renewal refers to the annually required resubmissions for IRB approval of research still in progress. Progress report refers to a brief statement of the status of data collection, and of problems encountered in collecting the data. A completed project is a project in which all subjects have been run and no further data collection or interaction with subjects will take place.

b. Submission Procedures:
A Progress Report/Annual Renewal Form will be sent to the PI or FA by the IRB Office approximately six weeks prior to the expiration of IRB approval. To assure that the form gets to the PI whenever the PI is a student, it will be sent to the FA for forwarding. Detailed instructions for completing the form are in the *Instructions for Completing the Progress Report/Annual Renewal Form Section* of this manual. Final chapters must be filed for completed projects.

Length of Time for the Review Process

The IRB determines the length of time needed to process human subject applications. When proposals reach the IRB, exemptions will generally be processed within a few working days, expedited reviews in two to three weeks, and full reviews at the earliest possible monthly IRB meeting. Generally, proposals requiring full review must reach the IRB at least four weeks prior to a monthly meeting, in order to be considered at that meeting. Delays may be incurred if the IRB requires additional information from the investigators.

INSTRUCTIONS FOR PREPARING THE HUMAN SUBJECTS APPLICATION

Every request for review of research involving human subjects must include a Human Subjects Application, which is available in the Office of Institutional Research and Effectiveness. They are also included in this manual and may be photocopied.

The original and one copy of the Application should be forwarded to the IRB for every submission. The School, Department, or Research Unit should keep a copy for its file.

Record of Approval or IRB Exemption

One copy of the application will be returned to the Primary Investigator (PI) or Faculty Advisor (FA), if the investigator is a student, signed by the IRB Chair indicating IRB exemption from further review (unless protocol changes), approval, conditional approval, or non-approval. In the latter two cases, the reasons for the action will be attached.

Specific Items

The PI or FA should complete all portions of the application.
An IRB Log Number will be assigned by the Office of Institutional Research and Effectiveness when the application and supporting documentation is received.

List the title of the proposal project and the name of the principal investigator, telephone number, and mailing address. For student projects, theses, and dissertations, list the faculty advisor's name in the appropriate space. Either the PI or FA must be an individual authorized to submit proposals for extramural support, generally a full-time employee.

Indicate the type of review requested, the proposed start/completion date, the number of subjects proposed, and the composition of the study group.
Indicate the names, addresses, and phone numbers of all co-investigators and students.

Following the assurance, the PI or FA should sign the application.
The type of review, contingencies for approval, and review frequency will be completed by the IRB Chair.

Final Action

A copy of the application with the final decision of the IRB will be sent directly to the PI or FA, if the PI is a student.

INSTRUCTIONS FOR PREPARING THE CONSENT FORM CHECKLIST

Application forms are available in the Office of Institutional Research and Effectiveness. They are also included in this manual and may be photocopied. Do not substitute grant applications or collaborative protocols for these forms. When appropriate, portions of those documents may be used as supplementary materials.

Criteria for Approval of Research

The Principal Investigator or Faculty Advisor should read the criteria for the approval of research. In an attachment, refer to each of the criteria, and provide a response as requested.

INSTRUCTIONS FOR COMPLETING THE PROGRESS REPORT/ANNUAL RENEWAL FORM

This form will be sent by the IRB to the Principal Investigator (PI) or Faculty Advisor (FA), if the investigator is a student, approximately six weeks prior to the expiration of IRB approval of each projects or protocol change. Annual renewals are required for all continuing projects, but not for projects that have been exempted from further IRB review.

All items listed on the Proposal Report/Annual Renewal form should be completed by the PI or FA.
If the project was never sun, this item should be checked on the form, or if it was never funded, this item should be checked. Return the form to the IRB office.

Work Still in Progress

For work still in progress:

> The IRB assigns a new IRB log number (corresponding to the current year) and completes this on the form.
>
> If the protocol has changed for the coming year, a description of the proposal changes should be attached.

Complete the remainder of the form. If needed, you may attach additional sheets to describe any problems encountered and how they were handled, or you may add any other comments you believe to be of interest to the IRB. Indicate how many subjects have been included in the research to date and how many more are anticipated.

If the project has been completed, indicate this and complete the remainder of the form. If needed, you may attach additional sheets to describe any problems encountered and how they were handled, or you may add any other comments you believe to be of interest to the IRB. Indicate how many subjects have been included in the research.

Submit a copy of the form to the Office of Institutional Research and Effectiveness.

SAMPLE A: Minimal Risk Procedure

I agree to participate in a study of individuals involved in the Transitional Living Program at the Institute of Rehabilitation and Research. The Transitional Living Program is a six-week live-in program designed to help severely physically disabled persons acquire adaptive skills. This study is being conducted by Dr. Jane Doe of Mississippi Valley State University. The purpose of this study is to evaluate the effectiveness of this program. We hope to use the information obtained from this study to modify this program so that it will better serve physically disabled persons.

As a participant, I understand that my involvement in the Transitional Living Program will coincide with my participation in this research project. I understand that periodically (2-4 times) I will be expected to participate in a number of experimental tasks, including the completion of forms, checklists, and questionnaires relating to my knowledge, attitudes, behavior, and the occasional observation of my activities. These instruments may include behavioral logs or diaries, attitudinal surveys, activity checklists, and informational quizzes. In addition, I have been told that I may be asked to participate further in this research several months after my involvement in the Transitional Living Program is ended. If I am asked to continue participation, I will be told exactly what further participation will entail.

I have been informed that any information obtained in this study will be recorded with a code number that will allow Dr. Doe to determine my identity. At the conclusion of the study the key that relates my name with my assigned code number will be destroyed. Under this condition, I agree that any information obtained from this research may be used in any way thought best for publication or education.

I understand that there is no personal risk or discomfort directly involved with this research. Participation is voluntary and there is no penalty for not participating, and I am free to withdraw my consent and discontinue participation in this study at any time. A decision to withdraw from the study will not affect the services available to me from the Institute for Rehabilitation and Research or my participation in the Transitional Living Program.

If I have any questions or concerns that arise in connection with my participation in this study, I should contact Dr. Doe or her assistant, Mary Smith at (662) 555-1212. I also may contact the Mississippi Valley State University Institutional Review Board, if I have questions or concerns about my rights as a research subject (contact Dr. Joseph Wahome, Chair, MVSU IRB, Fielding L. Wright Building, Mississippi Valley State University, Itta Bena, MS 38941-1400; Phone 662-254-3384).

_____	_____
(Date)	(Signature of Participant)
_____	_____
(Date)	(Signature of Participant)

*Witness signature is required only when the capacity of the subject to understand the description of the project and its associated risks is in questions or when otherwise required by the Institutional Research and Effectiveness Institutional Review Board.

SAMPLE B: Cover Letter for a Mailed Anonymous Questionnaire

Dear _____

I am conducting a multi-organizational study of employee turnover. This research project is funded by the U. S. Department of Labor. The objective of this research project is to attempt to understand why people leave their jobs.

Enclosed with this letter is a brief questionnaire that asks a variety of questions about your attitudes toward your job with the University. I am asking you to look over the questionnaire and, if you choose to do so, complete the questionnaire and send it back to me. Do not write your name on the questionnaire. I do not need to know who you are. The results of this project will be summarized and appropriate people at the University will be given a summary report. I guarantee that your responses will not be identified with your personally. Nothing you do or say will in any way influence your present or future employment with the University. Also, this information will not affect your use of the University as a previous employer or any job references that you may list. I plan to compare the answers of people who have left with a group of people who are still employed with the University.

I hope you will take a few minutes to complete this questionnaire and to return it in the enclosed self-addressed stamped envelope. Without the help of people like you, research on employees would not be conducted. Your participation is voluntary, and there is no penalty if you do not participate. Regardless of whether you choose to participate, you can have a summary of our findings. To receive a summary, use the enclosed letter size self-addressed stamped envelope and the address form. To preserve your anonymity, you can send this request by separate mail. In this way, I have no way of knowing who sent back a questionnaire and who requested a summary of the results.

Understanding why people quit their jobs is very important. Through your participation, I eventually hope to understand how best to satisfy the needs of the organization its employees.

Sincerely,

John Q. Doe
Associate Professor
(662) 555-1212

You may contact the Mississippi Valley State University Institutional review Board if you have any questions or concerns about your rights as a research subject (contact Dr. Joseph Wahome, Chair, MVSU IRB, Fielding L. Wright Building, Mississippi Valley State University, Itta Bena, MS 38941-1400; Phone 662-254-3384.

SAMPLE C: Parental Consent Letter

Dear Parent or Guardian:

I am conducting a research product on how children think and develop strategies in games. I request permission for your child to participate. The study consists of two 20-minute sessions where children will play Tic-Tac-Toe one day and a guessing game on another. The goals of the study are to detail the strategies of game playing used by children of different ages, and to see how thinking strategies differ in the two games.

Each child will be invited to leave the classroom to participate in this special activity. The project will be explained in terms that your child can understand, and your child will accompany me only if he or she is willing to do so. Children usually enjoy games, so I expect that they will be interested and enthusiastic about participating; however, any child who expresses a desire to return to the classroom will be escorted back immediately. Interviews will be conducted by me and videotaped by my research assistant. At the conclusion of the study I will erase the tapes. Children's responses will be reported as group results only. Only I and members of my research staff will view the tapes. In addition to your child's game participation, I will need to look at the school's records to obtain your child's birth date and mathematics scores on the Iowa Tests of Basic Skills.

Participation in this study is voluntary. Your decision whether to allow your child to participate will not affect the services normally provided to your child by the school. At the conclusion of the study, a summary of group results will be made available to all interested parents and teachers. Should you have any questions or desire further information, please call me at (662) 555-1212. Retain this letter after tearing off and completing the bottom portion and returning it to your child's school. Thank you in advance for your cooperation and support.

Sincerely,
John Q. Doe,
Associate Professor

THIS STUDY HAS BEEN REVIEWED BY THE MISSISSIPPI VALLEY STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD. You may contact the Mississippi Valley State University Institutional Review Board if you have any questions or concerns about your rights as a research subject (contact Dr. Joseph Wahome, Chair, MVSU IRB, Fielding L Wright Building, Mississippi Valley State University, Itta Bena, MS 38941-1400; Phone 662-254-3384.

Please indicate whether or not you wish to have your child participate in this project by checking a statement below, signing your name, and returning this portion to your child's school.

____ I do grant permission for my child_____ to participate in Dr. Doe's games project.
(SIGN BOTH COPIES AND KEEP ONE FOR YOUR FILE)

____ I do not grant permission for my child_____ to participate in Dr. Doe's games project.

(SIGN ONLY ONE COPY AND RETURN THE SIGNED AND UNSIGNED COPIES)

_____ _____
(Parent/Guardian Signature) (Date)

HUMAN SUBJECTS APPLICATION

IRB Log # _____

Title of Proposal: _____

_____

Principal Investigator: _____

MVSU Employee/Status: _____

Department Address: _____

MVSU Phone #: _____ **Home Phone #:** _____

Will this study receive any direct or indirect federal support? (Including use of federal facilities):
Yes_____ No_____ Agency_____

Type of review requested: Exempt_____ Expedited_____ Full_____

Proposed start/completion date: _____/_____

Composition of study group (age, sex, race, disadvantaged, etc.): _____

_____

Name, MVSU Address, Phone of Co-Investigators and Students: _____

_____

_____

Principal Investigator Assurance:

On behalf of my co-investigators, associated students, staff and myself, I agree: To perform the research according to the ethical principles of the Belmont Report, requirements of 45CFR46 to strictly adhere to the research protocol as it relates to human subjects, and to promptly report to the IRB any proposed change in the research activity, and to ensure that no changes be made in the activity without obtaining prior IRB approval (except that a change may be made to eliminate apparent immediate hazards to the subject); to comply with any contingencies upon which approval may be granted; to promptly notify any member of the IRB verbally (with written confirmation) of unanticipated problems involving risk to subjects or others and of any other adverse circumstance actions affecting the subjects that arise from the research.

Principal Investigator: _____/_____

IRB USE: Exempt_____ Expedited_____ Full_____

Contingencies for Approval: _____
_____

Re-review Frequency: _____

Approved/Disapproved: _____/_____
Signature (Chair) IRB, Date

MVSU INSTITUTIONAL REVIEW BOARD CONSENT FORM CHECKLIST

IRB Log #_____

Proposer: _____

Signature: _____ Date: _____

Proposal Title: _____
_____

The primary investigator (PI) or Faculty Advisor (FA), if the investigator is a student, must answer following questions YES, NO, or NA and provide satisfactory explanation if answer is "NO"; Otherwise the Consent Form must be revised to eliminate "NO" answers.

_____1. Is the consent form written in "lay language" and presented in a way comprehended by the participant? (Explain on the reverse special arrangements for those unable to read the consent form).

_____2. Is it free of any exculpatory language through which the participant is made to waive any legal rights, including any release of the investigator, sponsor, institution or its agents from liability for negligence?

_____3. Will the participant be provided a copy of the consent document?

_____4. If the blood is to be withdrawn, is the standard blood withdrawal information included?

a. Number of times; amount, period of time covered; minimal risk of "bruising, inflammation of vein, and infection?"
b. Have all personnel handling blood been immunized against Hepatitis B?
c. Does your laboratory have approved exposure control plans for blood-borne or other pathogens?
d. Has your laboratory conformed to all applicable OSHA regulations concerning blood-borne or other pathogens?

_____5. If children (individuals who have not reached the legal age of consent, 18 in Alaska) are participants, is provision made for securing the assent of the child and the consent of the parent or guardian?

_____6. If investigational drugs or devices are to be used, or of approved drugs or devices are to be used in a manner for which they have not been approved, are such drugs or devices identified as "experimental?"

_____7. Does the consent form include each of the following basic elements of informed consent?

a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of participation?
b. A description of the procedures to which the participant will be subjected, and identification of those that are experimental?
c. A description of any benefits to the participant or to others?
d. A full disclosure of any reasonably foreseeable risks or discomforts, or a statement that minimal risk is considered to be associated with participation in the study?
e. For research involving more than minimal risk, a description of medical care, or other compensation is available, and who to contact to access such resources?
f. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
g. Information on who to contact for answers to questions about the research, participant's rights?
h. A statement that participation is voluntary at all times, and the choice not to participate, or to discontinue participation will involve no penalty or loss of benefits to which the individual is entitled.
i. In the case of evaluation of a medical procedure or therapy, a disclosure of alternative procedures that might be advantageous to the participant?

_____8. Is provision of any of the following information appropriate, and if so, is it provided in a consent form?
a. A statement that the procedure may involve risks to the subject or fetus (if the subject is or may become pregnant) which are currently unforeseeable?
b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent? (A concern if the subject benefits by participation.)
c. Any additional costs to the subject from participation?
d. Any consequences of a participant's decision to withdraw from the research, and procedures for orderly termination of participation by the subject?
e. A statement that significant new findings developed during the course of the research that might affect the subject's willingness to continue participation will be provided to the subject?

IRB Consent Form Approved By: _____ Date: _____

IRB APPROVAL CANNOT BE GRANTED UNTIL A COPY OF THE APPROVED CONSET FORM IS ON FILE.

❑ **INSTITUTIONAL REVIEW BOARD** ❑ **ANNUAL RENEWAL FORM**

School/Department/Division: _____

NEW IRB Log#: _____ (If a renewal, a new number will be assigned.)

Name of Principal Investigator (PI):

_____

Name of Faculty Advisor (FA), if PI is a student: _____

Other Investigator(s):

_____

_____

_____

STATUS: ❑ Faculty ❑ Staff ❑ Graduate Student ❑ Undergrad Student

Last year's IRB Approval # _____ Date: _____

❑ This project was never run. (If PI decides to conduct the study after the IRB approval has expired, a new application will need to be submitted to the IRB.)

❑ This project was never funded. PI will/will not pursue this project. (If the PI wishes to pursue this study, a new cover sheet and proposal form will need to be submitted to the IRB Office.)

Is this project completed? ❑ Yes ❑ No

If NO, does the PI plan to run any more subjects? ❑ Yes ❑ No

If YES, has the protocol changed? ❑ Yes ❑ No

If YES, attach a description of the changes for this year.

Please attach a brief progress or final report and include the number of subjects run.

Did any subjects voice complaints about the study or their participation in it? Did any subjects become upset or suffer other ill effects as a result of their participation in the study? If so, please describe in an attachment.

This progress report □/annual renewal form ❑ (CHECK ONE) was completed by:

_____ ❑ PI ❑ FA

IRB APPENDIX: American Psychological Association Standards

Standards for Research with Human Participants

Planning Research

(a) Investigators design, conduct, and report research in accordance with recognized standards of scientific competence and ethical research.
(b) Investigators plan their research so as to minimize the possibility that results will be misleading.
(c) In planning research, investigators consider its ethical acceptability under the Ethics Code. If an ethical issue is unclear, investigators seek to resolve the issue through consultation with the institutional Review Boards.
(d) Investigators take responsible steps to implement appropriate protections for the rights and welfare of human participants and other persons affected by the research.

Responsibility

(a) Investigators conduct research competently and with due concern for the dignity and welfare of the participants.
(b) Investigators are responsible for the ethical conduct of research conducted by them or by others under their supervision or control.
(c) Researchers and assistants are permitted to perform only those tasks for which they are appropriately trained and prepared.
(d) As part of the process of development and implementation or research projects, investigators consult those with expertise concerning any special population under investigation or most likely to be affected.

Compliance with Law and Standards

Investigators plan and conduct research in a manner consistent with federal and state law and regulations, as well as professional standards governing the conduct of research, and particularly those standards governing research with human participants.

Institutional Approval

Investigators obtain from host institutions or organizations appropriate approval prior to conducting research, and they provide accurate information about their research proposals. They conduct the research in accordance with the approved research protocol.

Research Responsibilities

Prior to conducting research (except research involving only anonymous surveys, naturalistic observations, or similar research), investigators enter into an agreement with participants that clarifies the nature of the research and the responsibilities of each party.

Informed Consent to Research

(a) Investigators use language that is reasonably understandable to research participants in obtaining their appropriate informed consent (except as provided under the standard labeled "Dispensing with Informed Consent"). Such informed consent is appropriately documented.

(b) Using language that is reasonably understandable to participants, investigators inform participants of the nature of the research; they inform participants that they are free to participate or to withdraw from the research; they explain the foreseeable consequences of declining or withdrawing; they inform participants of significant factors that may be expected to influence their willingness to participate (such as risks, discomfort, adverse effects, or limitations on confidentiality, except as provided under the standard labeled "Deception in Research"); and they explain the aspects about which the prospective participants inquire.

(c) When investigators conduct research with individuals such as students or subordinates, investigators take special care to protect the prospective participants from adverse consequences of declining or withdrawing from participation.

(d) When research participation is a course requirement or opportunity for extra credit, the prospective participant is given the choice of equitable alternative activities.

(e) For persons who are legally incapable of giving informed consent, investigators nevertheless (1) provide an appropriate explanation, (2) obtain the participant's assent, and (3) obtain appropriate permission from a legally authorized person, if such substitute consent is permitted by law.

Dispensing with Informed Consent

Before determining that planned research (such as involving only anonymous questionnaires, naturalistic observations, or certain kinds of archival research) does not require the informed consent of research participants, investigators consider applicable regulations and Institutional Review Board requirements, and they consult with colleagues as appropriate.

Informed Consent in Research Filming or Recording

Investigators obtain informed consent from research participants prior to filming or recording them in any form, unless the research involves simply naturalistic observations in public places and it is not anticipated that the recording will be used in a manner that could cause personal identification or harm.

Offering Inducements for Research Participants

(a) In offering professional services as an inducement to obtain research participants, investigators make clear the nature of the services, as well as the risks, obligations, and limitations. (See also Standard 1.18, Barter [With Patients or Clients] on file in MVSU IRB Office).
(b) Investigators do not offer excessive or inappropriate financial or other inducements to obtain research participants, particularly when it might tend to coerce participation.

Deception in Research

(a) Investigators do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's prospective scientific, educational, or applied value and that equally effective alternative procedures that do not use deception are not feasible.
(b) Investigators never deceive research participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experiences.
(c) Any other deception that is an integral feature of the design and conduct of an experiment must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research (See also the standard labeled "Providing Participants with Information about the Study").

Sharing and Utilizing Data

Investigators inform research participants of their anticipated sharing or further use of personally identifiable research data and of the possibility of unanticipated future uses.

Minimizing Invasiveness

In conducting research, investigators interfere with the participants or milieu from which data are collected only in a manner that is warranted by an appropriate research design and that is consistent with investigators' roles as scientific investigators.

Providing Participants with Information about the Study

(a) Investigators provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and investigators attempt to correct any misconceptions that participants may have.
(b) If scientific or humane values justify delaying or withholding this information, investigators take reasonable measures to reduce the risk of harm.

Honoring Commitments

Investigators take reasonable measures to honor all commitments they have made to research participants.

BEFORE SUBMITTING YOUR PROTOCOL FOR IRB REVIEW, MAKE SURE YOU HAVE INCLUDED THE FOLLOWING (IF APPLICABLE):

_____ Survey, Questionnaire, or Interview Questions
_____ Consent and Assent forms
_____ Recruiting materials
_____ Permission letters from participating institutions
_____ Signed Investigator Assurance form
_____ Clear, concise description of procedures to be used (feel free to also attach any proposals that may further explain your project)

Additionally, these assurances must be made:

_____ all personnel listed must have completed IRB/Human Subjects Training. If not, your application cannot be approved until the training has been completed.

_____ ***IF APPLICABLE***, the advisor has thoroughly reviewed this application to ensure readability and accuracy.

PLEASE NOTE:

- The determination of the IRB will be communicated to you in writing. Submission of an application to the IRB does not equal IRB approval. You ***may not begin*** this research until you have the IRB approval.

- If your research has not yet received funding needed to create instruments and other associated materials. provide a ***timeline*** of when those items will be developed.

If you have any questions, please feel free to contact our office at 254-3392.

Send to:
IRB
Mississippi Valley State University
14000 Hwy. 82 West Box 7298
Itta Bena, MS 38941-1400

INVESTIGATOR'S ASSURANCE

Mississippi Valley State University
Institutional Review Board

Project Title:

As Primary Investigator, I have the ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to all Institutional Review Board (IRB) requirements, federal regulations, and state statutes for human subjects' research. I hereby assure the following:

The information provided in this application is accurate to the best of my knowledge.

All named individuals on this project have been given a copy of the protocol and have acknowledged an understanding of the procedures outlined in the application.

All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.

I understand that, should I use the project described in this application as a basis for a proposal for funding (either intramural or extramural), it is my responsibility to ensure that the description of human subjects' use in the funding proposal(s) is identical in principle to that contained in this application. I will submit modifications and/or changes to the IRB as necessary to ensure these are identical.

I and all the co-investigators and research personnel in this study agree to comply with all applicable requirements for the protection of human subjects in research including, but not limited to, the following:

- Obtaining the legally effective informed consent of all human subjects or their legally authorized representatives, and using only the currently approved consent form (if applicable); and
- Making no changes to the approved protocol or consent form without first having submitted those changes for review and approval by the Institutional Review Board; and
- Reporting serious and unexpected adverse effects to IRB Administration verbally within 48 hours and in writing within 10 days of occurrence, and all other unexpected adverse events in writing within 10 days of occurrence; and
- Promptly providing the IRB with any information requested relative to the project; and
- Promptly and completely complying with an IRB decision to suspend or withdraw its approval for the project; and

- Obtaining continuing review prior to the approval date before this study expires. I understand if I fail to apply for continuing review, approval for the study will automatically expire, and study activity must cease until IRB current approval is obtained.
- Your study and any associated records may be audited by the IRB to ensure compliance with the approved protocol.

Name of Primary Investigator/Researcher:

Signature:

I assume responsibility for ensuring the competence, integrity and ethical conduct of the investigator(s) for this research project. The investigator(s) is/are fully competent to accomplish the goals and techniques stated in the attached proposal. Further, I certify that I have thoroughly reviewed this application for readability and accuracy, and the study is clearly described herein.

Name of Advisor:

Signature:

THE MISSISSIPPI VALLEY STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

Protocol Submission Form

Principal Investigator/Researcher Information

Name: Dr./Mr./Ms./ Mrs.
MVSU Net ID:
Daytime Phone Number:
Mailing Address:
(If on-campus, provide mailbox)

City/State/Zip:
Email Address:
Department:
IRB and Human Subjects Protections Education completed on _____

Faculty Advisor (Faculty member supervising the student for this project)
(If you are a student, you must have an advisor for this project)
Advisor:
MVSU Net ID:
Daytime Phone Number:
Advisor's Email Address:

Department:
Campus Mailbox:
IRB and Human Subjects Protections Education completed on _____

Additional Investigators/Researchers
Will additional researchers be involved with this project? If so, list them along with their Net IDs, phone numbers, addresses, and email addresses. Indicate the date in which they completed IRB and Human Subjects Education.

Title of Project:

Is this an original submission or a revision?

If this a revised application, please list the docket number assigned to the first submission of the study.

PROJECT PERIOD: from _____ to _____
Includes both data collection and data analysis

*** NOTE: Beginning date cannot predate IRB approval date. If you intend to begin immediately upon IRB approval, list beginning date as "upon IRB approval".**

STUDY FUNDING

Providing information about how the study costs will be supported.

_____ Department Funds _____ Personal Funds
_____ No Cost Study _____ Other, specify_____ External Funding

Agency:

SPA Proposal or Fund/Account Number:
PI of Award (if different than Principal Investigator/Researcher listed above):

ADDRESS EACH OF THE FOLLOWING ITEMS IN YOUR WRITTEN PROTOCOL

I. Personnel & Qualifications

NOTE:

- In this section, the principal investigator is to describe the qualifications of all researchers involved in the study to perform the responsibilities assigned.

- As principal investigator, it is your responsibility to ensure that all individuals conducting procedures described in this application are adequately trained prior to involving human participants.

- All personnel listed on this application are required to successfully complete the MVSU IRB & Human Subjects training course or and MVSU IRB approved alternative. **APPROVAL WILL NOT BE GRANTED UNTIL ALL INDIVIDUALS HAVE COMPLETED THIS TRAINING**.

- As personnel change, you must submit a modification request to the IRB for approval before they can work with human subjects or identifiable or confidential information.

A. Including yourself, provide the name of each individual who will be responsible for the design or conduct of the study, have access to human participants, have access to identifying or confidential information.

B. For each person identified above, identify his/her role in the project and clearly state the procedures or techniques he/she will be performing.

C. For each person identified above, describe his/her level of experience with the procedures or techniques he/she will be performing.

D. Indicate where each of the personnel listed received training to perform the identified procedures and who supervised or provided the training.

E. Explain how these skills/abilities will be periodically reviewed.

II. Research Protocol

1. **SITE OF WORK:**
   List each site where the research procedures will be performed. If any of the sites are off-site (i.e. not at MVSU or MVSU remote or branch sites), please provide information about that site (address, type of business/institution, etc). If a cooperating institution (school, hospital, prison, etc.) is involved, append letters that have been prepared on the official letterhead of the cooperating institution and signed by an authorized representative.

2. **Provide a brief description of the GENERAL PURPOSE of the project**.

3. **In your view, what *BENEFITS* may result from the study that would justify asking the subjects to participate**?

4. **Give details of the *PROCEDURES* that relate to the subjects' participation.**
If the procedures are in an existing document (for example, a grant or dissertation proposal), you may want to attach the document or the pertinent parts of the document. Be sure to reference the attachment.

5. **List *ALL* vulnerable subject populations to be included and additional precautions being taken to ensure their protection**.
Examples include Minors (under age 18), College students, Prisoners, Employees, Pregnant women/Fetuses, Adults with Cognitive Impairments, Substance abusers and non-English speaking people.

6. **How will the subjects be selected and recruited?**
Append copy of the letter, advertisement, and transcript of verbal announcement if applicable.

7. **What inducement will be offered?**
Provide justification for any inducement other than those of trivial benefit.

8. **How many subjects will be used? List any salient characteristics of subjects (e.g., age range, sex, institutional affiliation and other pertinent characterizations.)**

9. **How many times will researchers interact with each subject?**

10. **What will the subjects do, or what will be done to them, in the study?**
APPEND COPY OF QUESTIONNAIRES OR TRST INSTRUMENTS, DESCRIPTIONS OF PROCEDURE TO BE CONDUCTED ON THE SUBJECT.
If the procedures involve observation, please include the type of behavior or action you expect to observe or record. If the procedures involve an interview, attach a sample of questions you plan to ask.

11. **How do you intend to obtain the subjects' *INFORMED CONSENT*?**
(N/A is not an acceptable answer to this question.)
If in writing, attach a copy of the consent form. If not in writing, include a written transcript of what is to be said to the subject(s), and justify the reason that oral, rather than written consent is being used. Each subject should be fully informed by written or oral statement that indicates at a minimum: the purpose of the project, the benefits to be derived, a full description of the procedures to be carried out in which the subjects are involved, the amount of time that is required of subjects and who to contact with questions.

12. **Assessment of *RISK***
Do you see any chance that subjects might be harmed in any way? Do you deceive them in any way? Are there any physical or Psychological risks? (Might a subject feel demeaned or embarrassed or worried or upset?) Social (Possible loss of status, privacy, reputation)? How will you control for the risks you've identified?

13. **How do you ensure *CONFIDENTIALITY* of information collected?**
Who will have access to the data? Where will data be stored? Where will signed consent forms be stored (*be specific regarding location*)? What identifiers (*direct or indirect*) will be collected? What purpose do the identifiers serve? When will identifiers be removed or "de-linked" from the data? (*Identifiers include a code number, which may be linked to another document containing names or other identifying information*.) Will the data be retained or destroyed? If the data will be destroyed, how and at what point in time (*be as specific as possible*)?

14. **Are approvals needed from another MVSU regulatory committee (i.e. IACUC for animals or IBC for infectious agents or recombinant DNA)? If so, please attach approval letter(s) from appropriate committee(s). If approval has not yet been obtained, where are you in the approval process?**