

MISSISSIPPI UNIVERSITY FOR WOMEN
INSTITUTIONAL REVIEW BOARD

Following is a summary of documents needed for use in the review.

Form A - Identification of Investigators and Brief Review of Proposed Research
(submitted by the researcher)

Form B - Evaluation Form for Committee Review (submitted by the researcher)

Form C - Sample of Informed Consent (submitted by the researcher)

Form D - Guidelines for the Protection of Human Rights (used by the Review Panel)

Form E - Definition of Terms (given to the researcher)

FORM A

MISSISSIPPI UNIVERSITY FOR WOMEN
INSTITUTIONAL REVIEW BOARD

IDENTIFICATION OF INVESTIGATORS AND BRIEF DESCRIPTION OF
INVESTIGATORS AND BRIEF DESCRIPTION OF
PROPOSED RESEARCH REVIEW

TITLE OF STUDY:

PRINCIPAL
INVESTIGATOR: _____

(Signature)

DEPARTMENT _____ (Date) _____

RESEARCH ADVISOR:

(Signature)

Instructions: In the space below (use additional sheets where necessary):

1. Briefly describe the purpose and nature of the present research proposal. State what, if any, benefit is to be gained by the subject(s) or what information is to be added to the general body of knowledge as a result of this research.
2. List all procedures to be used on human subjects with a description of those you consider beyond already established and accepted techniques.
3. Describe the necessary safeguards to be applied to protect the subject.
4. State whether or not you consider the subject to be "at risk." If you consider the subject to be "at risk", in what respect do the potential benefits to the subject or contributions to the general body of knowledge outweigh the risks?
5. If you consider the subject to be "at risk," state exactly what you tell him in lay language to obtain informed consent relative to each procedure wherein he is "at risk. " This must be a form that is given or read to the subject particularly for this purpose. If subjects are children what will be told to parent or legal guardian?
6. State from whom documentation of informed consent will be obtained.
7. Attach copies of all questionnaires to be used.

FORM B

EVALUATION FORM FOR
INSTITUTIONAL REVIEW BOARD

Date Submitted to Committee: _____

Title of
Investigation: _____

Principal
Investigator: _____

Funding
Agency: _____

Funding Agency Grant Number: (NIH, BEH, when applicable): Anticipated number of
human subjects to be studied (when applicable): _____

Projected duration of
investigation _____

Age range of human subjects:

Any mental or physical impairment present in the subjects:

Criteria for subject selection:

Potential for beneficial effect to human subject arising from investigation

Potential adverse effects (psychological, behavioral and physiological) arising from
investigation: _____

Potential or established side effects of drugs used in investigation:

Brief justification of research where immediate benefit to specific human subject is
absent or unknown:

For On-Going Investigations Only. Number of subjects studied:

Documented adverse psychological, behavioral, physiological and pharmacological
effects of study:

Precautions used to detect, prevent, minimize or reverse adverse side effects:

Change in methods or procedures (when applicable):

Change in intent, direction or scope of research (when applicable):

FORM C

SAMPLE OF INFORMED CONSENT
INSTITUTIONAL REVIEW BOARD

1. State exactly what you will tell subject, parent/guardian.
2. State how you will obtain documentation of informed consent. (Submit sample document).

FORM D

GUIDELINES FOR THE PROTECTION OF HUMAN RIGHTS
INSTITUTIONAL REVIEW BOARD

Review Form D

If "no" checked, please explain in writing and attach.

1. Right to Privacy YES / NO

- 1.1 Obtained free and informed voluntary written consent. _____
- 1.2 Provide for anonymity _____
- 1.3 Information obtained held in confidence _____
- 1.4 When a reasonable possibility exists that others may obtain access to information, plans for protecting the confidentiality are explained to the subject. _____

2. Right to Self-determination

- 2.1 Voluntary consent obtained without overt or covert coercion. _____
- 2.2 Deception of subject or concealment of purpose avoided _____
- 2.3 When concealment is necessary, it is communicated to the subject and a contract is made to inform the subject as the design permits. _____
- 2.4 Explanations are not ambiguous and the terminology used is appropriate to the subjects level of understanding. _____
- 2.5 Subject free to withdraw consent at any point and informed of such. _____
- 2.6 Obtained third party written consent if necessary. _____

3. Rights of Minors and Legally Incompetent Persons

- 3.1 If a minor, informed written consent from parents required and obtained. _____
- 3.2 If legally incompetent, informed written consent from legal guardian required and obtained. _____
- 3.3 Supplemental written consent obtained from minor when minor has capacity to comprehend implications of study. _____

4. Right of Conservation of Personal Resources

- 4.1 Time, freedom from constraint, and personal resources are not abused. _____
- 4.2 Subject is informed about the nature, extent, and possible consequences of study. _____

5. Right to Freedom from Arbitrary Hurt 5.1 Subject protected from arbitrary mental and/or physical suffering as a result of study. _____

6. Right to Freedom from Intrinsic Risk of Injury

6.1 Subject has full information about proposed investigation if there is a risk of emotional and/or physical injury. _____

7. Additional Safeguards

7.1 Deviation from any of the above principles. _____

7.2 Evidence demonstrated that appropriate expert advice has been received that it is acceptable to deviate. _____

7.3 The researcher has demonstrated that research assistants have been, or will be trained in the ethics involved in carrying out the research design. _____

Vice President for Academic Affairs

Date

REFERENCE: ANA Ethical Guidelines APA Ethical Principles University of Michigan, Guidelines for the Protection of Human Rights University of Indiana, Guidelines for the Protection of Human Rights

FORM E

DEFINITIONS OF TERMS USED BY INSTITUTIONAL REVIEW BOARD

Investigator*:

A graduate student enrolled in or a faculty member who desires to conduct research with human rights who

1. Is representing himself/herself as a student or faculty member.

Research 1

Any organized research, research, potentially publishable to include theses and funded research.

Subject 2

Any individual who may be "at risk" as a consequence of participation as a subject in research.

At Risk 2

Any individual is considered "at risk" if he may be exposed to harm physical, psychological, sociological, or other as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet his needs.

Informed Consent 2

Informed consent is the agreement obtained from a subject, or from his authorized representative, to the subject's participation in an activity.

1. The basic elements of informed consent are:
2. A fair explanation of the procedures to be followed, including an identification of those which are experimental;
3. A description of the attendant discomforts and risks;
4. A description of the benefits to be expected;
5. A disclosure of appropriate alternative procedures that would be advantageous for the subject;
6. An offer to answer any inquiries concerning the procedures;
7. An instruction that the subject is free to withdraw his consent and to discontinue participation in the study or activity at any time.

*Any other person conducting research who desires human rights review by this Committee.

1- Mississippi University for Women Faculty Council, March 25, 1980.

2- United States Department of Health, Education, and Welfare: Policy on Protection of Human Subjects, 1971.