Guidelines for Human Subjects Research

GENERAL

(A.) Muskingum University’s program for protection of human research project is required by and formulated in compliance with federal regulations (45 CFR Part 690.101-690.124) and is required to fulfill the following five purposes:

1.) To guard against abuse to human research subjects,
2.) To provide a degree of protection from liability in an arena of increasing exposure and risk,
3.) To underscore the professionalism and credibility of the College’s program of research,
4.) To provide an educational, a “real world” experience for students, particularly those going on to or enrolled in graduate programs and professions which involve human subject research, and
5.) To provide a method to inform the campus of human subject research issues and activities.

(B.) The College’s program for protection of human research subjects is guided by the following Statement of Principles:

In its mission statement, Muskingum University affirms the importance of respecting human dignity. To this end, the College deems it appropriate to protect the current and long-term rights and welfare of all human subjects who participate in research conducted at or sponsored by Muskingum University. The College believes that research employing human subjects can make significant contributions toward increasing knowledge of human behavior and can ultimately contribute to the intellectual, spiritual, social, and physical development of human beings. However, the needs of research should not be judged more important than the needs and rights of the individual. Research conducted at or sponsored by Muskingum University or off-campus research in fulfillment of course or program are required to respect the human dignity, welfare, and rights of its subjects and to take care to avoid causing temporary or permanent negative effects on the human subjects involved.

(C.) The College’s Animal Care and Use/Human Subjects Research Committee is charged with the responsibility to insure that this commitment is fulfilled by regularly reviewing the institution’s program of research and be reviewing all research protocols involving human subjects.

APPLICABILITY

All human subjects research conducted by Muskingum University or off-campus research in fulfillment of course or program requirements is subject to review by the Human Subjects Research Committee.

Human Subjects Research Committee approval is required for any research designed to test a hypothesis or that ends with a hypothesis (quantitative/qualitative) and that involves:

1) Collection of data through interaction or intervention with an individual or individuals, or
2) Identifiable private information.

ETHIC GUIDELINES

With all research involving human subjects, the following guidelines should be taken into consideration:

Risks to the subject are minimized. Procedures should be consistent with sound research design and should not expose the subjects to unnecessary risks.

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

Selection of subjects is fair and equitable. The purpose of the research and the setting must be considered.

Indications of coercion must not be present and participation must be clearly voluntary.
Informed consent should be secured and appropriately documented. This content should be obtained from each participating subject or in the case of minors and special populations, from the subject’s legally authorized representative.

Adequate provisions must be made to protect the privacy of the individuals and the confidentiality of the data as well as the rights and welfare of the individuals participating in the project.

ITEMS TO INCLUDE
Informed consent must be secured from each subject (or subject’s parent or legal guardian) in your study. Your consent form must be submitted to the Human Subjects Research Committee along with your research review form and must include the following elements, at a minimum:

1) A statement that the study involves research, a readily understood explanation of the purposes of the research and the expected duration of the subject’s participation,
   B) A simple description of the procedures to be followed, and
   C) Identification of any procedures which are experimental

2) A description of any reasonably foreseeable risks or discomforts to the subject

3) A) Characteristics of subject population,
   B) Identify criteria for inclusion,
   C) Explain rationale for involvement of special classes of subjects,
   D) A description of any benefits to subject or to others which may reasonably be expected from research (if no direct benefit, this should be stated)

4) A) Identify sources of research material,
   B) Indicate whether material or data will be obtained specifically for research purposes.

5) A) Describe plans for recruitment of subjects and consent procedures,
   B) A STATEMENT THAT PARTICIPATION IS VOLUNTARY, REFUSAL TO PARTICIPATE WILL INVOLVE NO PENALTY OR LOSS OF BENEFITS TO WHICH THE SUBJECT IS OTHERWISE ENTITLED, AND THE SUBJECT MAY WITHDRAW FROM THE STUDY AT ANY TIME.

6) A) Describe any potential risks, assess their likelihood and seriousness,
   B) A statement concerning costs or compensation to the subject, if any.

7) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

8) Signed letter of permission/cooperation from any participating agency, school, institution or organization.

PREVIOUSLY APPROVED PROJECTS
If your study was previously approved by the Human Subjects Research Committee, and you are continuing or repeating the study beyond the initially named project period, you may submit the following in lieu of a review form:

1) The project number under which the project was most recently approved
2) Any substantive changes to the procedures or methods, and
3) Copies of the consent form, even if it has not been changed.

RESPONSE TIME
A response from the Human Subjects Research Committee may be expected to be forwarded to the Director of Graduate Studies for MAE students within three weeks, provided this is during the regular academic year and not during extended holiday breaks. Research may commence only after approval has been received from the Human Subjects Research Committee.

The Committee will accept and consider your proposals on a “rolling basis.” Submit your proposal as early as possible to avoid a last minute rush and delay which might affect your desired graduation date. The Human Subject Research Review form must be typed and submitted with 4 copies.

For Graduate Student questions regarding the review process or completion of the review form, please contact: Graduate & Continuing Studies at 740-826-8038.
Human Subject Research Review Form

Researcher's Name

Researcher's Status (Check One):
Student/Undergraduate Graduate Faculty

Other (Explain)

Address / Phone 

Name of Research Advisor:

Area of Concentration / Course for which this is an assignment:

Title of Research:

Desired Start Date: Length of Project:

Will this research be submitted to an external agency for funding:

If yes, please name agency:
1. PURPOSE OF RESEARCH - Describe the overall goals and purpose of the proposed research.

2. PROCEDURES - Explain exactly what tasks or activities the subjects in this research will be doing.

3. SUBJECT POPULATION

   A) Describe the characteristics of the subject population. Include their anticipated number, age range, gender, racial and ethnic composition, and health status.

   B) Identify the criteria for inclusion.

   C) Explain the rationale for the involvement of special classes of subjects (e.g., children, pregnant women, persons with disabilities, prisoners, or other institutionalized individuals, etc.)

   D) Description of any benefits to subject or to others which may reasonably be expected from research (if not direct benefit, this should be stated)
4. SOURCES OF RESOURCE MATERIAL

A) Identify the sources of research material obtained from individually identifiably living human subjects in the form of specimens, records, or data.

B) Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

5. SUBJECT RECRUITMENT

A) Describe plans for the recruitment of subjects and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

B) Do permission letters include the statement: “Participation in the project is strictly voluntary and refusal to participate will involve no penalty. This is a confidential survey in which the results will not be used to identify individual children or adults?”

   YES    NO    (Circle One)

6. RISKS

A) Describe any potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

B) Statement concerning costs or compensation to the subject, if any.
7. PROTECTION AGAINST RISKS

Describe the procedures for protecting against or minimizing any potential risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for assuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe provisions for monitoring the data collected to ensure the safety of subjects.

8. SUBJECT DISCLOSURE

Before participation, will the subject be given a complete explanation of the nature of the research, his/her involvement in it, and any attendant discomforts or risks?

YES NO (Circle One)

If NO, (i.e., important information is to be withheld or deception used), at what point and how will this information be provided to the subject?

9. AGENCY INVOLVEMENT - Does this research involve the cooperation, participation, or approval of any agency, school, institution, or organization other than Muskingum University?

YES NO (Circle One)

If YES, please list them, state the extent of their involvement, and provide proof of this cooperation (letter from teacher, principal, agency director, etc.)
ITEMS TO INCLUDE WITH THIS APPLICATION:

1. Signed letter of permission/cooperation from any participating agency, school, institution, or organization.

2. Sample of the parental permission slip or consent form you will be using to secure subject's participation.

3. Copy of any material to be delivered to the subject in conjunction with the research.

I certify that the above information is an accurate and complete statement of the nature of my research.

Signature of Researcher:__________________________________________________________

Date:________________________________________

Signature of Research Advisor:____________________________________________________

Date:________________________________________

Graduate Students: Submit the original and four (4) copies of this form (which must be typed) and any attachments to the Graduate & Continuing Studies, Montgomery Hall 117.

Important reminder: Federal law does not permit any research involving human subjects without prior permission.