STATEMENT OF PURPOSE

Otterbein University recognizes the need for investigations in which human beings may serve as research subjects. The University also acknowledges its responsibility for ensuring that the privacy, safety, health, and welfare of such subjects are adequately protected. Consequently, Otterbein has established the Institutional Review Board committee to review and approve the adequacy of human subject protection. The IRB may approve, disapprove or state conditions for the conduct of human subject research. The ethical principles and guidelines utilized are primarily drawn from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (The Belmont Report).
CRITERIA FOR REVIEW

All individuals conducting human subject research must submit proposals for approval by the Institutional Review Board (IRB). The IRB must receive such proposals if the research:

1) is in any way sponsored by the University

2) is conducted by, or under the direction of, any employee or agent of the University as part of their institutional responsibilities

3) is conducted by, or under the direction of, any employee or agent of the University using University facilities or properties

4) involves the use of the institution's non-public information to contact or identify participants or prospective participants.

Violation of these procedures can result in serious consequences for the University. First, it could jeopardize our eligibility for research funds, and second it could leave us open to costly lawsuits. As innocuous as the research might seem, Federal Guidelines mandate that all research must be approved by the IRB.

In addition to research in the classic sense, research that is conducted as part of classroom experience should be reviewed. Although this may seem somewhat overwhelming, if a standard classroom procedure continues to be used across years, you will need to do little to renew. Many of these procedures would qualify for an expedited review.

Projects that must come under review include, but are not limited to: medical research, psychological research, educational research, and survey research involving the use of questionnaires. Some of these projects are eligible for expedited review. Please see the section on expedited review in this packet.
ACTIVITIES WHICH MAY BE ELIGIBLE FOR EXEMPTION OR EXPEDITED REVIEW

Expedited reviews may be carried out for (a) research projects which are considered either eligible for exemption or expedited review, (b) projects that have been previously approved by the IRB, in which minor protocol changes have been made, or (c) projects that have been previously approved by the IRB and whose approval date exceeds one year. In this latter case, the expedited approval takes the form of an "update."

To apply for expedited review, the standard protocol form must be submitted for review by the chair of the IRB. Protocols falling within the expedited review guidelines will be reviewed by the IRB chair. If the protocol fits the expedited review categories, a notification will be sent out immediately to the PI. Upon receipt of this notification, the PI may begin the research. Protocols that do not fit the expedited review category will be sent to the full committee for review. In conducting expedited review, the chair may exercise all of the authorities of the IRB except that they may not disapprove the research. A research activity may be disapproved only after review in accordance with the ordinary, non-expedited procedure set forth in the guidelines.

Research Eligible for Exemption

Research activities involving human subjects that are exempt from IRB review are identified in Title 45 Code of Federal Regulations [45 CFR.101(b)(1)-(6)]. Institutions may not create new categories of exempt research under 45 CFR Part 46. The Office for Protection from Research Risks (OPRR) advises that investigators should not have the authority to make an independent determination of what is exempt. Research activities in which the only involvement of human subjects will be in one or more of the following categories are considered "exempt" and may be reviewed through the expedited review procedures. These exemptions do not apply when deception of subject may be an element of the research, when the activity might expose the subject to discomfort or harassment beyond levels encountered in daily life, or when individuals involuntarily confined or detained in penal institutions are subjects of the activity. The exemptions of Categories 3 and 4 do not apply when individuals under the age of 18 are subjects of the activity.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   a. research on regular and special educational strategies,
   b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
3. Research involving survey or interview procedures, except where responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and either:

   a. the subject’s responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability, or
   b. the research deals with sensitive aspects of the subjects own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

4. Research involving the observation (including the observation by participants) of public behavior, except where observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and either:

   a. the subject’s responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability, or
   b. the research deals with sensitive aspects of the subjects own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

5. 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 subjects.

6. Unless specifically required by statute (and except to the extent specified by the Secretary of Health and Human Services), research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine:

   a. programs under the Social Security Act, or other public benefit or service program
   b. procedures for obtaining benefits or services under those programs;
   c. possible changes in or alternatives to those programs or procedures; or
   d. possible changes in methods or levels of payment for benefits or services under those programs.

Research Eligible for Expedited Review

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the Institutional Review Board through the expedited review procedures authorized in 46.110 of 45 CFR Part 46.

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

8. 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.

9. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical 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 the electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

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

11. 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.

12. Voice recordings made for research purposes such as investigation of speech defects.

13. Moderate exercise by healthy volunteers.

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

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

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

I, __________________________, hereby authorize or direct _________________________ associates or assistants of his/her choosing, to perform the following treatment or procedure (describe in general terms),

upon _________________________

(myself or name of subject)

The experimental (research) portion of the treatment or procedure is:

This is done as part of an investigation entitled:

1. Purpose of the procedure or treatment:
2. Possible appropriate alternative procedures or treatment (not to participate in the study is always an option):
3. Discomforts and risks reasonably to be expected:
4. Possible benefits for subjects/society:
5. Anticipated duration of subject's participation (including number of visits):

I hereby acknowledge that _________________ has provided information about the procedure described above, about my rights as a subject, and he/she answered all questions to my satisfaction. I understand that I may contact him/her at Phone No. _____________ should I have additional questions. He/She has explained the risks described above, and I understand them; he/she also offered to explain all possible risks or complications.

I understand that my participation will remain confidential. I understand that I am free to withdraw my consent and participation in this project at any time after notifying the project director without prejudicing future care. No guarantee has been given to me concerning this treatment or procedure.

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy has been given to me.

Date: ___________ Time____________ AM Signed _______________________________ (Subject)

Witness(es) ________________________________________ (Person Authorized to Consent for Subject, If Required)

If Required ________________

I certify that I have personally completed all blanks in this form and explained them to the subject or his/her representative requesting the subject or his/her representative to sign it.

Signed ________________________________

(Signature of Project Director or his/her Authorized Representative)
Example of Informed Consent
(Project Involving No More Than Minimal Risk)

The Department of _________________________________ at Otterbein University supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish to participate in the present study. You should be aware that even if you agree to participate, you are free to withdraw at any time without penalty.

We are interested in studying the effects of media on how people view themselves, their problems, and their futures. You will be participating in two sessions that will involve filling out some questionnaires, watching some videotaped materials, talking with the researcher, and doing some written and verbal tasks. It is estimated that this will take no more than two hours of your time. Although it is not likely, there is a chance that you might feel slightly uncomfortable with some of the questions and parts of the videotapes. Although participation will not directly benefit you, we believe that the information will be useful in evaluating the effects of media on viewers.

Your participation is solicited although strictly voluntary. We assure you that your name will not be associated in any way with the research findings. The information will be identified only by a code number.

If you would like additional information concerning this study before or after it is complete, please feel free to contact me by phone or mail.

Sincerely,

John Doe, Principal Investigator
Campus Address
Campus Phone

____________________________________________
Signature of subject agreeing to participate

With my signature I affirm that I am at least 18 years of age.