INSTITUTIONAL REVIEW BOARD

GUIDELINES FOR SUBMISSION OF PROTOCOLS

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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).

DEFINITIONS

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

a. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

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 may need to 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.

PROCEDURE FOR REVIEW

All human subjects research proposals must be reviewed by the IRB. In many cases, expedited or limited IRB review (by the IRB Chair or designate) is sufficient, while in other cases, review by the full IRB committee is required. Regardless of the type of review, the application process is the same. Investigators or research teams must submit a signed copy of the IRB application form to the IRB Chair either electronically (IRB@Otterbein.edu) or by hard copy (campus mail address: IRB Chair, Department of Psychology). 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. Upon IRB review, researchers may be approved, asked for revisions to the protocol(approval with stipulations) or rejected. Researchers will receive written notice of the action of the IRB.

Regardless of the type of review, investigators may not begin collecting data until they have received notification of approval from the IRB. Upon receipt of this notification, the PI may begin the research.

ACTIVITIES WHICH MAY BE ELIGIBLE FOR EXEMPTION, LIMITED REVIEW, OR EXPEDITED REVIEW

Expedited reviews may be carried out for (a) research projects which are considered either eligible for exemption or expedited review [*Note: 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*], (b) projects that have been previously approved by the IRB, in which minor protocol changes have been made, or (c) projects requiring full committee review that have been previously approved by the IRB and whose approval date exceeds one year. In this latter case, the expedited review procedure may be used if no changes were made. Below are listed 18 categories of research that may be eligible for exempt/expedited/limited review.

Research Eligible for Exemption from Full Committee Review

Research activities involving human subjects that are **exempt** from full IRB review are identified in Title 45 Code of Federal Regulations [45 CFR 46.104(d)(1)-(8)]. Institutions may not create new categories of exempt research under 45 CFR Part 46. 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.

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an **adult** subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities [additional restrictions apply, see 45 CFR 46.104.(d)].

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or 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) If 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 or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

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.

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

(10) 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.

(11) 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'sprivacy. 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).

(12) 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.

(13) 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.

(14) Voice recordings made for research purposes such as investigation of speech defects.

(15) Moderate exercise by healthy volunteers.

(16) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(17) 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.

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

INFORMED CONSENT REQUIREMENTS

Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative. This consent must be written in a language that the subject can understand and include information about the purpose, duration, procedure, risks, and benefits of the research, as well as statements about the rights of the participants. Example informed consent documents are appended to these guidelines.

The IRB may waive or alter the requirements to obtain informed consent. If the investigator is requesting a waiver or alteration, all the following criteria must be met:
(i) The research involves no more than minimal risk to the subjects;
(ii) The research could not practicably be carried out without the requested waiver or alteration;
(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation

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.*

**If participants will be endorsing electronic consent statements instead of a hard copy consent form, replace this signature line and text with the following.*

By clicking on the (Next/Submit/>>/I agree) button below, I consent to be in this study and affirm that I am at least 18 years of age.

OTTERBEIN UNIVERSITY **PROTOCOL NO. _____**

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 PM Signed _____
(Subject)

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