

OHIO UNIVERSITY INSTITUTIONAL REVIEW BOARD (IRB) GUIDELINES

All research investigations involving human subjects, conducted by faculty, staff or students at or under the auspices or financial support of Ohio University, must be reviewed and approved by the Institutional Review Board for Review of Research Involving Human Subjects (IRB), or be declared exempt from IRB review by the Office of Research Compliance. The IRB operates under the policies and procedures of the university (No. 19.052), established to ensure compliance with the National Research Act (P.L. 93-348) and the regulations set forth in Part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46) and where applicable, Code of Federal Regulations (21 CFR 50 and 21 CFR 56). The purpose of IRB review is to protect the rights and personal privacy of individuals and assure a favorable climate for conduct of scientific inquiry at Ohio University.

RESEARCH REQUIRING REVIEW:

All research conducted by members of the university faculty, staff, and students that involves the use of human subjects and will have a “public presentation” must be reviewed by the IRB. Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A “public presentation” includes research conducted for presentation at a meeting, as a part of a report to the public or an external sponsor, for a journal or magazine article, for dissertations or master’s thesis, etc. If the research is conducted as an evaluation of the university or one of its unit’s performance for the purpose of improving that performance, this type of research does not need IRB approval. The most obvious example of this type of research is student evaluations of classes. Research conducted by students as a part of a classroom assignment that involves members of the university or Athens community outside of the immediate members of the class should be reviewed by the IRB. The instructor of the class can request a single review of the assigned activity each year and should contact the IRB staff for further information.

NATURE OF THE REVIEW

The IRB applies three basic principles in its review of research using human subjects:

- respect for the personal dignity and autonomy of subjects and special protection for those persons with diminished autonomy
- the obligation to protect subjects from harm by maximizing benefits and minimizing possible risks of harm
- fair distribution of the benefits and burdens of research

These principles underlie the information requested in the application: the need to obtain informed consent; the need to engage in a risk/benefit analysis and to minimize risk; and the need to select subjects fairly.

APPLICATION PROCESS

All requests to the IRB for approval of a research project must include, where applicable:

- ◇ Completed and signed IRB Project Outline Form
- ◇ Consent Form or Consent Text, if oral (**Appendix A**)
- ◇ A copy of all recruitment tools (advertisements, posters, etc.) (**Appendix B**)
- ◇ A copy of all instruments (surveys, standardized tests, questionnaires, interview topics, etc.) (**Appendix C**)
- ◇ Debriefing information or forms (**Appendix D**)
- ◇ Copies of other approvals (other IRB, school district, etc.) (**Appendix E**)
- ◇ Copies of any additional materials that will assist the Board in its review (**Appendix F**)
- ◇ Copies of any grant proposals (**Appendix G**)
- ◇ Copies of human subjects training certificates (**Appendix H**)

One copy of the form and all information and documentation must be submitted to the Office of Research Compliance and must bear the original signature of the project director. If the project director is an undergraduate or graduate student, the project proposal form must be signed by the student's faculty advisor for the research in question. All materials shall be submitted to: Human Subjects Research, Office of Research Compliance, 117 Research and Technology Center, Ohio University, Athens, OH 45701-2979.

COMPLETING THE FORM

The project director should review the guidelines and respond to the sections outlined on the Project Outline Form.

Investigator(s) Information

Provide contact information for all investigators. Correspondence and final approval will be sent to the address(es) listed in this section. Please complete the email address only if it is an acceptable means of communication to you, i.e. you check it daily. Email may be used for correspondence other than final approval.

If you are applying for funding from an external agency (NIH, CDC, FDA, etc.), federal regulations now require IRBs to review these grant proposals as part of the IRB review. You must submit a full copy of all such grant proposals related to this human subjects research (**Appendix G**).

As of June 1, 2001, all researchers conducting non-exempt human subjects research must undergo training in the protection of human subjects of research. In order to comply with this new requirement, a web-based module is available for completion. All key personnel, including academic advisors, involved in the research must complete the training. The online training module is available at:

<http://cscwww.cats.ohiou.edu/research/compliance/citiprogram.html>

Please complete the module, print the certificate that is generated upon completion, and provide a copy as **Appendix H**. An IRB approval cannot be issued until the certificate is provided.

The anticipated starting date is the realistic date you hope to begin the contact with subjects (including recruitment) or records, specimens, etc. This date should never precede the date of submission. No work (including advertising or recruitment) can begin prior to IRB approval.

The duration is the total time it will take to complete the project, including data analysis.

Review Level

Based on level of risk and the federally defined categories, one of the following review levels will apply:

- ❑ Exempt Review – A designated member of the Board reviews all requests for exemption from review. (see categories in **Appendix A**)
- ❑ Expedited Review - The chair of the Board or one or more IRB may conduct expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. (See categories in **Appendix B**)
- ❑ Full Committee Review – Any human subjects research that does not meet criteria for exempt or expedited review must be reviewed in a convened meeting of the IRB. The committee currently meets once a month. For full committee reviews, the researcher (and his/her advisor, if appropriate) may be asked to attend the meeting to discuss the research protocol. The researcher may also request attendance at a meeting in which their proposal will be reviewed. To coordinate attendance, send an email to compliance@ohio.edu.

Recruitment/Selection of Subjects

The requirement for an equitable selection of subjects helps ensure that the burdens and benefits of research will be fairly distributed. Some points to consider:

- a. subjects should not feel 'pressured' to participate (e.g. researcher recruiting own students as subjects, offering excessive monetary incentives). Please describe any potential for coercion and describe what steps will be taken to minimize the possibility. For example, instructors recruiting from their own classes would raise issues of pressure and should consider an alternative method of recruiting students from other departments.
- b. study design should allow for adequate representation of women and minorities where possible, if participants are limited by gender, age, or other criteria, a rationale **must** be provided.
- c. consider burden on those who are already overburdened (e.g. by physical or mental disabilities, institutionalization, or economic or educational disadvantage)
- d. DHHS regulation set forth provision for classes of subjects deemed particularly vulnerable:
 - fetuses, pregnant women, and human in vitro fertilization
 - prisoners
 - children/minors
 - mentally disabled persons
 - economically or educationally disadvantaged persons

Provide an estimate of the maximum number of participants. If you intend to contact 500 individuals in order to get the 300 responses needed for statistical validity, list 500 as the number of human subjects. Once approved, this number must not be exceeded without approval of an addendum.

Provide a brief description of the methods that will be used to select and/or recruit subjects. Include copies of notices or advertisements that will be posted (**Appendix B**) to solicit participants and a description of where the notices will be posted or advertised. If recruitment will be oral (by phone or in person), provide a copy of the script.

Project Description

Description of Project

- A general project description, including previous relevant research or activities of the project director (and/or advisor);
- The specific aims and objectives of the research component under review; and
- The research design

Description of Risks and Benefits:

- Describe the risks (physical, psychological, social) to the subjects; and
- Describe the benefits (physical, psychological, social) to the subjects and/or the importance of the knowledge to be gained and significance of the research.

Description of the Methodology and Personnel:

- Detailed description of the methodology and procedures to be used, especially as they relate to human subjects; where the research will be conducted and how long the subjects will be participating and
- Identify the personnel, including the principal investigator, who will participate in the project and their qualifications for participation.

Data Analysis:

- Describe the type of analysis and justification for the analytical approach

Instruments

List all questionnaires, tests, instruments and give a brief description of it. Copies of all instruments must be provided in Appendix C.

Please note the following regarding the content of questionnaires:

<i>If the instrument contains questions about:</i>	<i>The following must be done:</i>
Abuse	Include a statement in the consent document regarding what instances might require mandatory reporting to outside officials.
Illegal Activity	Describe (in the proposal and consent form) how confidentiality or anonymity will be protected; can these records be subpoenaed? If so, subjects must be informed.
Suicidal Tendencies or Thoughts	You must provide a list of counseling resources to all participants

Any time you are asking subjects about personal information (depression, sexual abuse, eating disorders, etc.) and can minimize the risk from research participation by providing resources (pamphlets, list of agencies, list of coping skills, etc.), you should do so.

Informed Consent

Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

An investigator shall seek the consent of the prospective subject, or the subject's legally authorized representative under circumstances that:

- provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate
- minimize the possibility of coercion or undue influence
- present the information to the subject or the representative in language understandable to the subject or representative
- do not include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The informed consent process shall be documented for review by the committee by the use of a written consent document that embodies the elements of informed consent enumerated below (see Basic Elements of Informed Consent). This form should be approved by the IRB and signed and dated by the subject or the subject's representative. A copy shall be given to the person signing the form. For readability, all consent forms should be composed in 12-point font.

In some research, the requirement for a signed consent form for some or all subjects may be waived by the IRB if it finds either:

- a). That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with research, and the subject's wishes will govern; or
- b). That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where a signed consent form is not required, the IRB will require the submission of a copy of the oral 'text' that will be presented to subjects, and you may be required to provide subjects with a written statement regarding the research.

Basic Elements of Informed Consent

In seeking informed consent the following information must be provided to each subject:

- ❑ A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- ❑ A description of any reasonably foreseeable risks or discomforts to the subject;
- ❑ A description of any benefits to the subject or to others which may reasonably be expected from the research;
- ❑ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- ❑ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- ❑ For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- ❑ Please Note: Unless additional arrangements have been made, all Consent Forms used at Ohio University must include the following waiver:

I agree that all known risk to me have been explained to my satisfaction and I understand that no compensation is available from Ohio University and its employees for any injury resulting from my participation in this research.

- ❑ An explanation of whom to contact for answers to pertinent questions about:
 - the research - Researcher and Advisor (if applicable)
 - research subjects' rights - Director of Research Compliance, (740) 594-0664
 - whom to contact in the event of a research-related injury to the subject; and
- ❑ 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 discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

The following additional elements may be required, as appropriate:

- ❑ A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- ❑ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

- ❑ Any additional costs to the subject that may result from participation in the research
- ❑ The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- ❑ A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- ❑ The approximate number of subjects involved in the study

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above if the research could not practicably be carried out without the waiver or alteration; and provided the IRB finds and documents that:

- a). The research involves no more than minimal risk to the subjects;
- b). The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- c). Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Deception or Incomplete Disclosure

In some research, particularly behavioral research, investigators plan to withhold information about the real purpose of the research or even give subjects false information about some aspect of the research. This means that the subject's consent may not be fully informed. If deception or incomplete disclosure is necessary for your research, please describe why it is necessary. You must provide subjects with additional information after their participation is complete. This process is referred to as debriefing. A copy of your debriefing information must be included as **Appendix D**.

Agreements

Approval: You may not begin your research until it is approved by the IRB. Approvals will be granted for no more than one year.

Renewal: To renew a previously approved protocol, you must submit a Periodic Review Form 60 days prior to the expiration date of your approval.

Changes: You must submit any proposed changes to the research to the IRB and receive approval of changes prior to implementation.

Notification of Adverse Effects: You must submit notification of any adverse events to the IRB for review.

Suspension of Approval: The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

Appendix A – Exempt Categories

Exemption Status

If the project director believes that the research is exempt from the need for the IRB review and approval, a completed project outline form must be submitted. A decision on the request will be confirmed in writing and will be made as soon as possible after receipt of the request.

It is the responsibility of the project director to obtain approval or a determination of exempt status **before** the research activity is initiated. Research activities in which the only involvement of human subjects will be in one or more of the following categories may be given an exempt determination. There are three protected classes of subjects for which exemptions are not permitted or are permitted in limited categories (see below).

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 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), 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 the 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 (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(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) 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.

Protection for Special Classes of Subjects:

Research involving prisoners, pregnant women, fetuses and human in vitro fertilization must receive a full review by the IRB. Research involving minor children (under the age of eighteen) may be exempt only as it applies to categories 1, 3, 4, 5 and 6 above. Research involving minors which falls under category 2 above may be exempt for educational tests and observation (when the investigator does not participate in the activities being observed). Research involving survey or interview procedures may not be exempted for children under the age of 18.

Appendix B – Expedited Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an

invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and [\(b\)\(3\)](#). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.