

Institutional Review Board

Policy and Guidelines

Primary Author: Dennis M. Sullivan, MD, MA (Ethics)

(Revised: 2/5/2018)

I. INTRODUCTION

The Institutional Review Board (IRB) is a faculty panel whose task is oversight and ethical review of any and all research involving human participants conducted by faculty, staff, administrators, and students under the purview of Cedarville University (CU).

Such oversight springs from our common commitment to the principles of human value and human dignity arising from God's Word (Psalm 8; Genesis 1:26-28; Psalm 139: 13-16). Our respect for human life at all stages, from conception until death, requires the implementation of careful, concise internal standards to protect individuals participating in research initiatives from intentional or unintentional harm, and to affirm their value as fellow bearers of God's image.

In the history of the United States, research on human participants has not always been conducted in an ethical manner. Certain highly publicized abuses led to the 1979 Belmont Report, which specifically outlines the principles for the treatment of human research participants. In 1981, based on this report, the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) established regulatory guidelines for such research, which are still in place to this day. The Cedarville IRB policy is designed to be compliant with DHHS and FDA regulations.

The ethical principles undergirding this IRB policy include human autonomy, beneficence, nonmaleficence, and justice. Autonomy requires that every person has the right to make his or her own decisions about participation in research. This requires complete disclosure of the risks and benefits of such participation. Those with diminished autonomy must be protected by the informed consent of an appropriate surrogate.

Beneficence and nonmaleficence require that no research study cause intentional or preventable injury, loss of function, or undermining of personal dignity. The potential benefits of participation for research participants must outweigh the risks. There must also be no foreseeable violation of privacy or exposure to embarrassment or legal liability. Justice (sometimes amplified by the phrase "distributive justice") requires that all participants be treated in the same manner, regardless of gender, ethnicity, socio-economic status, religion, or other non-relevant factors.

Finally, certain vulnerable special groups require extra protection and consideration. These include pregnant women, the unborn, children, prisoners, and those with physical and mental disabilities. Research involving such groups will require special scrutiny. For all research participants in the healthcare arena, strict adherence to principles of confidentiality of private information must be maintained, in accordance with HIPAA regulations (Health Insurance Portability and Accountability Act of 1996).

II. ORGANIZATION AND PERSONNEL

The Institutional Review Board (IRB) is a diverse committee of men and women with expertise in different scientific, non-scientific, and ethical issues. This diversity in constituent members and their fields of investigation is essential to foster a comprehensive approach to protecting the God-given rights and privileges of research participants. Therefore, the IRB of Cedarville University shall have at least six members, with different academic and cultural backgrounds to provide complete and thorough review of research activities commonly conducted at Cedarville University. These members shall be appointed by the chairperson of the IRB for a three year renewable term. After serving three years, the same members may be reappointed to the IRB.

The IRB will report to and is accountable to an Institutional Official (IO). The IO may serve in an advisory role to the committee, at the discretion of the chair, but may not vote. The IO is responsible for appointing the chairperson of the IRB, who shall be an active researcher and is appointed for a three year renewable term. Currently, the IO for the Cedarville University IRB is the Dean of the School of Pharmacy.

Members of the IRB of Cedarville University shall be chosen according to the following guidelines:

1. The IRB shall always include persons knowledgeable in the fields of human subjects research conducted at Cedarville University.
2. If the IRB reviews research that involves vulnerable categories of participants, such as children, prisoners, pregnant women, handicapped, or persons with cognitive disabilities, the committee will consider including one or more knowledgeable and/or experienced individuals from that category of participants.
3. The IRB shall include at least one member whose primary concerns are in the scientific area, at least one member whose primary concerns are in nonscientific areas, and one member whose primary concern is in biblical/ethical areas.

4. The IRB shall include at least one “outside member” who is not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution.
5. An IRB committee member with a potential conflict of interest in a particular research project shall not participate in the review of that project, but may provide the committee with needed information.
6. The IRB may, at its discretion, invite additional individuals with competence in special areas to assist in the review of specific research projects. Such invited guests may not vote with the IRB.

III. CATEGORIES OF RESEARCH REQUIRING IRB APPROVAL

1. Administrative (Exempt) Review

Cedarville University requires that all research involving human participants receive review and approval before the research begins. However, there are specific categories of research that are exempt from continuing IRB review. Such proposed research must undergo an initial review and be approved as “exempt.” Research activities in which the only involvement of human participants will be in or more of the following categories may be considered for administrative (exempt) review. The exempt categories do not apply to research involving prisoners.

- A. Research conducted in established or commonly accepted educational settings, or involving normal educational practices, such as:
 - (1) Research on regular and special education instructional strategies, *or*
 - (2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
 - (1) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; *and*
 - (2) Any disclosure of the human participants’ responses outside of the research could reasonably place participants at risk of criminal or civil liability, or be damaging to participants’ financial standing, employability, or reputation.
 - (3) Note: Exemption category (B) does not apply to research with minors, except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed.

- C. 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:
 - (1) The human participants are elected or appointed public officials or candidates for public office; or
 - (2) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter.
- D. 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 participants cannot be identified, directly or through identifiers linked to the participants.
- E. 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:
 - (1) Public benefit or service programs;
 - (2) Procedures for obtaining benefits or services under those programs;
 - (3) Possible changes in or alternatives to those programs or procedures; or
 - (4) Possible changes in methods or levels of payment for benefits or services under those programs.
- F. Taste and food quality evaluation and consumer acceptance studies:
 - (1) If wholesome foods without additives are consumed, *or*
 - (2) If a food is consumed containing a food ingredient at or below the level and for a use found to be safe, or an 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.

If it is determined that a research project falls into the Administrative (exempt) Review Category, the primary reviewer for that application will be The IRB chair or a committee representative selected by the chair. The faculty sponsor or lead investigator will be notified via email of any modifications and/or additional information needed in order to complete the review. Once the project has been approved, the IRB will notify the faculty sponsor and/or lead investigator via email.

2. Expedited Review

Research activities that (1) present no more than minimal risk to human participants, and (2) involve only procedures listed in one or more of the following categories (see categories 1-9 below) may be reviewed by the IRB through the expedited review process. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure. The specific circumstances of the proposed research must involve no more than minimal risk to human participants.

Under an expedited review procedure, the review may be carried out by the IRB chair or by one or more experienced reviewers designated by the chair from the members of the IRB. In reviewing the research, committee members 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 a full committee review.

Note: The categories in this list apply regardless of the age of participants, except as noted. The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability, or be damaging to the participants. Such damage may include financial standing, employability, insurability, reputation, or social stigma, unless reasonable and appropriate protections are implemented. The risks related to invasion of privacy and breach of confidentiality should be no greater than minimal.

The expedited review procedure may not be used for classified research involving human participants. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review, expedited or full board review, utilized by the IRB. Categories A through G pertain to both initial and continuing IRB review.

A. Clinical studies of drugs and medical devices only when either condition (1) or (2) is met:

(1) Research on drugs for which an investigational new drug application, e.g., Code of Federal Regulations (CFR), Title 21, Part 312, is not required.¹ (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.)

(2) Research on medical devices for which:

- i. an investigational device exemption application (21 CFR Part 812)¹ 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.

B. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- (1) From healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, 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*
- (2) From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

C. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

- (1) Hair and nail clippings in a non-disfiguring manner;
- (2) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- (3) Permanent teeth if routine patient care indicates a need for extraction;
- (4) Excreta and external secretions (including sweat);
- (5) Un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
- (6) Placenta removed at delivery;
- (7) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- (8) 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;
- (9) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- (10) Sputum collected after saline mist nebulization.

- D. 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. Note: 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:
- (1) 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 participant or an invasion of the participant's privacy;
 - (2) Weighing or testing sensory acuity;
 - (3) Magnetic resonance imaging;
 - (4) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;
 - (5) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate, given the age, weight, and health of the individual.
- E. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as medical treatment or diagnosis). Note: Some research in this category may be exempt from Health and Human Services (HHS) regulations for the protection of human participants: 45 CFR 46.101(b)(4).² This listing refers only to research that is not exempt.
- F. Collection of data from voice, video, digital, or image recordings made for research purposes.
- G. 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).² This listing refers only to research that is not exempt.

- H. Continuing review of research previously approved by the convened IRB as follows:
- (1) Where:
 - i. the research is permanently closed to the enrollment of new participants;
 - ii. all participants have completed all research-related interventions; and
 - iii. the research remains active only for long-term follow-up of participants;

or
 - (2) Where no participants have been enrolled and no additional risks have been identified; *or*
 - (3) Where the remaining research activities are limited to data analysis.
- I. Continuing review of research not conducted under an investigational new drug application or investigational device exemption, where categories B through H do not apply, but the IRB has determined and documented that the research involves no greater than minimal risk and no additional risks have been identified.

An expedited review procedure consists of a review by the IRB Chairperson and/or by one or more experienced reviewers designated by the Chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.²

3. Full Board Review

Except when an expedited review procedure is used, review of proposed research will occur at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in non-scientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. The IRB shall require that information given to participants as part of informed consent is in accordance with 45 CFR 46.116.² The IRB may also require additional information be given to the participants when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of participants. The IRB shall require documentation of informed consent or may waive documentation in accordance with CFR 46.117.² Other required documents for full review include a description of the recruitment/selection of participants, a project description, a copy of all recruitment tools, a copy of all instruments, copies of approval from

other IRB's where applicable, copies of any additional materials that will assist the Board in its review, and copies of grant proposals.

The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. The IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

IRB Policy References:

1. U.S._Government_Publishing_Office. Title 21. *Code of Federal Regulations* 2018; https://www.ecfr.gov/cgi-bin/text-idx?SID=207275ddc1bff50f032da182daddc166&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl.
2. OHRP. Code of Federal Regulations. *Title 45 Part 46* 2010; <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>.