

BY-LAWS
OF THE
INDIANA UNIVERSITY EAST
INSTITUTIONAL REVIEW BOARDS

Article I. Name

The name of the committee is the Indiana University East Institutional Review Board (herein referred to as “the Board” or “IRB”)

Article II. Object

The Board is to ensure the observance of the Federal Policy for the Protection of Human Subjects, published in the Federal Register, Vol. 56, No. 117, June 18, 1991, beginning at 28001 (the “Regulations”), and observance policies of Indiana University concerning research involving human subjects.

Article III. Authority

The Board is established under and pursuant to the letter of assurance, ~~dated December 1, 2003~~ ~~(~~expires~~ ~~expires~~ - September 16, 2011) December 1, 2006~~ between Indiana University and the Department of Health and Human Services (HHS), as an institutional review board (IRB) under title 45 CFR, 46.103 of the HHS Regulations, empowered to:

1. Review all funded and unfunded research by faculty, students, or staff that involves the use of human subjects *prior* to the beginning of the research.
2. Determine the type of review (exempt, expedited, or full committee) the research requires.
3. Disapprove, modify, or approve research proposals based upon the consideration of the protection of human subjects.
4. Suspend or terminate a research project.
5. Require progress reports and perform such monitoring it deems necessary.

Article IV. Relationship to the University

The Board shall be directly responsible to the Office of the Vice President of Research and through that office to the President of the University. The Board shall coordinate its actions and policies with those of the Indiana University Policy Committee on the Protection of Human Subjects in Research, a unit that is concerned with policy issues rather than individual projects. The chairperson of the Indiana University East Institutional Review Board shall be members of the Indiana University Policy Committee on the Protection of Human Subjects in Research.

Indiana University East shall provide needed clerical support, files, copying facilities, supplies, equipment, and space.

Article V. Membership

The Membership of the Board shall consist of no fewer than five (5) persons. The members shall be appointed by the Indiana University East Chancellor or designee (e.g. Vice Chancellor of Academic Affairs) and approved for membership by the Vice President of Research. In making appointments to the Board, the appointing authority shall take such reasonable steps as necessary to achieve a membership with diversity in race, sex, and professional qualifications. At a minimum, to assure diversity, the membership of the Board shall include:

1. a person whose primary concerns are in scientific areas, and;
2. a person whose primary concerns are in non-scientific areas, and;

3. a person (community representative) who is not otherwise affiliated with the institution and who is not a member of the immediate family of a person affiliated with the institution.

The Board members will be appointed every two years. A member may be reappointed for an unlimited number of terms. If for any reason a member is unable to complete a full term of membership, the chair may request the Indiana University East Chancellor appoint another member to the Board, contingent on approval by the Vice President of Research.

Members receive no compensation. Liability insurance shall be provided by the University under its umbrella coverage.

Article VI. Officers

The Indiana University East Chancellor (or designee) shall appoint a chairperson or two (2) co-chairs of the Board, here after identified as chair. The chair shall be appointed annually. The chair may be reappointed for an unlimited number of terms. The chair may appoint an acting chair to function in his or her absence. The chair shall be a voting member of the committee.

Article VII. Meetings

The Board shall meet at least monthly throughout the year unless a meeting is cancelled by the chairperson for good cause. Notice of the time and place of the meeting shall be given at least one week in advance. The chairperson may call a special meeting upon three days written and/or telephone notice.

A majority of the membership of the Board shall constitute a quorum, which shall include at least one member whose primary concerns are in nonscientific areas. Members who leave the meeting cannot be counted for determination of a quorum.

Minutes of each meeting shall be kept by the Board chairperson. Attached to the minutes should be a list of the proposals that received approval since the previous meeting.

Article VIII. Decisions of the Board

Decisions by the Board shall be by majority vote of members in attendance at the meeting. A member having significant conflicting interest in a matter before the Board shall not vote on that matter. When a member is barred from voting because of a conflicting interest, said member shall not be counted in determining the number of votes needed for a majority, notwithstanding that the presence of said member has been counted to determine a quorum. Such member shall be absent from the room during deliberation and vote. Voting shall proceed openly, after an opportunity for full discussion and debate has been afforded. Each member of the board shall have one vote.

Business may be conducted by telephone or teleconferencing whereby all members can hear each other simultaneously. Prior to telephone or teleconferencing, board members should receive copies of the proposals under consideration during the telephone or teleconference meeting.

The Board shall be empowered to approve or disapprove a proposal. It may table proposals whose review requires more information.

In the review process, the Board shall have as its primary criteria: the degrees of physical, social, and psychological risk; the need for and degree of confidentiality; the presence, absence or adequacy of informed consent; and the protection of particularly vulnerable subjects. The Board shall not concern itself with the quality of the proposal or its methodology unless more than minimal risk is involved, in which case quality, and methodology are appropriately considered in assessing the risk-benefit ratio.

Individuals whose proposals have been reviewed shall be notified of the Board's decision in writing within one week. The Board shall retain all proposals.

There shall be no mechanism for appeals by investigators. An investigator may re-submit a proposal once it has been modified in such a way as to remove the Board's objections.

Article IX. Subcommittees

The chairperson may, from time to time, appoint subcommittees to ask members to execute various duties related to the objectives and policies of the Board including, but not limited to:

1. assisting the chair in preparation of the agenda for regular meetings of the Board;
2. performing periodic ongoing review of investigations previously reviewed by the Board or any of its subcommittees, including review of terminated investigations;
3. reviewing research proposals to determine whether such proposals may obtain expedited review by a subcommittee;
4. performing expedited review of research proposals;
5. assisting the chair in reviewing modifications of previously approved research projects to determine whether such modifications warrant reconsideration of projects for action by the Board or subcommittee;
6. reviewing reports of adverse and/or unexpected developments in previously approved research projects to determine whether such developments warrant reconsideration of a project by the Board or a subcommittee;
7. performing emergency review of research proposals when, in the opinion of the chair, the employment of any other approval procedure may, because of the time required, seriously impair the mission of the University or the medical or other interests of any subject or potential subject of research;
8. granting final approval to research proposals, upon a determination that conditions required for approval by the Board or a subcommittee have been met.

Subcommittees shall be composed only of Board members and requested consultants. Subcommittees may be comprised of any number of Board members. Subcommittees shall report any action take to the next regular meeting of the full Board.

Article X. Exempt and Expedited Review

In accordance with the 46.101b and 46.110 of the Regulations, the chairperson, or some other member of the Board designated by the chairperson shall be empowered to perform exempt and expedited review: approving proposals that appear to present no more than minimal risk. A proposal that appears to present more than minimal risk or that involves research on illegal behavior, sexual behavior, or alcohol/drug use (which is not otherwise exempt under the Federal regulations) shall not receive exempt or expedited review but shall be referred to the Board.

The chairperson may only disapprove an exempt or expedited application if the investigator: (1) fails to respond to requests for revisions or additional information within a time period of two months or (2) proceeds to collect data without an approval. Such an application shall be noted as not approved with the reason stated. Otherwise, a research activity may be disapproved only after a review by the full Board.

Article XI. Participation of Non-Members

The meetings of the Board may be attended by persons who are not members with the consent of the chairperson. A person who is not a member of the Board shall, with the consent of the chair, be permitted to express views or opinions and offer comments, explanatory or otherwise, to the Board. Consultants with competence in special areas may be invited to assist in the reviews and research issues that require expertise different from that available on the Board.

Article XII. Monitoring

In accordance with the regulations and policies of the Federal Departments/Agencies and of Indiana University, the Board shall have the authority to monitor those research projects which the Board judges to involve more than minimal risk to the subjects. Such monitoring may include requesting periodic written or oral reports or unannounced site visits.

The Board will review expedited and full Board studies on at least an annual basis. If a study is inadvertently terminated by the investigator, it may be reactivated within 60 days without having to submit a newly complete application to the Board as a new study.

The chairperson of the Board may delegate authority to one or more experienced members of the Board to conduct and approve uneventful continuing reviews of expedited studies, and termination reports of uneventful full review studies. Full Board studies must have the continuing review conducted by the full Board.

The chairperson or designees will have authority to review amendments to exempt and expedited studies. Amendments to full Board studies that encompass minor changes or minimal risk may be reviewed by the chairpersons. Amendments to full Board studies that encompass more than minimal risk must be reviewed by the full Board.

In the event that the Board (1) becomes aware of any serious or continuing noncompliance with the Regulations or the policies of the Board, or (2) suspends or terminates a Board approval, written notice of such noncompliance, suspension, or termination will be given to the Institution by way of the IU East Vice Chancellor of Academic Affairs and the Vice President of Research, to the appropriate Federal funding agency, and to the Office for Human Research Protection within seven (7) working days.

XIII. Records

The chairperson shall see that proper records are maintained, specifically: (1) Minutes of each meeting with the names of those present, the proposals acted upon, a summary of the discussion of controversial issues, other Board actions and discussion, and a list of approved exempt, expedited, and amended proposals; (2) Copies of proposals Summary Safeguard Statement, documentation of review, notification of Board action, and any other relevant data; (3) Correspondence; (4) Reference books and journal articles.

Board members will be provided with the minutes of the last meeting in advance of the next meeting. The minutes shall be kept in perpetuity; all proposals shall be kept for three years after the completion of the research.

XIV. Amendments

Amendments to these Bylaws may be proposed by a member of the Board. The amendment may be adopted by majority vote.