BYLAWS OF THE
IUSB INSTITUTIONAL REVIEW BOARD FOR THE
PROTECTION OF HUMAN SUBJECTS

Article I. NAME
The name of the board is the Indiana University South Bend Institutional Review Board (hereinafter called "SB-IRB").

Article II. OBJECT
The SB-IRB is to ensure 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 of policies of Indiana University concerning research involving human subjects. The SB-IRB will review all research conducted by our faculty, students, or staff that directly, or indirectly, involves human subjects.

Article III. AUTHORITY
The SB-IRB is established under and pursuant to the letter of assurance which expires on September 16, 2011, between Indiana University and the Department of Health and Human Services (HHS), as an institutional review board (IRB) under 45 CFR §46.103 of the HHS Regulations, empowered to:
1) Review all funded and unfunded research by faculty, staff, or students that involves the use of human subjects, prior to the beginning of the research.
2) Determine the type of review (exempt, expedited, or full board) the research requires.
3) Disapprove, modify, or approve research protocols based upon consideration of the protection of human subjects.
4) Suspend or terminate a research project.
5) Require progress reports and perform such monitoring, as it deems necessary.

Article IV. RELATIONSHIP TO THE UNIVERSITY
The SB-IRB shall be directly responsible to the IU Vice President for Research. The SB-IRB shall coordinate its actions and policies with the University Office of Research Administration which supports a University-wide IRB policy committee. The Chairperson and the SB-IRB Administrator shall be members of the University-wide IRB Policy Committee.

The campus shall provide the SB-IRB with needed clerical support, files, copying facilities, supplies, equipment and space.

Article V. MEMBERSHIP
The SB-IRB’s membership, appointed by the IU Vice President for Research, shall consist of:
1) Individuals with expertise in those fields which generate the most research protocols.
2) An individual with primary concerns in non-scientific areas.
3) An individual not affiliated with the University and not part of the immediate family of a person affiliated with the University.

In making appointments to the Committee, the appointing authority shall take such reasonable steps as necessary to achieve a membership with diversity in race, gender, cultural backgrounds, and professional qualifications. The members shall be appointed for a two-year term, may be reappointed, and shall be removed only for stated cause. Failure to attend four (4) consecutive meetings may constitute cause for removal and replacement by another individual designated by the IU Vice President for Research. The IU Vice President for Research may also appoint alternates who will be invited to attend all meetings and training sessions and who may serve in the place of absent members as necessary.

Members receive no compensation. The University shall provide liability coverage under its umbrella coverage.

The SB-IRB shall consist of no fewer than five members. The IRB Administrator may serve as a voting member of the committee if appointed by the IU Vice President for Research.

**Article VI. OFFICERS**

The IU Vice President for Research shall appoint a chairperson of the SB-IRB. The chairperson shall be a voting member of the SB-IRB. The chairperson may appoint an acting chairperson to function in his or her absence. Other officers may be appointed to carry out activities of the board.

**Article VII. MEETINGS**

The IRB shall meet at least monthly throughout the year unless a meeting is cancelled by the chairperson for good cause. Notice of time and place shall be given at least one week in advance. The chairperson may call a special meeting upon three (3) days written or telephone notice.

Minutes of each meeting shall be kept by the SB-IRB Administrator. Attached to the minutes shall be a list of the protocol actions taken since the previous meeting.

A quorum shall consist of a simple majority, including at least one member whose primary concerns are non-scientific. Members who leave the meeting cannot be counted for determination of a quorum.

**Article VIII. DECISIONS OF THE IRB**

Full review by the SB-IRB shall consist of all members, or alternates, that will be attending the meeting reviewing each protocol.

In emergencies where time is a serious problem, the chairperson shall be empowered to circulate a copy or copies of the protocol to the Committee for review and conduct a telephone conference meeting whereby the members can hear each other simultaneously.

The SB-IRB shall be empowered to approve or disapprove a protocol, and to give conditional approval (i.e., approval if the investigator agrees to follow the SB-IRB requirements
for protecting subjects). It may also table protocols whose review requires more information.

In the review process the SB-IRB 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 SB-IRB shall not concern itself with the quality of the protocol 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.

In deciding whether a protocol shall be approved, disapproved, tabled, or conditionally approved, the SB-IRB shall seek consensus. The action taken shall be determined by a simple majority of those attending the meeting. A member or alternate having conflicting interest in a matter before the SB-IRB shall not vote on that matter. When a member or alternate is barred from voting because of a conflicting interest, said member or alternate shall not be counted in determining the number of votes needed for a majority, notwithstanding that the presence of said member or alternate has been counted to determine a quorum. Such members shall be absent from the room during the deliberation and vote except for the purpose of providing information requested by the SB-IRB.

Each SB-IRB member shall have one vote. Voting shall proceed openly, after an opportunity for full discussion and debate has been afforded.

Individuals whose protocols have been reviewed shall be notified of the SB-IRB decision in writing within one week.

The SB-IRB shall retain all protocols. With regard to protocols requesting funding, notification of the SB-IRB’s decision will be given to the Sponsored Research Service Office with the Office of the Vice President for Research.

The SB-IRB, upon the request of an investigator or on its own initiative, may reconsider any protocol and reverse its own determination or that of a subcommittee.

An investigator may re-submit a protocol for re-review once it has been modified in such a way as to remove the SB-IRB’s objections. There shall be no mechanism for appeal by investigators beyond the IRB.

Article IX. SUBCOMMITTEES

The chairperson shall, if necessary, appoint subcommittees from the SB-IRB membership to execute various duties related to the objectives and policies of the IRB.

A few academic units generate a large number of research protocols, particularly student research protocols. The SB-IRB shall encourage the formation of departmental/academic unit screening committees to review these protocols, to identify issues likely to concern the SB-IRB, prior to forwarding them to the IRB. At least one member of each such committee must be a regular member of the IRB.

Article X. EXEMPT AND EXPEDITED REVIEW

In accordance with §46.101b and §46.110 of the Regulations, the chairperson, or some other members of the SB-IRB designated by the chairperson, shall be empowered to perform exempt and expedited reviews: approving protocols which appear to present no more than minimal risk. A protocol which appears to present more than minimal risk or which 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 full SB-IRB.

The SB-IRB will terminate any project where the PI proceeds to collect data without IRB approval.

Article XI. PARTICIPATION OF NON-MEMBERS

Meetings of the SB-IRB may be attended by persons who are not members with the consent of the chairperson. Such persons ordinarily would be (1) persons with special expertise needed by the SB-IRB, (2) persons who have submitted protocols which in the SB-IRB’s opinion require oral explanation and questioning, (3) persons whose research in progress requires monitoring, or (4) office staff.

Article XI. MONITORING

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

The SB-IRB will conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. In some circumstances, a shorter review interval may be required. The IRB will require review more frequently than annually for those studies deemed “high-risk.” If a study is inadvertently terminated by the investigator, it may be reactivated within 60 days without having to submit a newly completed application to the SB-IRB as a new study.

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

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

Article XII. RECORDS

The chairperson or IRB Administrator shall see that proper records are maintained, specifically: (1) Minutes of each meeting with the names of those present, the protocols acted upon, a summary of the discussion of controverted issues, other SB-IRB actions and discussion, all vote counts, and a list of exempt, expedited, and amended protocols; (2) Copies of protocols' Summary Safeguard Statement, Documentation of Review, notification of the SB-IRB action and any other relevant data; (3) Correspondence; (4) Reference books and journal articles.

SB-IRB 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 protocols shall be kept for three years after completion of the research.

**Article XIII. SB-IRB REQUIREMENTS OF THE INVESTIGATOR**

For protocols requiring full review the SB-IRB shall require the investigator to fill out and sign the Documentation of Review and Approval and Summary Safeguard Statement and submit these documents two weeks in advance of the SB-IRB meeting.

The Summary Safeguard Statement contains a check-list whose purpose is to ascertain the type of review required under existing Regulations. The investigator shall fill out the required parts of the Summary Safeguard Statement and append such supporting documents, as instructed in the application packet, so as to fully inform the SB-IRB as to the essentials of the proposed research.

These shall include:

- Title
- Principal Investigator and Co-Investigators with address, telephone number, and signature
- Student/Faculty status (if not faculty, name of faculty sponsor and signature)
- Purpose
- Proposed or current funding agency
- Description and approximate number of subjects
- Description of research design and procedures
- Description of risks and benefits
- Description of what compensation and/or services are available in case of significant physical or mental health issues resulting from the research participation (if applicable)
- Relationship of researcher to subject (if any)
- Statement that participation is voluntary and may be discontinued at any time without prejudice or penalty
- Provisions for obtaining informed consent (and/or parent/guardian consent if needed)
- Provisions for maintaining confidentiality