

**BYLAWS OF THE
IUPUI AND CLARIAN HEALTH PARTNERS (IUPUI/CLARIAN)
INSTITUTIONAL REVIEW BOARDS**

Article I. Name

The name of the committees shall be the Institutional Review Boards (hereinafter referred to as "the Board" or "Board.")

Article II. Object

- A. The object of the Board activities is to ensure compliance with and fulfillment of 1) the policies contained in IUPUI Standard Operating Procedures and the document entitled "IRB Instruction Packet for Submitting a Research Protocol Involving Human Subjects" and 2) regulations relating to the Board, which have been promulgated by the United States, the State of Indiana, Indiana University, or other appropriate authorities.
- B. The Board is charged with the review and acceptance where appropriate of the minutes of the subcommittees.
- C. Those subcommittees which are duly constituted and created under these bylaws shall have those powers and functions delegated by the Board and shall report to the Board as the Board determines.

Article III. Members

- A. The membership of the Board shall consist of no less than five (5) persons.
- B. IUPUI Policy: The members shall be appointed by the Vice Chancellor for Research at Indiana University-Purdue University Indianapolis (IUPUI). The Vice Chancellor for Research shall appoint a reasonable number of alternates who may serve in the place of

absent members to the Board as necessary. The Chair, or the Chair's designee, shall select an alternate for an absent member so as to assure, insofar as possible, that the professional diversity of the members and alternates in attendance at the meeting reflects that of the Board membership.

- C. Methodist Policy: The Chair will make recommendations for the appointment of the regular members of the IRB. The Chair shall make recommendations for the appointment of a reasonable number of alternates who may serve in the place of absent members to the Board as necessary. These appointment recommendations will be then forwarded to the Vice Chancellor for Research at IUPUI. The Vice Chancellor for Research shall then appoint regular and alternate members. The Chair, or the Chair's designee, shall select an alternate for an absent member so as to assure, insofar as possible, that the professional diversity of the members and alternates in attendance at the meeting reflects that of the Board membership.
- D. 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.
- E. 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.
- F. Decisions made by the Board are made by a majority vote of the voting members in attendance at the Board meeting. A majority of the Board constitutes a quorum which must include at least one member whose primary concerns are in nonscientific areas.

Frequent absence of non-affiliated (community) members is not acceptable. If quorum fails during a meeting due to a lack of a majority of Board members being present or an absence of all non-scientific members, the Board cannot take action or vote until the quorum is restored. An IRB can also lose its quorum when members with a conflicting interest leave the room for deliberation and voting.

- G. The Board members and alternates will be appointed biennially. A member or alternate may be reappointed for an unlimited number of terms.
- H. If for any reason a member is unable to complete a full term of membership, the Chair or the Chair's designee may request the Vice Chancellor for Research to appoint another member or alternate.

Article IV. Officers

- A. IUPUI Policy: The Vice Chancellor for Research (upon recommendation from the RCA Director after input from the research community) referred to in Article III-B shall appoint a Chair of the Board biennially. The Chair may be reappointed for an unlimited number of terms.

Methodist Policy: The Executive Vice President of Academic Affairs at Clarian, with appropriate consultation with the RCA Director and the research community, will make recommendations for the appointment of the Chair. Such recommendations will be forwarded to the Vice Chancellor for Research. The Vice Chancellor for Research shall appoint the Chair of the Board biennially. The Chair may be reappointed for an unlimited number of terms.

- B. IUPUI Policy: The Vice Chancellor for Research (upon recommendation from the RCA Director after input from the research community) shall appoint one or more Co- or Vice

Chairs biennially, who shall preside over meetings in the absence of the Chair. The Co- or Vice Chair(s) may be reappointed for an unlimited number of terms.

Methodist Policy: The Executive Vice President of Academic Affairs at Clarian, with appropriate consultation with the RCA Director and the research community, will make recommendations for the appointment of the Director of the Methodist Research Institute to serve as the Vice Chair. Such recommendations will be forwarded to the Vice Chancellor for Research. The Vice Chancellor for Research shall appoint the Vice Chair who shall preside over meetings in the absence of the Chair. The Vice Chair may be reappointed for an unlimited number of terms.

- C. The Chair, or in the Chair's absence, the Co- or Vice-Chair(s), shall perform the duties prescribed by these bylaws.
- D. Other individuals may be appointed to carry out the activities of the Board.
- E. The Board officers may, from time to time, appoint a member to temporarily fulfill their functions.
- F. The Chair and Co- or Vice-Chair(s) shall be members of the Board.
- G. The Chair and Vice Chair are expected to have the background and reputation that engenders respect from the IRB members, the IRB staff, investigators, research coordinators and IUPUI/Clarian administration.
- H. The Chair and Vice Chair are expected to have the leadership, management and interpersonal skills that allow them to be role models as well as fair and impartial leaders of the IRB.
- I. The Chair and Vice Chair are expected to have an in depth understanding of the ethical issues, institutional policy, and federal, state and local regulations that are applicable to research that is reviewed by the IRB.

- J. The Chair and Vice Chair will serve on the IRB Executive Committee to develop and implement research policies and projects, and develop sound education programs for the IUPUI/Clarian professionals engaged in research.
- K. When applicable, the Chair or his/her designee will seek guidance from IUPUI/Clarian legal counsel.
- L. The Chair will have primary responsibility for conducting the IRB meetings to ensure that they are efficient and effective. The Vice Chair will have this responsibility in the Chair's absence.
- M. The Chair and Vice Chair will be full members of the IRB and will vote.
- N. The Chair and Vice Chair will assist the IRB administrative staff, as needed, in drafting letters from the IRB to investigators regarding IRB decisions.
- O. The Chair and Vice Chair will work with IRB members, institutional officials, and investigators to ensure that the rights and welfare of research subjects are adequately protected.
- P. The Chair will be responsible for reviewing all research that can be categorized as "Expedited" or will delegate this responsibility to one or more experienced members of the IRB.

Article V. Meetings

- A. The Board shall ordinarily meet once a month. The time, date, and place of the meetings shall be determined by the Chair or the Chair's designee and each member shall be notified in writing of the meeting schedule.
- B. The Chair may call a meeting at other than the scheduled monthly interval.

- C. 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. Determination of a quorum shall be subject to the following exceptions:
 - 1) a number of members and alternates equal to a majority of the membership shall constitute a quorum;
 - 2) consultants shall not be counted toward the establishment of a quorum.

Article VI. Decisions of the Board

- A. Decisions by the Board shall be by majority vote of members and alternates in attendance at the meeting. A member or alternate having a conflicting interest in a matter before the Board 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 member shall be absent from the room during the deliberation and vote.
- B. Consultants shall not have voting rights on the Board.
- C. Voting shall proceed openly, after an opportunity for full discussion and debate has been afforded.
- D. Circumstances may occasionally warrant conducting IRB meetings via telephone conference call. IRB meetings conducted via telephone conference call will be considered convened when:
 - 1) each participating IRB member has received all pertinent material prior to the meeting and,
 - 2) each participating IRB member can actively and equally participate in the discussions of all protocols.

When IRB meetings are conducted via telephone conference call, the above two conditions will be documented in the IRB meeting minutes.

Article VII. Subcommittees

- A. The Chair may, from time to time, appoint subcommittees or 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 a 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.

- B. Subcommittees shall be composed only of Board members or alternates and requested consultants.
- C. Subcommittees may be comprised of any number of Board members or alternates, including the Chair, except as provided in Sections D of this article.
- D. A subcommittee appointed pursuant to Section A(7) of this article shall have at least five members.
- E. Subcommittees shall report any action taken to the next regular meeting of the full Board.

Article VIII. Action on Research Proposals

- A. The Board or subcommittee shall review research proposals submitted to it and shall periodically conduct ongoing review of approved research projects. If a study is inadvertently terminated, it may be reactivated within 6 months without submitting it to the IRB as a new study. If a study has inadvertently expired, the continuing review may be reviewed by the IRB within 6 months of the notice of expiration.
- B. Consideration will be given during the approval process by the Board to determine the review frequency for the study.
- C. The Board may appoint a subcommittee to review amendments to and continuing reviews of projects approved by the Board. Such delegated review shall be deemed to be the review of the Board upon report to and approval by the Board.
- D. The Board may delegate review of research proposals which fall within the categories for expedited review as listed by the United States Department of Health and Human Services to a subcommittee established pursuant to Article VII, Sections A(5) and D. Such determinations will be reported to the Board.
- E. The Board may delegate authority to Research Compliance Administration and the Clarian IRB Office staff, or one or more experienced members of the Board, to review

research proposals to determine whether such proposals may be exempted from obtaining Board or subcommittee approval. Such determinations will be reported to the Board.

- F. The Board, or a subcommittee conducting expedited review may approve, grant provisional approval, table, or disapprove a proposal. When provisional approval is granted, the Board or subcommittee may require that the revised proposal be resubmitted to the Board or subcommittee for final approval, or may delegate the authority for final approval to the Chair or a subcommittee, upon showing that the conditions of approval have been complied with.
- G. The Board may, upon the request of an investigator or on its own initiative, reconsider any proposal and reverse its own determination or that of a subcommittee; however, proposals which are tabled or denied approval by the Board cannot be resubmitted in any form for approval by a subcommittee or another Board in an attempt to bypass the Board.
- H. The Board may delegate authority to the Chair to review and approve certain kinds of research proposals which involve no more than minimal risk to the subject(s) or involve minor changes in previously approved proposals. Such review and approval may be conducted by the Chair or by one or more experienced members of the Board designated by the Chair.

Article IX. Participation of Non-Members

- A. The meetings of the Board may be attended by persons who are not members with the consent of the Chair. 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.
- B. Consultants with competence in special areas may be invited to assist in the reviews and research issues which require expertise different from that available on the Board.

Article X. Procedure for Board Meetings

- A. The Board may delegate authority to Research Compliance Administration and the Clarian IRB Office to initially review and process all research-related documentation to assure completeness for submission to the Board or subcommittees.
- B. The members of the Board shall be furnished with advance copies of the agenda for its regular meetings.
- C. The agenda shall be prepared by the Chair, or the Chair's designee appointed for that purpose.
- D. Except as provided in Section G of this Article, no decision shall be taken on a research proposal unless it is included in the agenda.
- E. A research proposal, unless suitable for delegated expedited review, shall be placed on the agenda for the next scheduled meeting if such proposal has been received at least two weeks in advance of the meeting, or, if the research proposal has been received less than two weeks in advance of the meeting, at the discretion of the Chair.
- F. In addition to review of research proposals not delegated to a subcommittee for expedited review, the agenda shall include the following:
 - (1) review of the minutes of the previous Board meeting;
 - (2) review of minutes from the Board mentioned in Section B of Article II, if available;
 - (3) review of previously approved research projects which have been modified or of the report of the subcommittee appointed to review such modification;
 - (4) review of previously approved research projects in which unanticipated difficulties have occurred or of the report of a subcommittee appointed to review such projects and difficulties;

- (5) Ongoing review of previously approved projects or of the report of a subcommittee appointed to review such matters;
 - (6) review of the report of any subcommittee appointed to perform expedited review;
 - (7) review of the report of any subcommittee appointed to perform emergency review;
 - (8) review of terminated projects or of the report of subcommittee appointed to review such projects;
 - (9) such other matters as the Chair or any member shall consider appropriate.
- G. Whenever, in the opinion of the Chair or Vice Chair and a majority of the members and alternates constituting the quorum of a meeting, a delay in making a decision on a research proposal may seriously impair the mission of the University or the medical or other interests of a subject or potential subject of research, a decision may be reached on the proposal notwithstanding that the proposal has not been placed on the agenda.

Article XI. Minutes

- A. The Chair shall prepare, or cause to be prepared, minutes of each meeting that shall be furnished to each member of the Board.
- B. The Chair shall preserve, or cause to be preserved, an archive of the minutes of the meetings.

Article XII. Amendments

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