

BOARD ASSIGNMENT AND REVIEWER ASSIGNMENT FOR CONVENED REVIEW

1. Overview

OSU research involving human subjects that requires Institutional Review Board (IRB) review is reviewed by one of three OSU IRBs, Western IRB (WIRB), or Nationwide Children's IRB. A primary reviewer system is used for convened IRB review. Board assignments and reviewer assignments are made to ensure that proposed research receives appropriate scientific or scholarly review by individuals with the qualifications to determine that the rights and welfare of human research subjects are protected.

This policy describes the process used to assign each protocol to the appropriate IRB for convened review, as well as the process followed for assigning specific reviewers to each protocol to be reviewed.

2. Definitions

Convened IRB Review: Review of proposed human subjects research by an Institutional Review Board that meets the membership requirements specified in federal regulations regarding the number, qualifications, diversity, and affiliation of its members, at which a majority of the members are present including at least one member whose primary concerns are in nonscientific areas.

3. Board Assignment

Research proposals are directed to the most appropriate IRB for convened review based on type of research proposed and its funding source, as described below. OSU research requiring IRB review is reviewed by one of three OSU IRBs – Behavioral and Social Sciences, Biomedical Sciences, or Cancer – or by WIRB or Nationwide Children's IRB. Final determination of Board assignment is made by the Board's IRB Administrative Manager, who consults with the Chair of the selected IRB as needed. Investigators are encouraged to contact ORRP with questions regarding appropriate Board assignment before preparing submissions.

3.1 OSU IRBs

- A. The Behavioral and Social Sciences IRB reviews investigator-initiated (funded or unfunded) research that does not involve medical procedures, drugs, or devices, originating from a variety of disciplines including the arts, humanities, business, communication, education, music, nursing, political science, psychology, sociology, and social work.
- B. The Biomedical Sciences IRB reviews investigator-initiated (funded or unfunded) biomedical research, excluding cancer research. The Biomedical

Sciences IRB does not review industry-initiated, industry-sponsored clinical trials (see section 3.2 below).

- C. The Cancer IRB reviews investigator-initiated (funded or unfunded) research involving cancer surveillance, etiology, diagnosis, early detection, prevention, treatment, symptom control and survivorship studies, including quantitative, observational and interventional study designs. The Cancer IRB does not review industry-initiated, industry-sponsored cancer clinical trials (see section 3.2 below).

3.2 Western IRB

- A. OSU research that is industry-initiated and industry-sponsored is reviewed externally by Western IRB. WIRB provides review and oversight for research that meets all of the following conditions:

- The project is a controlled study involving human subjects designed to prospectively evaluate the safety and effectiveness of new drugs or devices or of behavioral interventions;
- The only sponsor of the project is a for-profit entity/company;
- The project protocol was designed and written by the sponsor; and
- The sponsor holds all INDs/IDEs for the protocol.

Sub-studies or extension studies (e.g., pharmacokinetics, registries) associated with clinical trials reviewed by WIRB are also sent to WIRB for review.

- B. Submission of OSU research to WIRB requires pre-screening of the application by ORRP to determine that institutional requirements have been met (e.g., COI disclosure, education, etc.) and that the research meets the conditions above before it is forwarded for WIRB review.
- C. Research involving any the following, regardless of funding source, is reviewed by an OSU IRB and is not sent to WIRB for review:
- Planned emergency research
 - Xenotransplantation
 - Gene transfer
 - Embryonic stem cell research
 - Any other research requiring review and approval by the OSU Institutional Biosafety Committee.

3.3 Nationwide Children's Hospital IRB

Except for research that meets the conditions for review by WIRB, research conducted by OSU faculty in the Department of Pediatrics and OSU pediatric research conducted wholly or in part at Nationwide Children's Hospital is reviewed by Nationwide Children's Hospital IRB.

4. Reviewer Selection

Research requiring convened IRB review is assigned to primary and secondary reviewers based on conditions described below. Reviewer selection for review of research using expedited procedures is performed as described in OSU HRPP policy [[Expedited Review Procedures](#)].

4.1 Number of Reviewers

- A. IRB Protocol Analysts assign one primary reviewer and two secondary reviewers for initial convened review, and one primary reviewer and one secondary reviewer for continuing review and review of amendments by the convened IRB.
- B. Both the primary and secondary reviewer(s) are expected to perform an in-depth review of the research. The primary reviewer leads the IRB's discussion of the protocol, providing a summary of the research and potential concerns, if any. The secondary reviewer(s) provides additional comments or information before full Board discussion. Materials that are distributed to assigned reviewers and all other IRB members are listed in OSU HRPP policy [[Review of Research by the Convened IRB](#)].

4.2 Reviewer Expertise

- A. The IRB Protocol Analyst for the designated IRB pre-reviews the protocol submission to determine the expertise required to provide scientific or scholarly review of the research. (For more information on the pre-review process, see OSU HRPP policy [[IRB Submission and Pre-Review](#)]). Primary and secondary reviewer(s) are selected using the IRB roster and/or IRB members' CVs (see below). An IRB Protocol Analyst and/or the IRB Administrative Manager reviews and approves or recommends changes to reviewer assignments.
- B. When making reviewer assignments, the IRB Protocol Analyst considers the following:
 - Reviewer's scientific and/or scholarly expertise
 - Reviewer experience
 - Reviewer's status as scientist or nonscientist

- Reviewer workload
- Potential conflicts of interest (as defined in OSU HRPP policy [[IRB Member and Consultant Conflict of Interest](#)])
- The need for special representation (e.g., vulnerable populations).

ORRP staff members consult with the IRB Chair as necessary when making reviewer assignments. The Chair may reassign the review of research as he/she determines to be appropriate.

- C. Only IRB members designated as scientists may serve as primary reviewers. Non-scientists may serve as secondary reviewers.
- D. When the research involves a vulnerable category of participants (e.g., children), a reviewer knowledgeable about and experienced in working with these participants will be selected.
- E. Board members with the expertise necessary to review proposed research from the same Department/Division/unit as the investigator(s) may be designated as primary or secondary reviewers; however, two reviewers from the same unit will not be assigned to the same review. IRB members will not review research in which they have a conflict of interest, according to OSU HRPP policy [[IRB Member and Consultant Conflict of Interest](#)].
- F. If the IRB Protocol Analyst, in consultation with the IRB Administrative Manager and/or Chair, believes that the IRB membership lacks sufficient expertise or experience to provide adequate review of the research or if the IRB member with the appropriate expertise/experience has a conflict of interest, the IRB Administrative Manager will be responsible for obtaining a consultant.

5. Distribution of Materials

IRB Protocol Analysts prepare and distribute IRB materials to the assigned reviewer(s) and IRB members 7-10 days before convened meetings as described by OSU HRPP policy [[Review of Research by the Convened IRB](#)]. In extenuating circumstances (e.g., IRB approval would lapse without review), when sufficient space exists on a meeting agenda for a late submission, every effort will be made to select reviewer(s) who can perform an in-depth review of the research and to forward materials to reviewer(s) and IRB members past this deadline.

Materials are made available to reviewers for expedited review of research as described in OSU HRPP policy [[Expedited Review Procedures](#)].



6. Applicable Regulations/Guidance

21 CFR 56.107, 21 CFR 56.108, 45 CFR 46.107, 45 CFR 46.108