



## BOARD ASSIGNMENT AND REVIEWER ASSIGNMENT FOR CONVENED REVIEW

### 1. Overview

Research involving human subjects that requires Institutional Review Board (IRB) review is reviewed by one of three university IRBs or by an external IRB acting on behalf of Ohio State. 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 research participants are protected.

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

### 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 review based on the type of research proposed and its funding source, as described below. Research requiring IRB review is overseen by one of three university IRBs – Behavioral and Social Sciences, Biomedical Sciences, or Cancer – or by an external IRB acting on behalf of Ohio State. Final determination of Board assignment is made by ORRP staff, who consults with the Chair of the selected IRB as needed. Investigators are encouraged to contact ORRP staff with questions regarding appropriate Board assignment before preparing submissions.

#### A. University IRBs

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. The Behavioral and Social Sciences IRB does not review FDA-regulated research.

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 “Western IRB” below).



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 “Western IRB” below).

## **B. Commercial and Other External IRBs**

A commercial/external IRB may provide review and oversight of research initiated and/or conducted by Ohio State investigators under the following conditions:

- The reliance and allocation of responsibilities between Ohio State and the commercial/external IRB is appropriately documented
- Federally conducted and/or supported research must comply with the Common Rule.

Commercial IRBs generally should be used for industry-initiated and/or industry-sponsored clinical trials meeting all of the following conditions:

- The only sponsor of the project is a for-profit entity/company
- The project was designed and written by the sponsor
- The sponsor holds all INDs/IDEs for the project.

Submission of Ohio State research to a commercial/external IRB requires pre-screening of the Buck-IRB application by ORRP staff to determine that institutional requirements have been met (e.g., COI disclosure, education, ancillary review completion, etc.) and that the research meets the conditions above before it is forwarded for review.

Research involving any the following, regardless of funding source, should be reviewed by a university IRB except in rare cases when granted an exception by the Institutional Official and/or the Office of Research Compliance:

- Planned emergency research
- Xenotransplantation
- Human gene transfer
- Embryonic stem cell research.

## **C. Nationwide Children’s Hospital IRB**

The Ohio State University has an IRB Authorization Agreement with Nationwide Children’s Hospital (NCH) that permits Ohio State and NCH to collaborate in the review and oversight of human subjects research that would otherwise require review by both organizations. This agreement applies in the following circumstances:

- An Ohio State investigator performs or is engaged in a study at NCH
- An NCH investigator performs or is engaged in a study at Ohio State



- An Ohio State or NCH investigator performs research engaging both locations.

Requests to rely on the NCH IRB requires pre-screening of an application in Buck-IRB to determine that Ohio State requirements have been met (e.g., COI disclosure, education, etc.) and that the research meets the conditions of the executed authorization agreement.

Research involving any the following must be reviewed by an Ohio State IRB except in rare circumstances determined on a case by case basis in consultation with the Institutional Official and/or Office of Research Compliance:

- Planned emergency research
- Xenotransplantation
- Human gene transfer
- Embryonic stem cell research.

#### **D. National Cancer Institute Central IRB (NCI CIRB)**

Select NCI-sponsored clinical trials are reviewed externally by the NCI CIRB. The NCI CIRB determines which studies will be reviewed by the CIRB and makes this list available to investigators on the CIRB website.

Submission of research to NCI CIRB requires pre-screening of the application by ORRP staff to determine that institutional requirements have been met (e.g., COI disclosure, education, etc.). Additionally, Ohio State serves as the Privacy Board for NCI CIRB studies and performs review of all HIPAA authorization waiver requests made by the investigator prior to submission to NCI CIRB.

#### **4. Reviewer Selection**

Research requiring convened Ohio State 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 HRPP policy [[Expedited Review Procedures](#)].

##### **A. Number of Reviewers**

ORRP staff assign one primary and one secondary reviewer for all submissions scheduled for convened review, including initial, continuing review, amendment, and event report submissions. ORRP staff may add reviewers for additional expertise, as necessary.

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 HRPP policy [[Review of Research by the Convened IRB](#)].

## B. Reviewer Expertise

1. The ORRP staff member supporting 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 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).
2. When making reviewer assignments, the ORRP staff member 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 HRPP policy [[IRB Member and Consultant Conflict of Interest](#)])
  - The need for special representation (e.g., vulnerable populations).

ORRP staff 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.

3. Only IRB members designated as scientists may serve as primary reviewers. Non-scientists may serve as secondary reviewers.
4. 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.
5. 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 HRPP policy [[IRB Member and Consultant Conflict of Interest](#)].
6. If the ORRP staff member, in consultation with the IRB Operations 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 Operations Manager will be responsible for obtaining a consultant.



## 5. Distribution of Materials

ORRP staff prepare and distribute IRB materials to the assigned reviewer(s) and IRB members 7-10 days before convened meetings as described by 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.

## 6. Applicable Regulations/Guidance

21 CFR 56.107, 21 CFR 56.108, 45 CFR 46.107, 45 CFR 46.108, 45 CFR 46.103e

## 7. History

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