

HUMAN SUBJECTS REVIEW



Study Team

Principal investigator and research personnel prepare study submissions [initial, continuing review (CR), annual status reports (ASR), amendments, event reports].

Study team completes personnel requirements

- Human Subjects Protection training
- Responsible Conduct of Research
- Conflict of Interest Disclosure

Buck-IRB

Study team submits the study submission through Buck-IRB.

Initial submissions receive department/college sign-off.

21% of submissions are ceded to external Institutional Review Boards (IRBs) such as lead institutions for collaborative multi-site studies and Western IRB for industry protocols.

ORRP & IRB

ORRP analysts screen submissions for compliance and completion.

9% of studies are determined exempt from IRB review.

One of three local Ohio State IRBs review submissions:

- Biomedical Sciences
- Social and Behavioral
- Cancer

The convened IRBs meet monthly or bimonthly. 18% of initial submissions undergo convened review. 82% of initial submissions qualify for expedited review and are processed weekly.

1819 continuing reviews were evaluated by the IRB, while 978 annual status reports were processed by ORRP staff.

Review Outcome

IRBs make the following determinations:

- Approved
- Modifications Required
- Deferred
- Disapproved
- Tabled

ORRP analysts record and communicate the review outcome and coordinate further review, if needed.

The Quality Improvement (QI) team performs post-approval monitoring as an educational service to investigators, to support IRB review and to ensure human subjects protections. Feedback received from QI monitoring is a way for the IRBs to inform and improve review and oversight of human subjects research.

Research

Research teams study advances in human health and welfare, making discoveries and innovations in human physiology, disease, treatments, behavior and learning.

ORRP Staff: **21 FTEs**

Active Studies: **4,995**

IRB Chairs: **3**

IRB Members: **89**

Investigators: **1,144**

Research Staff: **4,003**

Data from FY2018.