BIOSAFETY REVIEW

Study Team

Principal investigator and research personnel prepare study submissions.

Study team may need to complete the following personnel requirements:

- Online Occupational Health Risk Assessment
- Biohazard and Biosafety training
- Recombinant DNA and Gene Transfer training
- Lentiviral Safety training
- Responsible Conduct of Research
- Conflict of Interest Disclosure

e-Protocol

Study team submits the study submission through e-Protocol.

Initial submissions receive department/college sign off.

ORRP & IBC

Office of Responsible Research Practices (ORRP) analysts screen submissions for compliance and completion.

35% of studies are determined exempt from Institutional Biosafety Committee (IBC) review.

Submissions are reviewed by the IBC for accordance with the guidelines set forth by the National Institutes of Health (NIH).

The IBC meets monthly for convened review of 64% of initial submissions and 5% of amendments.

69% of submissions qualify for designated review and are processed regularly.

Review Outcome

IBC makes the following determinations:

- Approved
- Modifications Required
- Deferred
- Disapproved

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

Studies involving human gene transfer are identified. The IBC chair prepares a risk matrix and study summary that is forwarded to ORRP Human Subjects staff for dissemination to the appropriate Institutional Review Board (IRB).

Research

Research teams advance our knowledge for the benefit of humans, plants, and animals by making discoveries and innovations while using recombinant molecules or pathogenic microorganisms.

ORRP Staff: **.7 FTE**

Active Studies: **415**

IBC Chairs: **1**

IBC Members: **17**

Investigators: **293**

Research Staff: **1,599**

Data from FY2018.