HUMAN SUBJECTS INCIDENT REPORTING

Incident

Noncompliance allegations and potential unanticipated problems involving risks to subjects or others (UPRISOs) are referred to Office of Responsible Research Practices (ORRP) through various sources including:

- Anonymous reporting
- IRB referral
- ORRP staff screening
- Participant complaint
- Study team self reporting
- Post approval monitoring

Inquiry

ORRP conducts an initial inquiry and gathers information to further assess the incident. ORRP staff work with Institutional Review Board (IRB) leadership to determine one of the following:

- No further action required
- Corrective action(s)
- Convened IRB review for further determinations
- IRB Investigative Subcommittee (IIC) review
- Further investigation required
- Temporary suspension of research
- Referral to another university process

Investigation

The IRB Chair, Board, or Institutional Official (IO) may request further investigation and/or referral to the IIC.

The IIC consists of (at minimum):

- Representation from each IRB
- Legal affairs
- Office of Research Compliance staff
- ORRP staff
- IO

Further investigation may result in a formal audit report completed by ORRP staff and provided to the principal investigator (PI), the IIC for recommendations, and/or convened IRB of record for further determinations.

Outcome

The outcome of the initial inquiry or further investigation may result in the following IRB determinations and/or recommendations:

- No further action or review required
- Serious and/or continuing noncompliance
- UPIRSO
- Temporary suspension of research
- Termination of research
- Corrective actions, such as:
  - modifications to research
  - participant notification
  - increased monitoring
  - education and training
- Recommendations, may include;
  - limitation of PI privileges
  - referral to another university process

Reporting

Additional internal and external reporting is required for:

- Serious and/or continuing noncompliance
- Temporary suspension of research
- Termination of research
- UPIRSOs

Reporting may include:

- Food and Drug Administration
- Office of Human Research Protections
- Sponsor of research
- Institutional Official
- Dean and department chair (or equivalent)
- Research team members and collaborators

ORRP Staff: **1.5 FTEs**

UPIRSOs: **37**

Event Reports: 229

Noncompliance Allegations: **53 Studies**

Protocols Audited: **20**

Serious and/or Continuing NC: **32**

Data from calendar year 2017.

THE OHIO STATE UNIVERSITY

OFFICE OF RESEARCH
Office of Responsible Research Practices