

HRPP COMPLIANCE

AN IRB INFOSHORT
OCTOBER 2012

HUMAN RESEARCH PROTECTION PROGRAM (HRPP) COMPLIANCE

Mission:

“To facilitate compliance with the federal regulations, and protection of research participants”

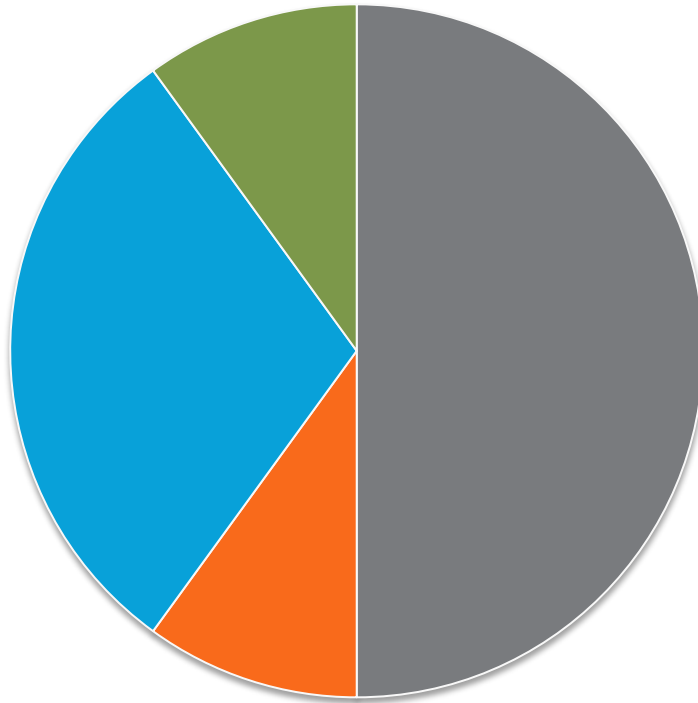
IRB

- What do they say they will do?

Compliance

- Are they doing what they said they would do?

COMPLIANCE GOALS



- 50% Education/outreach to Yale research community
- 10% Assessing compliance trends
- 30% Not for cause compliance reviews
- 10% For-cause investigations/audits

REGULATORY OVERSIGHT



- Office for Human Research Protections (OHRP)
- U.S. Food & Drug Administration (FDA)
- Office for Civil Rights (OCR)

NONCOMPLIANCE

Any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with the research plan as approved by a designated IRB or federal regulations or institutional policies governing such research.

Non-compliance may range from minor to serious, be unintentional or willful, and may occur once or several times.



REVIEW & INQUIRY

An IRB Chair, the HRPP Compliance Manager, or other qualified designee will initially assess a report/allegation of noncompliance and make a preliminary determination as to the seriousness or continuing nature of the noncompliance.

Next, a fact-finding inquiry will be conducted which may include:

- examination of study records; and
- discussions with the research team, other personnel, research participants, witnesses, the complainant (if applicable and not anonymous), and others, as appropriate.

If the inquiry suggests that the incident may constitute serious or continuing noncompliance, then the matter will be referred to a fully-convened IRB.

IRB'S ROLE

The IRB reviews the incident and results of the inquiry, and makes its own determination as follows:

1. Does not meet the criteria for serious or continuing noncompliance and recommends that it be handled as minor noncompliance; or
2. More information is required and may request that a further investigation be conducted by either:
 - the HRPP Compliance Manager or
 - an ad hoc panel of 3 IRB members (other than IRB Chair); or
3. The incident constitutes serious and/or continuing noncompliance.

ACTIONS BY IRB

The IRB may take any action it deems necessary to protect the rights and/or welfare of the research participants involved, including, but not limited to:

- Remediation or educational measures required of PI and research team.
 - Monitoring of research activities by appropriate person(s).
 - Notification of past or current research participants.
 - Re-consenting of participants.
 - Modification of the research protocol.
 - More frequent continuing review (renewal of approval) schedule.
 - Periodic audits by the HRPP Compliance Manager.
 - Restrictions to the PI's research practice (e.g., limiting the privilege to minimal risk or supervised projects).
 - Suspension or termination of approval for one or more of the PI's studies.
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