

HUMAN SUBJECTS POLICY DEVELOPMENT & APPROVAL



Resources

The ORRP Quality Improvement (QI) team employs Belmont Report principles, Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations, and other applicable agency guidance to develop and maintain the university's Human Research Protection Program (HRPP) policies, procedures, and guidance documents.

Evaluate

The ORRP QI team works with the IRB Policy Committee (IPC) to propose, develop, and revise policies and procedures that align with applicable federal regulations and focus on best practices in human subjects research.

In consultation with key institutional entities, the IPC guides new policy development in response to changing federal regulations, state laws, and university policies.

Identify

HRPP policy revisions and additions, and changes to ORRP SOPs are determined through evaluation and monitoring of the following:

- QI biennial communications, outreach, and compliance plans
- Surveys
- Internal data analysis
- Audit findings
- Incident reports
- Consultation and interactions with peer institutions
- AAHRPP standards
- Common Rule revisions
- Food and Drug Administration policy
- Office of Human Research Protections policy
- National Institutes of Health (NIH) policy

Implement

Proposed policies and procedures undergo a two-step internal ORRP review process before consideration by the IPC.

The IPC is authorized by the senior vice president for research to review and approve HRPP policies and procedures.

ORRP staff communicate IPC-approved new and/or amended policies to the research community, and provide guidance to investigators, IRB members, and staff.

Monitor

The QI team monitors HRPP policies and guidance in order to promote and maintain ethical human research and compliance with applicable regulations.

Existing policies are evaluated every three years to ensure applicability of current procedures to evolving regulatory requirements.

The QI team contributes to university-wide research policies and guidance, related to the following:

- CT.gov
- NIH Certificates of Confidentiality
- Consent E-signature
- New recruitment methods
- General Data Protocol Regulation

ORRP Staff: **1 FTE**

HRPP Approved Policies: **39**

IPC Members: **16**

QI Team Members: **4**

Reviewed: **Q3 Years**

New Policies (2017): **3**

Data from FY2018.