Office for Human Subject Protection: Key Resources

INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

The IRB at the University of Rochester is referred to as the Research Subject Review Board (RSRB). All reviews are conducted through an online platform referred to as <u>Click IRB</u>, a component of the <u>Integrated Online Research Administration System (IORA)</u>. Key resources for navigating the IRB review process include:

Getting Started Guide & Flowchart
When do I need to get RSRB approval?
Required Human Subject Protection Training
Preparing your RSRB Submission
IRB Submission Checklist

RSRB Review Process

Multi-Site GDL when UR is Reviewing IRB Multi-Site GDL when UR is Relying IRB

Templates
IRB Exemptions
IRB Fee Structure
Criteria for IRB Approval

INVESTIGATOR & STUDY STAFF RESPONSIBILITIES

It is critical for Investigators and study staff to understand their responsibilities prior to engaging in the conduct of human subject research. Prior to initiating research:

- Read all IRB approval letters and review the information provided related to OHSP Policy 901 Investigator
 <u>Responsibilities</u>, including corresponding summary sheets for <u>exempt</u> research, <u>non-FDA (Food & Drug Administration)</u> regulated research, and <u>FDA-regulated</u> research.
- For study-specific guidance on roles/responsibilities, regulatory compliance, and <u>study documentation</u> requirements and request a (free!) Post-Approval Consultation.

If you are new to the University or to conducting research, consider completing:

Orientation to Conducting Human Subject Research
Research Boot Camp

Core Training: Principal Investigator Oversight
Core Training: Study Operations

If you are responsible for overseeing and/or training study staff, see OHSP's <u>Guideline for Training Research</u> <u>Personnel</u> for training-related requirements, resources, and best practices, including OHSP's <u>Training Framework</u> and Study Team Member Onboarding Guides.

ADDITIONAL RESOURCES

A-Z Resource Index*
Information for Research Subjects
Informed Consent Resources
OHSP Contacts

OHSP Feedback
OHSP Policies

OHSP Services

Study Documentation Templates
Quality Improvement Reviews

Quality Management Plans & Consultation UR-HRPP Educational Forum & Recordings

Who's My IRB Coordinator?

*Note: The on-site search feature in the A-Z Resource Index is not as robust as an internet search engine (e.g., Google). You will get better results using: 1) 'OHSP and [insert topic]' via an internet search engine; or 2) Control+F (Windows) or Command+F (Macs) on the A-Z Resource Index page.