Quick Reference Guide

Human Research Protection Program Resources

The Human Research Protection Program at the University of Rochester (UR) is comprised of several departments, ancillary committees and intra-institutional relationships that provide a variety of oversight, support and educational opportunities for investigators, study coordinators and research staff conducting human subject research. The purpose of this brochure is to provide an overview of the primary entities that comprise the program as well as basic information on how to get started with your research endeavors.

Office for Human Subject Protection

The Office for Human Subject Protection (OHSP), under the direction of the Senior Vice President for Research, oversees the daily administration of the Human Research Protection Program and is responsible for oversight and monitoring of human subject research. The office is comprised of four divisions:

Research Subjects Review Board (RSRB)

The RSRB is the University's Institutional Review Board and is responsible for reviewing research that is conducted or supported by employees or agents of the UR to ensure that the rights and welfare of human subjects are adequately protected. The RSRB consists of 5 internal review boards and 1 external review board (Western Institutional Review Board). Board assignment is based on the department of the submitting Principal Investigator (PI), risk level and study sponsorship.

Research Education & Training

The Research Education & Training division is responsible for assisting researchers in protecting the rights, welfare and safety of human subjects by providing programs and educational resources in research ethics and human subject safety, with an emphasis on proper conduct of research. All study team members conducting human subject research must meet minimum training requirements set forth by this division prior to conducting any research.

Quality Improvement

The Quality Improvement division is responsible for the ongoing evaluation of the effectiveness of the UR's Human Research Protection Program by promoting institutional and investigator compliance with human subject protection regulations and Institutional policies and requirements.

Clinical & Regulatory Systems

The Clinical & Regulatory Systems division is responsible for the oversight and maintenance of the RSRB Online Submission System (ROSS) and for providing information technology systems support to OHSP staff.

The following services and resources are available through OHSP:

- OHSP policies & procedures
- Study team consultation with the RSRB
- Study team training opportunities including: Orientation, Boot Camp, Core Training & Advanced Training Classes, ROSS Training, Good Clinical Practice Training & Supplemental Online Training Resources
- Monthly educational seminar series
- Quarterly newsletters
- Customized individual or departmental training sessions
- Pre-study research file and study documentation consultations
- Study documentation templates
- On-site research file reviews

Contact Information:

Phone: (585) 273-4127

www.rochester.edu/ohsp

UNIVERSITY of ROCHESTER

Office of Research and Project Administration

The Office of Research and Project Administration (ORPA), under the direction of the Associate Vice President for Research Administration, facilitates and oversees the University's proposal and award administration with funding agencies, whether public or private.

Proposal Review and Submission

ORPA is the University office designated by the University's trustees to submit proposals to external sponsoring entities for financial support (e.g., agreements, contracts, grants) of research and other programs. ORPA reviews proposals to determine adherence to sponsor and University policy. When needed and appropriate, ORPA will negotiate terms and conditions with sponsors and will negotiate and sign nondisclosure agreements for information received from potential sponsors. ORPA will also negotiate and sign material transfer agreements or data use agreements for the exchange of biological materials or de-identified or limited data sets resulting from clinical research.

Acceptance of Funding

Only ORPA can legally accept and sign sponsored programs agreements on behalf of the University. ORPA requests Central Finance to establish a general ledger account for the new project and provides the Principal Investigator an award notice summary of the information contained in the award that includes applicable terms and conditions.

Project Management

ORPA staff provides advice on the allowability and allocation of sponsored project expenses, sponsor prior approval requirements, and intellectual property management. ORPA is the University's appointed sponsor liaison regarding administrative requests (e.g., extension of the project's period of performance), financial requests (e.g., re-budgeting requests and carry forward requests), or programmatic changes initiated by the Principal Investigator. If a project involves a subrecipient agreement, ORPA staff develops and executes the subrecipient agreement, with involvement of the Principal Investigator.

Project Closure

ORPA staff provides advice when a project terminates with regards to sponsor contractual and payment issues, non-financial reporting requirements, and subrecipient deliverables.

Education, Outreach and Resources

ORPA disseminates information on funding opportunities and major program announcements; maintains an informative web-site including University sponsored project policies; maintains an accessible database of the University's proposal and award data; recommends, drafts, and administers research administration policies in partnership with other University departments; and offers training on internal and external policies, processes and regulations.

Research Advocacy

ORPA participates in national university organizations and committees to advocate for the reduction of unnecessary administrative burden for our investigators and researchers, so that current and pending regulations do not negatively affect do not affect the ability to conduct research.

Contact Information:

Phone: (585) 275-4031

www.rochester.edu/ORPA

Scientific Review & Department Approval

Prior to initiation of review by an institutional review board (e.g., Research Subjects Review Board or Western Institutional Review Board), all human subject research protocols are required to undergo review by the Principal Investigator's home department. This review is facilitated and documented in the RSRB Online Submission System. Each department within the University has developed their own policy and procedure concerning this review. At a minimum, this review must evaluate the following for each human subject protocol: Scientific Merit, Risk Identification & Management, and Investigator Qualifications & Resources. Additional information can be obtained via the OHSP Policy 505: Scientific Review Standards and within each department.

Conflict of Interest Committee

The Conflict of Interest Committee (COI Committee) at the University of Rochester advises the Deans and Senior Vice President for Research on conflict of interest matters, including policy application and interpretation. All conflict of interest management plans approved by the Deans (sometimes aided by School-specific COI committees) must be submitted to the COI Committee for its review and approval. All faculty and staff are required to report, at least annually, external financial interests for review and consideration related to active research projects.

The COI Committee consists of: at least five full-time faculty members appointed by the Senior Vice President for Research; a representative from The Office of Counsel; the Director of the Office for Human Subject Protection; the Associate Vice President for Research Administration; and the Director of UR Ventures.

Contact Information:

Gunta Liders, Associate Vice President for Research Administration; Phone: (585) 275-5373; gunta_liders@urmc.rochester.edu

Privacy & Information Security Office

The Privacy and Information Security Offices are responsible for institutional compliance with regulations related to the Health Insurance Portability and Accountability Act (HIPAA).* These regulations aim to safeguard health information and include conditions under which a covered entity may use or disclose protected health information (PHI) for research purposes. HIPAA Privacy and Information Security policies apply to all covered entity research involving specimens, records or information from individuals, alive or deceased, regardless of sponsorship.

Generally, PHI can only be used or disclosed when one of the following conditions is met:

- Authorization is obtained from the subject;
- The PHI is de-identified;
- The PHI is part of a limited data set and a data use agreement is executed;
- The Research Subjects Review Board or the Privacy Office has approved a waiver of HIPAA authorization (permissible only under certain circumstances); or
- For reviews: 1) preparatory to research or 2) on decedent information, certification regarding the review and disclosure of the information obtained during the review is provided to the Privacy Office.

The Information Security Office oversees compliance with regulatory requirements for URMC information systems. The HIPAA Security Official for Research is available for assistance with safeguarding the collection, storage and transmission of electronic data.

*Note that HIPAA requirements only apply to research conducted under the covered entity UR Medicine and Affiliates including University of Rochester Medical Center, Highland Hospital, Mt. Hope Family Center, etc. While HIPAA may not apply to research conducted in the School of Arts, Sciences & Engineering, the Eastman School of Music, Simon Business School or the Warner School of Education, the Research Subjects Review Board may still consult with the Privacy Office regarding appropriate research procedures when necessary.

Contact Information:

Diane Healy, Privacy Officer for Research

Phone: (585) 784– 2431

diane_healy@urmc.rochester.edu

Steven Wormsley, Security Official for Research

Phone: (585) 273-2685

steven_wormsley@urmc.rochester.edu

https://sites.mc.rochester.edu/departments/hipaa/

Ancillary Committees

Ancillary Committee review, as described below, is facilitated and documented through the RSRB Online Submission System (ROSS). In some instances, an additional committee-specific application (outside of ROSS) is required. Please contact each applicable Ancillary Committee directly for information regarding their application process. Unless indicated below*, this review is conducted concurrently with Research Subject Review Board (RSRB) review, though final RSRB approval will be contingent upon Ancillary Committee approval.

Clinical Trials Office (Cancer Center)

The Clinical Trials Office (CTO) oversees all hematology/oncology-related research conducted at the UR. Proposals involving any hematology/oncology patients must be reviewed and approved by the CTO.

Contact Information:

Phone: (585) 275-5345

Emergency Medicine Research Committee

Emergency Medicine Research Committee review and approval is required for all studies involving the Department of Emergency Medicine staff as well as those planning to enroll subjects through the Emergency Department (ED).

Contact Information:

Phone: (585) 275-1198

www.urmc.rochester.edu/emergency-medicine/research/

Perinatal Research Committee

Review and approval from the Perinatal Research Committee is required for all studies involving pregnant women and newborns/infants in the normal nursery or neonatal intensive care unit at Strong Memorial Hospital or Highland Hospital.

Contact Information: Phone: (585) 275-7480

Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) is a responsible for reviewing and approving all recombinant DNA and biohazard research projects (including research involving the analysis of, or experimentation with, sera, blood products or other specimens derived from humans in any UR lab that is not accredited). Safety requirements and guidance documents for a variety of biological hazards found in UR laboratories are also available through their website.

Contact Information:

Phone: (585) 275-2402

www.safety.rochester.edu/homepages/ibchome.html

Surgical Pathology*

Review and approval from Surgical Pathology is required for all studies utilizing slides or tissue from the URMC Labs Department of Pathology and Laboratory Medicine. *Note that approval from Surgical Pathology is typically obtained *after* RSRB review and approval.

Contact Information:

Phone: (585) 276-4939

www.urmc.rochester.edu/urmc-labs/clinical/researchers.aspx

Human Use of Radiation Committee

The University of Rochester's Radiation Safety Unit is responsible for all activities dealing with radioactive material and radiation producing equipment. As such, protocols involving human subject exposure to ionizing radiation may require review by the Unit's Human Use of Radiation Committee (HURC).

Contact Information:

Phone: (585) 275-3781

http://extranet.urmc.rochester.edu/radiationSafety/X-RayQA.asp

Rochester Center for Brain Imaging

The Rochester Center for Brain Imaging (RCBI) is a research facility offering a state-of-the-art 3T magnet for the purpose of conducting investigations using magnetic resonance imaging (MRI). All protocols utilizing RCBI resources for human subject research require review and approval.

Contact Information:

Phone: (585) 275-4540

www.rcbi.rochester.edu/

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Clinical & Translational Science Institute

The University of Rochester's Clinical and Translational Science Institute (CTSI) is one of more than 60 institutions nationwide with funding from the National Institutes of Health to lead the emerging field of clinical and translational research. The CTSI, comprised of the 6 "pillars" described below, acts to build a foundation to assist researchers at the University of Rochester and across Upstate New York to produce innovative technology and methods that more efficiently and more quickly advance treatments to patients and communities.

Research Education

The goal of Research Education pillar within the CTSI is to develop an integrated program that has the breadth and flexibility to meet the needs of new investigators who are committed to careers in clinical and translational science. This includes offering predoctoral, postdoctoral and career development programs.

Funding Programs

The CTSI provides financial support to research teams to help them get new ideas off the ground. Programs include the Voucher Program, the Clinical and Translational Pilot Program and the Incubator Program.

Clinical Research Center

The Clinical Research Center (CRC) provides an optimal setting for clinical investigators to conduct safe, controlled, inpatient and outpatient studies. The CRC not only provides space to study teams to conduct research but also offers nursing, nutrition services, phlebotomy and DEXA scanning services.

Research Collaborations and Services

Through this pillar, the CTSI provides direct support for study teams by: 1) providing specialized research services directly to investigators (e.g., support for FDA regulatory filings, assistance with recruitment & retention of research subjects); 2) linking study teams to other research services and resources within the University (commonly referred to as the "Research Navigator Program"); and 3) supporting new collaborations by linking CTSI investigators to research with similar interests at the University and also at other institutions.

Population Health

Given the CTSI's ability to support research and that the University provides an academic home for some of the nation's top researchers in population health, health services and comparative effectiveness, a new goal of the CTSI will be to foster leadership in the development, testing and assessment of policies that improve population health.

Clinical Trial Methods and Technologies

The CTSI, in partnership with external entities, works towards bringing new methods and technologies to improve clinical trial efficiency and timeliness and to produce results relevant to the modern day health care practice.

The CTSI coordinates access to a range of resources and services to support study team members. Information and support is available for:

- Skill Building
- Study Design
- Data & Safety Monitoring Plan Development
- Recruitment & Retention Strategies
- Finding Available Shared Resources
- Finding Expertise
- Finding Funding Opportunities
- Policies and Regulations

The CTSI also provides specific services, including:

- The Research Help Desk
- FDA submission guidance and support
- Help with ClinicalTrials.gov registration and result reporting
- Support for using clinical data and clinical data systems for research (e.g. eRecord)
- Data management resources
- Informed consent training
- Support, networking and resources for research coordinators and staff through the Study Coordinator Organization for Research Education (SCORE)

Contact Information:

Email: researchhelp@urmc.rochester.edu

www.urmc.rochester.edu/ctsi/research-help/

UR Research-Related Services

Center for Human Experimental Therapeutics

The mission of the Center for Human Experimental Therapeutics (CHET) is to conduct hypothesis-driven, rigorously designed, initial investigations of novel therapeutic interventions for human disease. CHET is tightly integrated with the CTSI and includes a Clinical Trials Coordination Center (CTCC) and Clinical Materials Services Unit (CMSU) to support their mission. The CTCC operates to foster multi-institutional academic research and provides comprehensive trial services including protocol development, electronic data capture, database design & management, site monitoring, reporting services, biostatistics, data mining services and specimen repository. The CMSU is a regulatory-compliant facility providing investigational drug/device packaging, labeling, distribution and return services for large, multi-site clinical trials. Contact Information: www.urmc.rochester.edu/center-for-human-experimental-therapeutics.aspx

Clinical Trials Processing Laboratory & Cold Storage Core Facility

The University of Rochester Clinical Trials Processing Laboratory (URCTPL) is a fee-for-service core resource that supports clinical trials and basic science research. The laboratory provides technical services including processing of blood and tissue samples and DNA extractions for PI-initiated, pharmaceutical and NIH-funded clinical trials, as well as shipment of specimens according to study protocols. The Cold Storage Core (CSC) Facility is an alarmed and environmentally controlled area that provides a secure on-site environment for long-term storage of research materials at the main medical center campus. UR facilities also maintains four spare -80oC freezers in the CSC for emergency use by UR investigators. Contact Information: Christopher Lane (on global network)

Environmental Healthy & Safety

Environmental Health & Safety provides safety, compliance and advisory services to the UR community. This includes OSHA (Occupational Safety and Health Administration) training for laboratory personnel, training for staff shipping or transporting biological materials as well as guidance on proper waste disposal. Contact Information: www.safety.rochester.edu/index.html

Emergency Department Research Associate Program

The Emergency Department Research Associate (EDRA) program is a UR resource available to investigators who wish to access potential subjects seen in the Strong Memorial and Highland Hospital Emergency Departments. Through this program, Research Associates are available to assist in the screening, recruitment and enrollment of these subjects. Contact Information: www.urmc.rochester.edu/emergency-medicine/research/Research.cfm

Imaging Sciences Clinical Trial Services

The Department of Imaging Sciences provides a variety of radiologic services to address clinical trial needs, including imaging price quotes and requisition set-up as well as image management. Contact Information: www.urmc.rochester.edu/imaging/clinical-trials.aspx

Investigational Drug Service

Investigational Drug Service (IDS) provides clinical researchers with the support to assure safe and efficient conduct of clinical drug trials. IDS services include inventory control & storage, drug accountability, packaging & storage, drug information, drug dispensing and other special service (e.g., drug compounding). Contact Information: http://sites.mc.rochester.edu/departments/pharmacy/strong-memorial-hospital-inpatient-service-locations/investigational-drug-services/

University of Rochester Medical Center (URMC) Laboratory Services

URMC Labs hosts a variety of laboratory-related services for study teams. This includes central laboratory services (providing clinical and anatomic pathology services as well as full project management, data management and logistics to support for multi-site trials); clinical laboratory services (price quotes for laboratory and pathology diagnostic services, histology services, custom requisitions and report handling, specimen storage, technical services and consultation); Point of Care Testing policies and procedures; and human tissue requisition. Contact Information: www.urmc.rochester.edu/urmc-labs.aspx

Getting Started

Prior to initiating any human subject research, investigators and study team members will need to complete the following basic steps (as applicable, based on the nature of the research). Note that some of these steps may occur concurrently as depicted in Figure 1.

1. Determine whether your proposal involves human subject research.

Proposals that qualify as both "research" and involve "human subjects", per OHSP Policy 301, must undergo RSRB and any applicable ancillary committee review. Proposals that do not meet the definitions of "research" or "human subjects" do not require RSRB review and but may potentially require other oversight committee review.

2. Complete human subjects training and request a ROSS account.

All study team members must successfully complete human subjects training through OHSP prior to conducting any human subject research. Once this has been successfully completed, OHSP will issue a certification letter that will include instructions for requesting a ROSS (RSRB Online Submission System) account .

3. Verify whether the Principal Investigator (PI) qualifies to act as a PI.

Per UR Policy, PIs must hold full-time faculty positions or full-time positions enjoying similar rights and privileges. Part-time clinical faculty in the School of Medicine and Dentistry and the School of Nursing having the rank of Assistant Professor or above may also be PI. Studies that are deemed by the RSRB to be exempt, need not have a PI holding a faculty position.

4. Develop your study protocol and corresponding study materials.

Protocol, consent and study documentation templates are available through OHSP's website. Use of these templates are recommended, particularly for investigator-initiated research. All study materials should be reviewed for completeness and consistency prior to submission.

5. If the research is sponsored, initiate budget preparation and contract review through ORPA.

As described on page 2, ORPA will facilitate proposal submissions to external sponsoring entities. Part of this process, includes reviewing proposals to ensure adherence to both University and sponsor policy.

6. Identify and disclose any actual or apparent study team member conflicts of interest with the proposed research.

As described on page 3, all faculty and staff are required to disclose their outside financial interests to the University at least annually. Ad hoc reporting is also required as interests change, prior to entering into sponsored projects or procurement of materials or services.

7. Prepare and submit the ROSS application and any applicable ancillary committee documentation for review and approval.

Once an application is submitted for review via ROSS, the application will automatically be filtered to the PI's department for scientific review and sign-off (alternately, if departmental review does not occur via ROSS, instructions will be provided in ROSS for obtaining this review). Ancillary committees will also be notified of submissions via ROSS though some committees may require additional submissions external to ROSS.

Studies may not be initiated until the RSRB and all applicable ancillary committees have provided their approval and, if the research is sponsored, the clinical trial agreement has been executed.

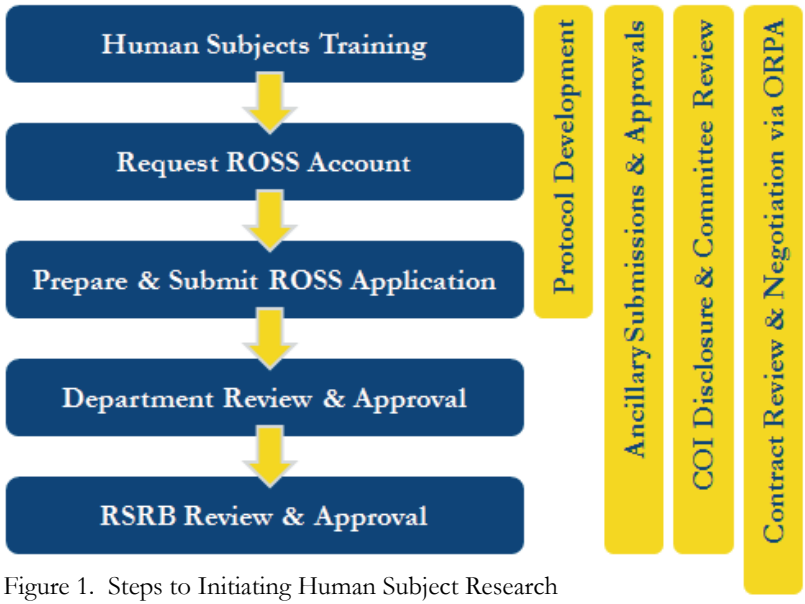

Figure 1. Steps to Initiating Human Subject Research