The purpose of the University of Rochester’s Human Research Protection Program (HRPP) is to ensure that individuals involved with human subject research understand and apply their obligations to protect the rights, dignity, welfare and privacy of research subjects at the University of Rochester (and its affiliates) by adhering to the highest ethical standards and by complying with applicable federal and state regulations, as well as institutional policies. The purpose of this guide is to summarize:

- Key components of the University of Rochester’s Human Research Protection Program (UR-HRPP);
- Basic UR-HRPP requirements;
- Steps for getting human subject research initiated; and
- Key resources and educational opportunities.

Key UR-HRPP Components

The President of the University, with concurrence of the Board of Trustees, has appointed the University’s Institutional Official (IO) with the responsibility to oversee the implementation and maintenance of the UR-HRPP. At the UR, the IO role is delegated to the Vice Provost for Research. Daily administration of the UR-HRPP is charged to the Office for Human Subject Protection (OHSP). OHSP is responsible for the oversight and monitoring of human subject research and is comprised of the following divisions:

- Research Subjects Review Board (RSRB) – The RSRB is the University’s Institutional Review Board (IRB) and is responsible for the review and approval of all human subject research conducted or supported by employees or agents of the UR. The RSRB also facilitates the review of human subject research by external IRBs, including other institutional IRBs and central (or independent) IRBs. All reviews are facilitated via an online review system, referred to as Click@IRB, and an IRB Coordinator.

- Education & Training – The OHSP division responsible for assisting researchers in protecting the rights, welfare and safety of human subjects by providing educational programs and resources in research ethics and human subject safety.

- Quality Improvement (QI) – The OHSP division responsible for conducting comprehensive, systematic, and independent (continued on page 2)

HRPP Accreditation

As a result of the UR-HRPP’s collaborative efforts, and the commitment of the UR research community at-large, the UR-HRPP has maintained accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2007.
(continued from page 1) assessments of human subject research to evaluate appropriate compliance with ethical principles, federal regulations and institutional policies and guidelines.

- Clinical & Regulatory Systems – The OHSP division responsible for the management of [Click IRB] and the [OHSP website].

To meet the needs of the UR-HRPP, the IO and OHSP coordinate efforts and collaborate with several other departments and institutional committees that provide a variety of oversight, support, and educational opportunities for investigators, study coordinators and research staff conducting human subject research. This includes, but is not limited to:

- **Office of Research & Project Administration (ORPA)**
- **Office of Counsel**
- **Research Privacy & Security Officer**
- **Conflict of Interest (COI) Advisory Committees**
- **Ethics Committee**

**Basic UR-HRPP Requirements**

- **All human subject research conducted by UR faculty, staff or students requires [Departmental and Institutional Review Board approval]** (including human subject research that meets exemption requirements). The UR is considered engaged in human subject research when its employees or agents:
  * Obtain data about human subject research subjects through intervention or interaction with them;
  * Obtain identifiable private information about human subjects, through direct or indirect interaction;
  * Obtain informed consent of human subjects for research; or
  * Conduct a clinical trial as defined by Food and Drug Administration (FDA) regulations.

- **All study team members engaged in the conduct of human subject research are minimally required to complete [human subject protection training] every 3 years.** Sponsors, Department Chairs, Administrators or other UR Senior (continued on page 3)
Leadership may require additional training (e.g., Good Clinical Practice [GCP] training).

- With the exception of research deemed exempt by the RSRB, Principal Investigators (PIs) must meet [UR PI eligibility requirements](UR_PI_eligibility).

- Human subject research involving collaborations with non-UR sites or Investigators may utilize a [non-UR IRB](non-UR_IRB). Research reviewed and approved by an external IRB requires a Reliance (aka IRB Authorization) Agreement to be in place before the IRB review can occur. The UR requires [administrative institutional review by the RSRB](administrative_IRB) prior to submission to the external IRB. This administrative review is facilitated via Click® IRB.

- All research-related contracts, grants and agreements are administered by the Office of Research & Project Administration (ORPA). Only ORPA representatives are permitted to execute (sign) contracts and communicate post-award administrative requests (e.g., project period extensions, budget modifications, programmatic changes) to funding sponsors on behalf of the University. This includes: proposals submitted to external entities for financial support; confidentiality agreements (aka non-disclosure agreements); clinical trial agreements; sponsored research agreements; data use agreements; data transfer agreements; and material transfer agreements.

- All clinical research must comply with the [Clinical Research Billing Policy](Clinical_Billing_Policy), ensuring that clinical procedures, items or tests that are experimental are billed appropriately.

- All faculty and research staff with the ability to influence the design, conduct and reporting of research are required to report annually all external financial interests for review. New or revised financial interests should be reported within 30 days of discovery or acquisition. In the event a financial conflict of interest is identified, the Dean will take action to eliminate, reduce, or manage the conflict through a Conflict of Interest Management Plan; these plans must be followed. Investigators with funding through Public Health Service are also required to complete conflict of interest training every 4 years, and report reimbursed or sponsored travel related to their institutional responsibilities.

- All research utilizing protected health information (PHI) conducted under the University of Rochester Medical Center (URMC) & Affiliates covered entity or with study team members that are part of the URMC & Affiliates covered entity must comply the [Health Insurance Portability and Accountability Act (HIPAA)](Health_Policy) and URMC HIPAA [Policies](HIPAA_Policies) and [Procedures](HIPAA_Procedures).

- [All data and/or biospecimen shared outside of the institution require the execution of a data use or material transfer agreement via ORPA](All_data_use_agreement) including data/biospecimens that have been de-identified.

- All research that is potentially subject to the [European Union’s General Data Protection Regulations (GDPR)](European_GDPR) must undergo review by the Privacy Office and Counsel.

- Review and approval by a UR research [ancillary committee](ancillary_committee) may be required for human subject research involving specific types of subject populations, procedures or research services.
**UR-HRPP Ancillary Committee**

Ancillary committees exist within the UR-HRPP to ensure: a) appropriate expertise is applied to the review of a human subject research proposal; b) applicable regulatory requirements that fall beyond the scope of IRB review are met; and c) adequate resources are available for the conduct of the specific type of research. Ancillary committee review is facilitated through Click® IRB, however some committees have additional application and/or review processes that fall outside of Click® IRB. Study teams should contact applicable ancillary committees early in the protocol development process to understand what the review process entails. A description of ancillary review requirements are provided in [OHSP Policy 503 Ancillary Committee Review](#).

<table>
<thead>
<tr>
<th>If the research involves…</th>
<th>Ancillary review is required by…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolling individuals with cancer or reviewing patient health information generated by the Cancer Center</td>
<td>Cancer Center Peer Review Committee 275-5345</td>
</tr>
<tr>
<td>Administration of radiation therapy at URMC &amp; Affiliates</td>
<td>Department of Radiation Oncology Protocol Review Committee <a href="mailto:DROIPR@urmc.rochester.edu">DROIPR@urmc.rochester.edu</a></td>
</tr>
<tr>
<td>Pregnant to post-partum women</td>
<td>Obstetrical Research Committee</td>
</tr>
<tr>
<td>Study procedures on hospitalized newborns</td>
<td>Neonatal Clinical Trials Group 275-1521</td>
</tr>
<tr>
<td>Enrolling patients in the Emergency Department</td>
<td>Emergency Medicine Research Committee 275-1198 <a href="mailto:EMResearch@urmc.rochester.edu">EMResearch@urmc.rochester.edu</a></td>
</tr>
<tr>
<td>Introduction of recombinant or synthetic nucleic acid molecules (plasmids, gene transfer vectors, viral vectors, etc.) into human subjects; cells that have been treated with recombinant or synthetic nucleic acid molecules into human subjects; introduction of genetically engineered micro-organisms into human subjects; or biohazardous organisms or materials handled at Biosafety Level 2 or higher</td>
<td>Institutional Biosafety Committee 275-2402</td>
</tr>
<tr>
<td>Obtaining fresh, banked or archived human tissue from Surgical Pathology</td>
<td>Surgical Pathology <a href="mailto:LabSRSS@urmc.rochester.edu">LabSRSS@urmc.rochester.edu</a></td>
</tr>
<tr>
<td>Radioisotopes or radiation-generating devices used for research purposes</td>
<td>Human Use of Radiation Committee 275-3781</td>
</tr>
<tr>
<td>Activities that require access to the UR Center for Advanced Brain Imaging &amp; Neurophysiology (UR CABIN)</td>
<td>UR Center for Advanced Brain Imaging &amp; Neurophysiology 275-4540</td>
</tr>
<tr>
<td>Resources within the Clinical Research Center</td>
<td>Clinical Research Center 275-0653</td>
</tr>
<tr>
<td>Subject recruitment, enrollment or the conduct of study procedures at Highland Hospital</td>
<td>Highland Hospital Administrative Research Review Committee</td>
</tr>
</tbody>
</table>
## Getting Started with Your Research

Prior to initiating 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: Some steps include multiple activities that may occur concurrently.

<table>
<thead>
<tr>
<th>STEP</th>
<th>TASK(S)</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Generate idea</td>
</tr>
<tr>
<td>2</td>
<td>Validate study feasibility</td>
</tr>
<tr>
<td></td>
<td>- Verify the study <em>should</em> be done: Is the research relevant? Is there scientific merit? Is the study designed to answer the question at hand?</td>
</tr>
<tr>
<td></td>
<td>- Verify the study <em>could</em> be done: Do you have adequate time, resources, population, and funding to accomplish the aims of the research?</td>
</tr>
<tr>
<td>3</td>
<td>Verify the proposal involves 'human subject research'</td>
</tr>
<tr>
<td></td>
<td>- To be considered ‘human subject research’, the proposal must meet the definition of ‘research’ and ‘human subject’ (see <a href="#">OHSP's Guideline on Determining Human Subject Research</a>).</td>
</tr>
<tr>
<td></td>
<td>- Proposals that do not meet the definition of ‘human subject research’ do not require review by an IRB.</td>
</tr>
<tr>
<td>4</td>
<td>Initiate funding proposals and/or contract review</td>
</tr>
<tr>
<td></td>
<td>- All grant submissions, agreements (including but not limited to non-disclosure agreements, clinical trial agreements, sponsored research agreements, data use agreements, data transfer agreements and material transfer agreements) and contracts must be reviewed and submitted through <a href="#">ORPA</a>. Note: Grant proposals involving multi-site research must identify the IRB acting as the Reviewing IRB for all sites (as applicable). See <a href="#">OHSP Policy 504 IRB Reliance and Cooperative Research</a> for additional information.</td>
</tr>
<tr>
<td></td>
<td>- Grant submissions should not be submitted for IRB review until they receive a ‘fundable’ score.</td>
</tr>
</tbody>
</table>

### Verify Principal Investigator eligibility

- 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 & Dentistry and the School of Nursing having the rank of Assistant Professor or above may also be PI.
- Exception = Studies deemed exempt by an IRB.

### Complete human subject protection training

- Per [OHSP Policy](#), all individuals engaged in the conduct of human subject research must complete basic human subjects training through the Collaborative Institutional Training Initiative (CITI). See additional instructions [here](#).
- 1-2 days following course completion, *internal* (UR) faculty, staff and students will be provided access to [Click® IRB](#).

### Prepare IRB/RSRB submission documents

- Basic IRB submissions include a study protocol, study measures, consent and recruitment materials (as applicable). A basic study submission checklist is available in the [Click® IRB Study Staff Manual](#).
- Protocol and consent form templates are available through OHSP.

### Disclose conflicts of interest

- Any new or revised conflict of interest (COI) related to the submission must be reported (applicable to all study team members). The resulting COI Management Plan or Transparency Checklist must be included in the IRB submission.

(continued on next page)
## Getting Started with Your Research

(continued from previous page)

### Prepare & submit IRB application(s)

- All human subject research undergoing review by the RSRB must be submitted through the [Click® IRB](#) review system. Step-by-step instructions for creating and submitting a new study in the review system are available in the [Click® IRB Study Staff Manual](#).
- All human subject research undergoing review by an IRB external to the UR (RSRB), must undergo administrative institutional review by the RSRB via the [Click® IRB](#) review system. Follow the instructions for creating and submitting an External IRB study in the [Click® IRB Study Staff Manual](#).

### Department review & approval conducted

- Upon submission of the proposal in Click® IRB, per [OHSP Policy](#), the RSRB will direct submissions to the PI’s department (primary appointment) for review and approval.

### RSRB review conducted | Ancillary Committee review conducted

- Following department review and approval, the proposal will be assigned to a RSRB board for review and approval. Board assignments are based on the submitting PI's department (primary appointment); each board is assigned an [IRB Coordinator](#) to facilitate review.
- Proposals undergoing review by an External IRB will be assigned to the [Reliance Coordinator](#) for administrative review. Submission to the External IRB may only be completed following RSRB sign-off. All External IRB reviews will be conducted per the External IRB's standard operating procedures.
- Proposals requiring Ancillary Committee review may be withheld from RSRB review until Ancillary Committee approval has been granted. See the [OHSP Policy 503 Ancillary Committee Reviews](#) for additional information.
- For additional information, see OHSP’s [Quick Reference Guide: Criteria for IRB Approval](#)

### Obtain approval by reviewing IRB (i.e., RSRB or External IRB) | Obtain approval from Ancillary Committees (as applicable) | Notice of Award (NOA) issued by ORPA (as applicable) | Contract(s) / Agreement(s) executed by ORPA (as applicable) | General account ledger assigned by ORACs (as applicable)

### Initiate study conduct

**Studies may not be initiated until all of the tasks identified in Step 8 above have been completed (as applicable).**

- The Principal Investigator has full and final responsibility for the conduct of the approved research. See [OHSP Policy 901 Investigator Responsibilities](#) for a summary of responsibilities, as well as the associated summary sheets for [exempt](#), [non-FDA regulated](#) and [FDA-regulated](#).
- The OHSP Division of Quality Improvement also offers [Study Start-Up Consultations](#) free-of-charge to aid study teams in achieving research compliance.
# Educational Opportunities, Resources & Services

## Key HRPP Offices & Departments
- Clinical & Translational Science Institute (CTSI)
- CTSI Office of Clinical Research (OCR)
- CTSI Office of Regulatory Support (ORS)
- Office for Human Subject Protection (OHSP)
- Office of Research & Project Administration (ORPA)
- Office of Research Accounting & Costing Standards (ORACS)
- URMC & Affiliates Privacy & Security Office

## HRPP People Finders
- CTSI Team Directory
- OHSP IRB Coordinator Lookup
- OHSP Staff Directory
- ORPA Material Transfer Agreement Cost Center Assignments
- ORPA Research Administrator Directory
- ORPA Staff Directory
- OCR Staff Directory
- URMC & Affiliates Privacy Officers & Security Officials

## HRPP Policies, Procedures & Guidelines
- HIPAA Policies and Procedures
- OHSP Policies & Guidance
- OHSP Quality Management Guidance
- OCR Policy 001 Public Disclosure of Clinical Trial Information (ClinicalTrials.gov)
- ORACS Policies & Procedures
- ORPA Award Management Guidance
- ORPA Clinical Trial Billing Compliance Policies, Procedures and Resources
- ORPA Notice of Award Guidance
- ORPA Proposal Development Guidance
- ORPA Sponsored Research Administration, Equipment & Property & Intellectual Property Policies
- ORS 21 CRF 11 Guidance

## Educational Opportunities
- CITI Human Subject Protection Training
- CITI Good Clinical Practice Training
- CTSI Early Stage Faculty Boot Camp
- CTSI Study Coordinators Organization for Research and Education
- Environmental Health & Safety Hazard Assessment Tool & Training Indicator
- OHSP Education & Training Framework
- ORPA Continuous Learning for Administrators of Sponsored Programs (CLASP) Training
- ORPA Training Videos
- ORPA Web Portal for Researchers
- ORS Investigational New Drug (IND) & Investigational Device Exemption (IDE) Training

## HRPP Email Distribution Lists
- CTSI Weekly Email Update
- CTSI Study Coordinator Organization for Research and Education
- OHSP Email Distribution List
- ORPA Email Distribution List

## Forms & Templates
- HIPAA Forms for Research
- OHSP Protocol & Consent Templates
- OHSP Self-Audit Tools
- OHSP Study Documentation Tools & Templates
- ORPA Forms & Checklists

## Funding-Related Resources
- CTSI Incubator Program
- CTSI Pilot Studies Program
- Funding Opportunities
- RSRB Fee Schedule

## HRPP Resources & Services
- Biostatistics Consulting Service
- Center for Health + Technology
- Clinical Materials Services Unit
- Clinical Trials Coordination Center
- Clinical Trials Processing Laboratory
- CTSI Biomedical Informatics Consultations
- CTSI Clinical Research Center
- CTSI Community Engagement Consultations
- CTSI Greater Rochester Practice-Based Research Network
- CTSI Recruitment Tools & Consultation Services
- CTSI Research Data Integrations & Analytics Team
- CTSI Research Methods Forum
- CTSI Research Request Dashboard
- CTSI Resource Finder
- Emergency Department Research Associate Program
- Grant Writing Resources
- Investigational Drug Service
- Miner Library Data Management Planning Resources
- OHSP Newsletter Archive and Index
- OHSP Study Start-Up Consultations
- OHSP Quality Management Consultation Service
- ORS ClinicalTrials.gov Support
- ORS Investigational Device Exemption (IDE) Support & Guidance
- ORS Investigational New Drug (IND) Support & Guidance
- REDCap Online Surveys & Data Collection
- UR Health Lab
- URMC Clinical Laboratory Services
- URMC Genomics Research Center
- URMC Shared Research Labs
- UR Ventures