GETTING STARTED WITH YOUR RESEARCH

The flowchart below demonstrates the steps for initiating most types of human subject research at the University of Rochester. Activities appearing in boxes outlined in blue apply to *all* human subject research; **activities appearing in yellow boxes may not apply, based on the nature of the research and/or funding source**.

Generate idea

Validate study feasibility

- Verify the study *should* be done: Is the research relevant? Is there scientific merit? Is the study designed to answer the question at hand?
- Verify the study *could* be done: Do you have adequate time, resources, population, and funding to accomplish the aims of the research? Per UR Policy, all research involving billable clinical services (e.g., clinical procedures, items or tests) are *required* to conduct a Coverage Analysis to mitigate the risk of billing errors and identify budget deficits. Trials with a planned deficit require Departmental/Division Sign-Off and the identification of an unrestricted account to absorb the deficit at trial close-out. Services are available through the CTSI's OCR to assist in feasibility assessment and pre-award finance planning.

Verify the proposal involves 'human subject research'

To be considered 'human subject research', the proposal must meet the definition of 'research' and 'human subject' (see the OHSP Guideline on Determining Human Subject Research & OHSP FAQ: When do I need to get IRB approval?). Proposals that do not meet the definition of 'human subject research' do not require review by an IRB. However, when unsure, when documentation is required for the funding agency or publisher, or the Investigator just would like documentation, proposals may still be submitted through Click IRB for formal review and determination of not human subject research.

Verify PI 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. Exceptions are made for students (including undergraduate, graduate, and medical students, as well as residents and fellows) conducting not human subject research or research deemed exempt.

Complete human subject protection training

Per OHSP Policy, all individuals engaged in the conduct of human subject research must complete basic human subject protection training through the Collaborative Institutional Training Initiate (CITI). See additional instructions here. One to two days following course completion, internal (UR) faculty, staff and students will be provided access to the Click IRB module in the IORA system.

Disclose conflicts of interest

Any new or revised financial interests 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 (see below).

Initiate funding proposals and/or contract/ agreement review

- 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 to ORPA via the IORA system.
- Grant proposals involving multi-site research must identify the IRB acting as the Reviewing IRB for all sites (as applicable). See OHSP Policy 504 IRB Reliance and Cooperative Research for additional information.
- PI-Initiated research that is externally funded may require an Institutional Risk Assessment if/when full indemnification is not offered/made available in the clinical trial agreement.
- Grant submissions should not be submitted for IRB review until they receive a 'fundable' score.

If the research involves a billable clinical service

Prepare & submit IRB application

All human subject research must be submitted to the RSRB, the University of Rochester's IRB, via the Click IRB review module in the IORA system. This includes studies where the RSRB will act as the Reviewing IRB, as well as studies that will be reviewed by an External IRB (administrative institutional review is required *prior* to submission to the External IRB). Basic IRB submissions include (as applicable) a study protocol, study measures, consent documents, recruitment materials, and a data security assessment form; a basic study submission checklist is available in the here. Step-by-step instructions for creating and submitting studies in IORA are available in the Click IRB Study Staff Manual.

Build study budget & calendar in OnCore

All research involving billable clinical services (e.g., clinical procedures, items or tests) are required to have their budget and study calendar in OnCore, the University's CTMS; this process can occur concurrently with IRB and contract/ agreement review. Services are available through OCR to assist in this process. To access OnCore, complete their request access form and designated training.

Budget submission & review

Once the study budget and calendar have been built in OnCore, review and sign-off is required by the Research Compliance Office (a division of ORPA), prior to contract/agreement execution.

Departmental scientific & resource review

Upon submission of a proposal, per OHSP Policy, the RSRB will direct all submissions to the PI's department (primary appointment) for scientific and resource review and approval. Note: Additional procedures may be required as part of this review process, based on department-specific procedures/practices.

RSRB review

Following departmental approval, the proposal will be assigned to an IRB Coordinator to facilitate review. For a summary of how RSRB review is carried out see OHSP Explains… The IRB Review Process. Note: Based on Ancillary review requirements, proposals may be withheld from RSRB review until applicable Ancillary Committee approval has been granted.

Ancillary Committee review

Following departmental approval, the RSRB will direct submissions to applicable Ancillary Committees for review and approval. Ancillary Committee review will then be conducted per the committee's standard operating procedures. The timing of review, in relation to RSRB review (i.e., before, concurrent with, or after RSRB review), is dependent on committee requirements.

Contract(s)/Agreement(s) executed by ORPA

If the Reviewing IRB is an External IRB

External IRB review

Following RSRB confirmation of reliance, submit the proposal to the External IRB for review and approval (per the External IRB's standard operating procedures). Once the study is approved, documentation of External IRB approval should be uploaded into the Click IRB system.

Receive NOA & general accounts ledger from ORPA/ORACS

If the research involves a billable clinical service

If the research involves a billable clinical service

Finalize & activate the study in OnCore

Following contract/agreement execution and IRB approval, the study must be finalized and activated in OnCore. OnCore activation results in the creation of a study record in eRecord if the study has billing risk.

Initiate study conduct

**** Studies cannot be initiated until all of the applicable activities identified above have been completed/approved. ****

- The PI 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 research deemed exempt, non-FDA regulated and FDA-regulated research. For collaborative research, additional responsibilities are summarized in OHSP Policy 504 IRB Reliance and Collaborative Research.
- All research must be conducted in accordance with the IRB-approved protocol (and all supporting documents). All revisions to the research must be submitted to the Reviewing IRB for review and approval *prior* to implementation. IRB approval must be maintained throughout the conduct of the research. If a study is assigned an expiration date, a continuing review (progress report) must be submitted and approved to continue conducting the research. If IRB approval lapses (i.e., the approval expiration date passes before the study is re-approved), all research activities must cease until re-approval is obtained.
- All participating sites engaged in multi-site research, where the RSRB is the Reviewing IRB, must be submitted and approved prior to study implementation at the participating site (participating sites are submitted following RSRB approval of the overall study, under the umbrella of the overall study). See OHSP' Guideline and Flow Charts When University of Rochester is the Reviewing IRB for additional information.
- Post-Approval Consultations are available free-of-charge through the OHSP Division of Quality Improvement to aid study teams in achieving research compliance.
- All administrative requests, financial requests or programmatic changes related to a grant or agreement must be communicated via the designated ORPA liaison.
- All new or revised COI Management Plans or Transparency Checklists that are put into place during the conduct of a research study must be submitted to the RSRB for continued review.

Acronyms & Definitions

CITI = Collaborative Institutional Training Initiative
COI = Conflict of Interest
CTMS = Clinical Trial Management System
CTSI = Clinical & Translational Science Institute
IORA = Integrated Online Research Administration
IRB = Institutional Review Board
Reviewing IRB = The IRB designated to review and approve the research
NOA = Notice of Award
OCR = Office of Clinical Research
OHSP = Office for Human Subject Protection
ORACS = Office of Research Accounting & Costing Standards
ORPA = Office of Research & Project Administration
PI = Principal Investigator
RSRB = Research Subjects Review Board (the University's IRB)