Getting Started with a New Research Project

OVERVIEW
Once it has been determined that a project is human subjects research, the Principal Investigator for the project should contact the St. Joseph Health (SJH) Center for Clinical Research.

The following flowchart outlines the general process for study start up at a SJH facility:

- Principal Investigator (PI) has New Study for Submission
  - PI Obtains Facility Support/Approval
  - PI contacts the Center for Clinical Research and forwards Protocol and Consent
  - Two processes then occur simultaneously

- Institutional Review Board (IRB)
  - IRB staff reviews protocol and consent to determine Level of IRB Review
  - IRB staff provide PI with preliminary steps required prior to IRB submission (e.g., CITI and CVs)
  - Upon approval from CORA, IRB staff works with the PI on the application process
  CONTACT: Mary Parga

- Central Office of Research Administration (CORA)
  - CORA staff reviews protocol and consent to determine hospital involvement and necessity of budget, contract, and feasibility
  - CORA provides investigator with preliminary steps required prior to IRB submission (e.g., Feasibility Assessment)
  CONTACT: Margaret Amaya
PRELIMINARY IRB REQUIREMENTS

Complete Human Subject Protections Training
All researchers must complete training in the protection of human subjects at the Collaborative Institutional Training Initiative (CITI) website. See the Guidance for Human Subjects Protection Training - CITI Training to register for the appropriate course.

Submit Your CV
All researchers and research staff are required to submit Curriculum Vitae to the HRPP Office.

Ensure Facility Support
Prior to submitting a project for IRB review, it is the investigator’s responsibility to obtain appropriate approvals (i.e. Institutional Officials, affected department managers, Leadership Teams, Research Council, etc.) from the facilities at which the research will be conducted.

Obtain Approval from CORA to Submit to IRB
CORA is the office responsible for:
  • Feasibility Assessment;
  • Review of Pregnancy Language (ensure a study aligns with the Ethical & Religious Directives for Catholic Health Care Services);
  • Clinical Effectiveness Committee (CEC) Review (determine if studies involving devices require submission to the CEC);
  • Medicare Coverage Analysis (identifying and analyzing a study budget to determine who the appropriate payor is for each item and service required by a study protocol);
  • Qualifying Clinical Trial Study Assessment (review of a study protocol to insure it meets the required characteristics to be considered research);
  • Budget Review and Negotiation;
  • Contract Facilitation; and
  • Billing and Accounting.

Please contact CORA to determine the steps that are necessary prior to IRB submission.

SUBMITTING TO THE IRB
Upon completion of the preliminary requirements, researchers should submit to the IRB.

Submit your Application for IRB Review
All levels of review require electronic submission via email.

Each application is designed to collect the appropriate information for determining if IRB approval can be granted.

Understand the IRB Review Process
HRPP staff will conduct a preliminary review of all submissions to ensure information and materials required for review are included. IRB Members will then review the information and materials submitted. After IRB review, the HRPP staff will communicate the IRB’s determination and requests to the researchers. If applicable, researchers will need to provide requested information or materials and complete requested revisions in order to complete the IRB review process.
For a more detailed description, please see the *HRPP General IRB Submission Process and Communication of Results* guidance.

**Understand your Responsibilities**
- Obtain IRB approval for *amendments* to previously approved research.
- Obtain *continuing review* at least once annually.
- Submit reports of *unanticipated problems* and *serious or continuing noncompliance*.
- Submit any *information* relevant to the conduct of your study.
- Submit a *Closure* report when your research is completed.

**Use the HRPP Office as your Resource**
It is strongly encouraged to work the HRPP staff in your submission and ask any questions at any stage of the IRB process. This will help to facilitate the review.

The main telephone number for the HRPP Office is (949) 381-4908.