Getting Started with a Research Study

OVERVIEW
The Center for Clinical Research (CCR) is comprised of the St. Joseph Health (SJH) Central Office for Research Administration (CORA) and Human Research Protections Program (HRPP). The HRPP houses the SJH Institutional Review Board (IRB), which is the ethical committee responsible for reviewing and approving human subjects research protocols in alignment with federal regulations.

The following flowchart outlines the general process for research study start up at a St. Joseph Health (SJH) facility.

---

Principal Investigator (PI) has New Study for Submission
- Determining that a project is human research
- PI Obtains Facility Support/Approval
- PI Completes Human Subjects Training
- PI contacts the CCR and forwards Protocol, Consent, and all other supplemental materials

Human Research Protections Program (HRPP)/Institutional Review Board (IRB)
- HRPP staff reviews protocol and consent to determine Level of IRB Review
- HRPP 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

Central Office of Research Administration (CORA)
- CORA staff reviews protocol and consent to determine hospital involvement and necessity of budget, contract, and/or feasibility
- CORA provides investigator with preliminary steps required prior to IRB submission (e.g. Feasibility Assessment)
STEP 1: DETERMINING WHETHER THE PROJECT INVOLVES HUMAN RESEARCH

Federal regulations and SJH policies require IRB review of research involving human subjects. Activities that meet the regulatory definitions of “research” and “human subjects” constitute human subjects research and require IRB approval and oversight, except in cases of exempt research.

If you have trouble making a determination of whether a project is human subjects research and requires IRB review, contact the HRPP Office for assistance at HRPP@stjoe.org.

STEP 2: ENSURING FACILITY APPROVAL AND ACCESS
The PI must 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.

In addition to support from the facility for the research, the PI must also ensure appropriate access is in place for the research team that will be accessing records, interacting with patients, and/or entering the facility.

If you have trouble determining who at the facility you should contact, contact the CCR for assistance.

STEP 3: HUMAN SUBJECTS TRAINING
All researchers and research staff including investigators, coordinators, clinical research nurses, regulatory staff, research pharmacists, data support/entry staff, IRB members, etc. are required to take the appropriate training in the protection of human subjects in research in order to participate in research under SJH.

This training must be completed at www.citiprogram.org. Please contact the HRPP Office for information on the appropriate course for your role.

STEP 4: INITIAL SUBMISSION OF RESEARCH STUDY MATERIALS
Once the above steps have been completed, you may submit your materials to CCR. Materials to submit include the protocol, consent form, data collection tools, Clinical Trial Agreement (CTA), sponsor budget, Investigator's Brochure, Pharmacy Manual, etc.

STEP 5: CORA START UP AND IRB SUBMISSION

PREGNANCY PREVENTION LANGUAGE
St. Joseph Health is a Catholic institution. In order to be in conformity with the Ethical and Religious Directives (ERDs) as set forth by the U.S. Conference of Catholic Bishops, abstinence must be an allowable method of pregnancy prevention for our patients, and we do not support the requirement of additional methods. CORA will review both the protocol and consent form to ensure conformity with the ERDs.

VERIFICATION OF TEST ARTICLES
A test article is any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation of the FDA. Clinical trials involving test articles (e.g. investigational drugs or devices) will be reviewed to verify that the test article has an Investigational New Drug (IND) or Investigational Device Exemption (IDE) with the FDA, or that the test article meets exemption criteria. IND and IDE number validity will be confirmed at this time.
Research at SJH facilities cannot begin until the information above is verified.

SUPPLY CHAIN REVIEW
For investigational device studies where the sponsor does not provide the device free of charge, submission of a New Product Request to the SJH Supply Chain is required. SJH Supply Chain and the ministry’s Materials Management Department will review the proposed study device with supporting documentation that is to be submitted by the investigator. Supporting documentation includes the research protocol, Instructions For Use, FDA approval letter, etc.

Following review and approval of the device, SJH Supply Chain will execute a Purchasing Agreement with the study Sponsor. Upon execution of the Purchasing Agreement, a charge code for the device will be generated and provide to both research and ministry staff for use at each study procedure.

RISK MANAGEMENT REVIEW
If the study is collecting information that could potentially put the organization at risk, the CCR will forward the study to Risk Management for clearance to proceed.

FEASIBILITY ASSESSMENT
Each study is assessed for impact upon the hospital and its staff. Information gathered during this process aides budget negotiations. The study coordinator or investigator completes the appropriate questionnaire and submits to CORA by email.

Once the questionnaire is received and reviewed, a Feasibility Assessment Meeting (FAM) will be held (via telephone) with the study coordinator, CORA, and hospital department representatives affected by the study to discuss logistics and troubleshoot potential procedural issues. A FAM findings report is presented to the IO at the facility in order to provide an opportunity to address questions or concerns.

Note: For studies in which the protocol adheres to commonly accepted or established practices, the research schedule of events will be assessed on a case by case basis in order to determine the necessity of a feasibility meeting.

IRB SUBMISSION
Once the study has been cleared for conformance with the ERDs, risk management, and feasibility, the study coordinator or investigator can submit the study to the SJH IRB for ethical considerations in human subjects protections.

MEDICARE ADMINISTRATIVE CONTRACTOR (MAC) SUBMISSION
For device studies, submission to and approval by the Regional Medicare fiscal intermediary for Part A & B services, is required prior to investigators enrolling Medicare patients.

DETERMINING OTHER COMMITTEE REVIEW

Conflict of Interest Committee Review
If the investigator or research associate discloses any potential or actual financial conflicts of interest, the information will be sent to the Conflict of Interest Review Committee (COIRC) for review. The COIRC will recommend a plan to the investigator to manage or dissolve the real or perceived conflict. In addition, the IRB may require disclosure of this information in the consent form.
Institutional Biosafety Committee (IBC) Review
Studies involving the use of hazardous biological material and recombinant or synthetic nucleic acids require review by an IBC. An IBC consists of experts in biosafety, human gene therapy, infectious disease, recombinant DNA, and occupational health. The IBC is responsible for establishing, monitoring, and enforcing policies and procedures involving hazardous biological materials, and recombinant/synthetic nucleic acids to meet applicable federal, state, local, and institutional regulations, guidelines and policies.

IBCs are specific to the research site and are not a centralized function. As SJH does not have an IBC, this oversight should be outsourced

CONTRACT FACILITATION
Once the investigator has received the CTA from the sponsor, this is to be forwarded to CORA for SJH legal counsel review and negotiation with the sponsor. Any additional agreements that may be required will be completed alongside the CTA.

If the study involves data collection using or disclosing Protected Health Information (PHI) or facility cost information, the appropriate data use or collection agreement will be completed alongside the CTA.

COVERAGE ANALYSIS (CA)
In order to determine which procedures within a research protocol are billable to Medicare, a Coverage Analysis (CA) must be performed. This is a tool used for budgeting, billing, auditing and monitoring.

BUDGET NEGOTIATION
After the FAM, CORA will begin budget negotiations between the hospital, investigator and sponsor. As a non-profit organization, the budget is created keeping in mind that costs (i.e. labs, ECGs, radiology services, etc.) are covered. A fair market value assessment for physician compensation will be completed as well to ensure all payments comply with Stark Law regulations.

GAP ANALYSIS
For federally funded studies or clinical trials without funding, the study coordinator or investigator will submit the Gap Analysis Questionnaire.

CORA will perform a Gap Analysis to determine the financial impact to the hospital as a result of participation in the study. If a loss is anticipated, then this must then be signed off by both the investigator, Institutional Official (IO) for Research and the CEO/President at the facility where the research will occur.

FINAL DOCUMENT RECONCILIATION
Prior to CTA execution, CORA will perform a final document reconciliation to ensure the CTA with budget, ICF language, and CA are in agreement.

STEP 6: RESEARCH COMMENCES
Upon CTA Execution, CORA will provide a notification to sites indicating that all CORA activities are complete. Upon receipt of a Go Letter, IRB Approval, and Site Initiation Visit (as applicable) the site may begin enrolling participants.