Getting Started with a New Research Study

OVERVIEW
The St. Joseph Health (SJH) Center for Clinical Research (CCR) is comprised of the SJH Central Office for Research Administration (CORA) and Human Research Protections Program (HRPP). The HRPP houses two Institutional Review Boards (IRB), which are ethical committees 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 facility. See addition detail of steps provided below the schema. For questions about any of the steps below, please contact CCR at hrpp@stjoe.org.

- Principal Investigator (PI) has a New Study for Submission
  - Determination that a project is human subjects research
  - PI Obtains Facility Support/Approval
  - PI Completes Human Subjects Training
  - PI contacts the CCR and submits the Protocol, Consent Forms, and all other supplemental materials
  - Key study personnel complete Human Subjects Training prior to IRB submission

- Central Office of Research Administration (CORA)
  - CORA staff reviews protocol and consent forms to determine hospital involvement and necessity of budget, contract, and/or feasibility assessment meeting
  - CORA provides investigator with preliminary steps required prior to IRB submission (e.g. Feasibility Assessment Meeting)

- Human Research Protections Program (HRPP)/Institutional Review Board (IRB)
  - HRPP staff reviews protocol and consent forms to determine Level of IRB Review
  - Upon approval from CORA, IRB staff facilitates the IRB review process
STEP 1: DETERMINING WHETHER THE PROJECT INVOLVES HUMAN SUBJECTS 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 are unsure whether a project is human subjects research, the HRPP Office must be contacted for assistance in making the determination at hrpp@stjoe.org. The HRPP Office has final authority to determine whether a project is human subjects research and requires IRB review or qualifies for exemption.

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. This can be facilitated through ministry Human Resources or Medical Staff office.

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, 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 refer to Guidance for Research Education for more information: https://www.stjhs.org/center-for-clinical-research/human-research-protections-program/for-researchers/guidance/.

STEP 4: INITIAL SUBMISSION OF RESEARCH STUDY MATERIALS

Once the above steps have been completed, you may submit your materials to CCR. Refer to the Material Required for IRB Review Checklist: (https://www.stjhs.org/center-for-clinical-research/human-research-protections-program/for-researchers/guidance/) and Clinical Research Trial Questionnaire (CRTQ): https://www.stjhs.org/center-for-clinical-research/human-research-protections-program/for-researchers/submission-forms/.

STEP 5: CORA START UP AND CLEARANCE FOR IRB REVIEW

PREGNANCY PREVENTION LANGUAGE

St. Joseph Health is a Catholic institution. In order to conform with the Ethical and Religious Directives (ERDs) as set forth by the U.S. Conference of Catholic Bishops, protocols and consent forms must allow for abstinence as a method of birth control. Consent forms do not have to list abstinence as a possible method of birth control, but cannot exclude it. CORA will review both the protocol and consent forms 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. In the case of IND- or IDE-exempt trials, additional documentation may be requested from the sponsor to support or confirm an exemption determination.

**STRATEGIC SOURCING REVIEW**

For investigational device studies, submission of a New Product Request to Strategic Sourcing is required. Strategic Sourcing and the ministry’s Materials Management Department will review the proposed study device with supporting documentation that is to be submitted by the investigator.

Following review and approval of the device, Strategic Sourcing will execute a Purchasing Agreement with the study Sponsor, if needed. A charge code for the device will be generated and provided to both research and ministry staff for use at each study procedure.

For device studies, a Medicare Administrative Contractor (MAC) submission will be completed, as needed, to cover both parts A and B.

**FEASIBILITY ASSESSMENT**

Each study is assessed for impact upon the hospital and its staff. Information gathered during this process aides budget negotiations.

A Feasibility Assessment Meeting (FAM) will be held (via telephone) with the study coordinator, CCR, impacted hospital service lines, and PI (as needed), to review logistics and troubleshoot potential procedural issues. A FAM findings report is provided to the ministry’s Institutional Official for Research.

If the study is collecting information that could potentially put the organization at risk, the CCR will forward the study to the appropriate Risk & Integrity Services representative for clearance to proceed.

*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.

**DETERMINING OTHER COMMITTEE REVIEW**

**Conflict of Interest Review and Oversight Committee**

If the investigator or research associate discloses any potential financial or other conflicts of interest, the information will be sent to the Conflict of Interest Review and Oversight Committee (COIROC) for review by the HRPP. The COIROC will determine a plan to either manage or dissolve the real or perceived conflict. The management plan will be provided to the IRB which will review and further determine whether the interest and its management allow the research to be approved.

**Institutional Biosafety Committee (IBC) Review**

Studies involving the use of hazardous biological material and recombinant or synthetic DNA or nucleic acids, including viral vectors, require review by an IBC. The IBC is responsible for establishing, monitoring, and enforcing policies and procedures involving studies with these types of materials to meet applicable federal, state, local, and
institutional regulations, guidelines and policies. An IBC consists of experts in biosafety, human gene therapy, infectious disease, recombinant DNA, and occupational health.

IBCs are specific to the research site and are not a centralized function. As SJH does not have an IBC, this oversight is outsourced to Western IBC Services. CCR will facilitate agreements with external IBCs for studies requiring IBC review, as necessary.

CLEARANCE FOR IRB REVIEW
Once the study has been cleared, the study coordinator or investigator can submit the draft consent form and any other materials required for IRB review (see Material Required for IRB Review Checklist: https://www.stjhs.org/center-for-clinical-research/human-research-protections-program/for-researchers/guidance/).

CONTRACT FACILITATION
The CTA is to be included in the study submission. CORA will facilitate contract negotiation with SJH legal counsel review and negotiation with the sponsor. This review entails ensuring various institutional requirements are addressed within the CTA. 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.

Contract negotiation will occur simultaneously with IRB review.

COVERAGE ANALYSIS (CA)
In order to determine which procedures within a research protocol are billable to insurers, a Coverage Analysis (CA) must be performed. This is a tool used for budgeting, billing, auditing and monitoring. This will be used as a tool to negotiate the study budget and will be reconciled against the final CTA, budget and ICF prior to the study being opened.

BUDGET NEGOTIATION
After the FAM, CORA will develop an internal budget template that will be reviewed by the investigator and research staff designee. Once the internal budget has been agreed upon as a starting point, CORA will begin budget negotiations with the sponsor. As a non-profit organization, SJH cannot subsidize for-profit research. The budget is created to ensure costs (i.e. labs, ECGs, radiology services, etc.) are covered, at minimum.

A fair market value (FMV) assessment for physician compensation will be completed to ensure all payments comply with Stark Law regulations. Investigator activity is translated into fifteen minutes blocks and will be calculated based on Sullivan Cotter FMV sub-specialty hourly rate.

GAP ANALYSIS
For minimally funded or unfunded studies, 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 the investigator, Institutional Official (IO) for Research and the CE/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, including a final document reconciliation and copies of all final documents. Upon receipt of a “Go Letter”, IRB Approval, and Site Initiation Visit (as applicable), the site may begin enrolling participants.