Study Start-Up Activities	CR-203
Clinical Research Standard Practices	**Effective Date:** August 2022

SCOPE AND PURPOSE The document is applicable to the people and processes of the following Penn State College of Medicine and Penn State Health entities specified below engaged in clinical research:

Entities:

[ ]	Penn State Health Shared Services
[X]	Milton S. Hershey Medical Center
[X]	St. Joseph Medical Center
[X]	Holy Spirit Medical Center
[X]	Hampden Medical Center
[X]	Penn State College of Medicine
[X]	Medical Group – Academic Practice Division
[X]	Medical Group - Community Practice Division
[X]	Penn State Health Life Lion, LLC

Roles:

[X]	Principal Investigator
[X]	Sub-Investigators
[X]	Study Coordinators/Associates
[X]	Data Specialist
[X]	Financial Analyst
[X]	Key Study Ancillary Personnel

This standard operating procedure (SOP) describes the processes followed at this investigative site when a sponsor of a study chooses the investigative site to be a study site. This SOP applies to the procedures for conducting the study start-up activity for all clinical studies involving human subjects in research during all investigational phases of development. It describes the steps followed by this clinical research site from selection as a study site up to the Site Initiation Visit.

POLICY AND PROCEDURE STATEMENTS

1. Obtain necessary documentation from Sponsor
    a. Request the following critical study documents which include, but are not limited to:
        i. Current approved protocol
        ii. Current investigator brochure or package insert
        iii. Current approved informed consent form(s)
        iv. All current manuals (e.g. Laboratory [must include any processing and shipping guidelines], Pharmacy, Radiology, etc.) if applicable
        v. Contract (in Word format)
        vi. Budget worksheet (in editable format)
        vii. Participant-specific documentation (e.g. questionnaires, wallet cards, diaries, etc.)

viii. Any recruitment materials
ix. IND, IDE or HUD numbers and documentation (FDA letter) (including non-redacted FDA letter or letter/email from sponsor if IND/IDE/HUD number(s) are not located within the protocol)
x. NCT registration number

b. Inform the Sponsor that the internal budget and contract processes and IRB application (if applicable) cannot be initiated without the above documents.
c. Budget, contract, and IRB processes run concurrently, so budget/contract approval is not required to begin the IRB process.
    i. Do not provide Sponsor with specific timelines as to initiation and completion of contract and budget negotiations and IRB approval as there are many variables which impact these timelines.
    ii. Do not provide Sponsor with specific names of ORA and CTO staff who will be conducting negotiations. They will be provided at a later time by the staff in those central offices

2. Office of Research Affairs processes
    a. A research team member or representative from the respective research team's department will create an Internal Approval Form (IAF).
        i. Please note the OSP number generated by the system for CATS-IRB.
        ii. You will need to have a copy of the budget and protocol in order to complete the IAF.
        iii. ORA reviews the IAF for completion/accuracy and communicates any required changes back to the research team for correction.
        iv. Once the IAF has been routed for all internal approvals ORA will approve the IAF at proposal state.
    b. ORA reviews and redlines the Clinical Trial Agreement (CTA), and Letter of Indemnification (LOI) if applicable, in preparation for the CTO budget meeting with the Study team.
        i. Note that ORA will not send redline comments on the CTA (and LOI if applicable) to the CRO or Sponsor until after the budget meeting has taken place. ORA will be notified by the CTO to being its review through STAR.
    c. Upon completion of the budget meeting CTO will send out homework notices to ancillary departments including ORA.
        i. ORA will review the homework and incorporate changes to the CTA accordingly.
        ii. Upon completion ORA will send the homework response along with the payment and termination provisions of the CTA to CRO for review and comment.
        iii. Once CTO reviews and provides comments ORA will finalize the initial redlined draft CTA and send to the CRO or Sponsor for review.
    d. Upon full execution of the CTA including budget ORA will write up the award paperwork.
        i. Prior to submission for award all applicable compliance approvals must be uploaded into the IAF by the research team.
        ii. Once all compliance approvals have been successfully uploaded ORA will submit the award paperwork for processing.

3. IRB submission via CATS-IRB
    a. If an External IRB (i.e. WIRB or Advarra) will be the IRB of record for all sites refer to the CATS IRB Library, HRP-819 Reliance Request Form. Contact your department's HRPP analyst if you have any questions with your specific study.
    b. If using the local IRB:
        i. The IRB works by rolling submission. This means that we do not have deadlines for our IRB full board meetings, and we have no way to guarantee that a study will be sent to a specific board meeting.
        ii. Before a study can be assigned to a board meeting, it certain types of studies must go through the Department's Scientific Review Committee, if applicable, and our IRB's pre-review process. Contact your department's HRPP analyst if you have any questions with your specific study. That information can be found at www.research.psu.edu/irb/analysts.
        iii. After we have developed a draft site-specific consent form(s), the document will be sent to the study sponsor for review.
        iv. IRB template documents are located in the Library in the CATS-IRB system. Make sure you use the current version of the templates from the CATS library when creating new submissions or your submission will be returned to you.
    c. If using the Study Tracking and Analysis for Research (STAR) clinical trial management system, you will initiate the creation of the submission in STAR by completing the "Create STAR Submission" page in CATS.
        i. See for what studies are required to be submitted through STAR.
    d. Additional information for the Institutional Review Board can be found at www.research.psu.edu/irb.

4. Clinical Trials Office processes
    a. Studies using Penn State Health (PSH) billable services (e.g., labs, radiology, etc.) for clinical research must be submitted through STAR and reviewed by the CTO
        i. The CTO can assist departments that do not have the resources or experience to develop their own study budgets when there are no PSH billable service.
    b. You will need to upload the draft contract, draft budget, and all manuals (i.e., lab, imaging, etc.) into STAR
        i. The protocol and sponsor's consent form(s) are uploaded into CATS-IRB, and do not need to uploaded into STAR for the initial study's submission.
        ii. See CTO website (InfoNet) for instructions on using STAR including which documents are to be uploaded to CATS IRB and which are to be uploaded to STAR.
    c. Budget, payment terms, and negotiation plan are communicated to study team members via STAR for their approval to initiate negotiation with the Sponsor.
    d. CTO and ORA negotiate the budget and contract, respectively, with the Sponsor/CRO in parallel.
    e. Depending on the outcome of the budget negotiation with the Sponsor, a follow up review with the team members may be conducted via email, phone, or in-person to discuss the team's intentions to proceed or discontinue work on the study.
    f. If there is a decision by the PI to go forward with the study, but there is a projected negative budgetary balance, the PI's Department Chair will need to

complete the CTO form, “Account Summary Page”.

g. Should the outcome of the budgetary evaluation determine that the study is not feasible, the PI or other member of research team will notify the Sponsor of his/her decision.

RELATED POLICIES AND REFERENCES

Code of Federal Regulations: Investigational New Drug Application (21 CFR 312.50, 52, 53, 60, 66, 68)

APPROVALS

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HISTORY OF REVIEWS AND REVISIONS

December 2022	
Scope and Purpose, Roles	Updated "Financial Analyst/**Research Accountants**". Added "Regulatory Specialists" and "Central Research Office Personnel."