RUTGERS
BIOMEDICAL AND HEALTH SCIENCES
Clinical Trials Office

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Study Startup Process

1. Initial Contact with Industry Sponsor: CDA/NDA

Generally, the first step after an investigator has been approached by an industry sponsor or contract research organization (CRO) about the possibility of conducting a study at Rutgers is for a request to execute a Confidential Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA.) This agreement will be between Rutgers and the sponsor, or between Rutgers and the contract research organization (CRO) on behalf of the sponsor.

Documents associated with Industry-sponsored clinical trials (such as the protocol document or materials related to the investigational drug or device) are typically considered proprietary, and will not be released without an executed CDA or NDA. Rutgers investigators are not permitted to sign these documents themselves.

To forward a CDA or NDA for review and execution, sign in to the Research Administration and Proposal Submission System (RAPSS) using your NetID and password: https://rapss.rutgers.edu/ Click on "Agreements" on the top and then "Create New Agreement." Once submitted through RAPSS, the CDA or NDA will be reviewed by an RBHS CTO Contract Negotiator.

2. Investigator Feasibility Review:

Once a CDA or NDA has been executed, the sponsor will send the clinical trial protocol or protocol synopsis in order for the study team to further gauge interest in conducting the trial. The study team will also likely also be asked to complete the sponsor's feasibility questionnaire. This survey will allow the sponsor or Contract Research Organization (CRO) to evaluate the suitability of Rutgers as a site for the trial. Should you have questions about how to complete anything on the survey, please contact the CTO: clinicaltrials@rbhs.rutgers.edu

The CTO may also be able to query the applicable EMR system using Deep6AI cohort builder to run a report of the number of patients who potentially meet the inclusion/exclusion criteria for the trial. For more information, please go to: https://clinicaltrials.rbhs.rutgers.edu/solutions/deep6/

3. Sponsor's Site selection Process:

The sponsor or CRO may request an on-site qualification visit, which will include a tour of the facility, including the clinical areas, investigational pharmacy, specimen processing area and office space for the research team. A qualification visit may also be conducted virtually.
After the sponsor's qualification process, the Principal Investigator will typically be notified in writing of the site selection decision. If selected, the sponsor or CRO will send the following documents for immediate action:

- Draft contract and budget
- Draft informed consent form(s)
- Final protocol

- Investigator's Brochure (for investigational drug studies) or information about the device (for IDE trials)
- Regulatory documents for completion, such as FDA Form 1572, Protocol Signature page, Delegation of Authority Logs, etc.

4. **Study Team completes OnCore ePRMS Submission**

Provided the investigator wishes to pursue the study, the investigator or study team must complete a profile for the study using the OnCore ePRMS module. This is done BEFORE beginning any IRB submission, and BEFORE requesting legal review of the contract. The ePRMS submission provides basic information about the study, the investigator and the study team, and is also the mechanism to forward the protocol, draft contract and budget and draft informed consent form to the CTO for review. (This ePRMS submission replaces the former mechanism for contract review submission to RAPSS.)

Minimum required documents to be included with the ePRMS submission include the following:

- Protocol
- Draft contract
- Draft budget
- Draft ICF(s)
- Sponsor contact information (you can provide a pdf the notification from the sponsor of site selection or similar e-mail communication)
- Relevant partner hospital submission forms (i.e. IRC application for RWJUH or UH-Newark Scope of Services form)

Optional (when available):

- Study manuals (radiology, laboratory, pathology, EDC guidelines, etc.)
- Device documents as applicable (such as CMS approval, IDE, Purchase Agreement, Instructions For Use; Medicare Reimbursement/Coding Guidelines)
- Investigator's Brochure
- Applicable standard of care guidelines for the therapeutic area
- FDA Form 1572 (unsigned if signed version is not yet available)

Note that any member of the study team who needs access/training for OnCore should visit the CTO website for information and to complete the access request form:
https://clinicaltrials.rbhs.rutgers.edu/training/oncore-training/

5. RBHS CTO Feasibility Review/Intake Assessment

Once the ePRMS submission with the required documents has been completed, the RBHS CTO will conduct a brief formal feasibility review. This review process should be completed within 2 to 5 business days and will encompass:

- Review for the participant population using Deep6 AI Cohort Builder if applicable and available, and if it was not already done in the preliminary feasibility review stage
- Review for any competing studies

- Review of resource needs (for example, whether specialized procedures are required as part of the protocol), logistical considerations and use of partner hospital facilities
- Determination of partner hospital billing risk: A study with "Billing risk" is a study in which clinical procedures performed for the study could potentially be billed to a patient's insurance. When a study has billing risk, the CTO will create a billing grid, listing all of the procedures and timepoints required as per protocol within OnCore. This billing grid will then be transmitted to Epic as applicable, which will enable the study team to review the patient's charges in Epic to determine whether the charges have been "bucketed" appropriately as research vs. standard of care
- The CTO Intake Coordinator will work with the study team to complete the study intake form. This form is designed to gather information on resources required (for example, whether ClinCard will be used for Participant payments and whether Deep6 AI Cohort Builder will be used to identify potentially eligible patients), as well as how various study procedures will be performed (for example, which laboratories or imaging facilities will be utilized, whether remote monitoring of Epic is anticipated), what procedures, if any, are needed from a partner hospital, etc. This information is critical in order to efficiently accomplish the remainder of the study start up procedures (such as contract/budget negotiation, required agreements with partner hospitals, etc.)

The end result of the RBHS CTO Feasibility Review/Intake Assessment is a notification from OnCore of "SRB approval" which means that contract/budget review and the rest of study start up procedures may commence.

6. **Study start up activities assigned and delegated**

The CTO staff will assign the following study start up activities to the appropriate individuals within the CTO and within the PI's department as applicable:

- Contract negotiation
- Budget negotiation
- Medicare Coverage Analysis
- Creation of the billing grid
- Partner hospital application
- IRB submission/Regulatory Document preparation

The end result of this process is a formal e-mail from the CTO Intake Coordinator to the study team which identifies the individuals responsible for each of the tasks above and provides a roadmap of next steps and action items required to reach "activation" (sponsor approval to begin enrolling).