Instructions to RBHS study teams outside of CINJ: Agreement Review/Documentation Process for Industry sponsored/funded clinical research within RAPSS and OnCore

1. **Overview**

   Legal agreements with industry sponsors related to clinical research must be negotiated by the appropriate university designees, and signed by the University signatory in accordance with the Rutgers signature matrix. It is critical that these legal agreements be routed in the appropriate electronic systems and in accordance with this standard operating procedure in order to ensure timely review.

2. **Purpose**

   Provide guidance to Department Personnel on how to use RAPSS and OnCore to facilitate review of clinical research agreements. This process applies to contracts for clinical research studies meeting the following criteria:

   - RBHS Principal Investigator outside of CINJ
   - Industry-sponsored
   - Study is either an NIH-defined clinical trial, or a non-clinical trial (i.e. either prospective observational study or single time point study which requires both consent of human subjects and entails billable clinical procedures.)

3. **Who Must Comply**
   - Department Personnel
   - Business Managers
   - Deans, Directors, Chairs and Department Heads
   - Principal Investigators
   - RBHS Clinical Trials Office
   - Research Contracting Services
   - Research Financial Services

4. **Definitions**

Billable clinical procedures: Procedures associated with a CPT code, such as physical examination, X-ray or clinical laboratory testing, which could potentially be billed to a patient's insurance. RBHS policy requires that studies which require billable clinical procedures which are performed at Rutgers or at a partner hospital facility be built into OnCore in order to ensure that the procedures are billed appropriately (i.e. either to a patient's insurance when allowed or to research account.)

Confidential Disclosure Agreement (or Non-Disclosure Agreement) (CDA/NDA): Legal agreement between parties which outlines information to be shared and which must be restricted from wider dissemination.

Clinical Trial Agreement/Clinical Study Agreement (CTA/CSA): A legal agreement which governs the conduct of a study and outlines the obligations of each party. A budget is typically part of the agreement.

Designated Budget Negotiator: The individual who has been assigned upon mutual agreement between the RBHS CTO and the study Principal Investigator to negotiate an industry-sponsored clinical trial budget. This person may work for the RBHS Clinical Trials Office, or may reside within the Principal Investigator's Department, or may be an individual designated by the Principal Investigator's School or Unit.

NIH definition of a clinical trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. More information is available at: https://grants.nih.gov/policy/clinical-trials/definition.htm

OnCore: A Clinical Trial Management System in place at Rutgers. This is an electronic system for management of all clinical research studies entailing billable clinical procedures within RBHS, and for management of participants in those studies.

RAPSS: Research Administration and Proposal Submission System. This is an electronic gateway for the submission, review, approval and tracking of funding projects and related budgets for research at Rutgers. The Office for Research maintains all information regarding grant and contract applications, budgets and on-going annual adjustments to research funding using this system

5. **Procedure**

Confidential Disclosure/Non-Disclosure Agreements which will potentially lead to a study meeting the definition above: Process is unchanged. Study team uploads draft document through "Document Review" (DR) in RAPSS. Research Contract Services (RCS) will assign review of the draft agreement to the RBHS CTO contracting associate. The RBHS CTO contracting associate reviews and finalizes with the sponsor and forwards the executable version to Executive Director, Research Contract Services or designee for signature. The RBHS CTO contracting associate will then upload the fully executed (FE) version to the DR in RAPSS.

Clinical Trial Agreements/Clinical Study Agreements: For studies which are submitted in OnCore (as is now required for all RBHS studies which meet the NIH definition of a clinical trial, or which are prospective or single time point studies with billable clinical procedures), the following process will be followed:

A. **OnCore ePRMS submission**: PI/study team submits draft clinical trial agreement (CTA), sponsor's budget template, protocol, and draft Informed consent form (ICF) to RBHS CTO via OnCore ePRMS module. The study team is also requested to upload a copy of the correspondence from the Sponsor/CRO which provides contact information for those responsible for negotiating the budget and contract on behalf of the sponsor. (For more information, see https://njacts.rbhs.rutgers.edu/clinical-trials-office/oncore/) Note that it is no longer necessary to submit a draft clinical trial agreement via "Document Review" (DR) in RAPSS so long as OnCore is being used.

B. **RBHS CTO Feasibility Review/ Intake Assessment:** An RBHS CTO Intake Coordinator will conduct a brief feasibility review and perform an intake assessment. Upon CTO feasibility approval, the OnCore Study ID is assigned (ex: NB22-Smith-001). This Study ID is used for tracking and correspondence purposes.

C. **Budget Negotiation**: The PI/study team informs the CTO intake coordinator as to whether they would like the CTO Finance team to negotiate the study budget with the sponsor or if they would prefer that a similarly qualified/experienced individual at the School or in the PI's department assume this responsibility. The **designated budget negotiator** (whether it be the CTO Finance team member or an individual in the PI's School or Department) then assumes responsibility for negotiating the budget AND creating the RAPSS Funding Proposal (FP.) (Note: If the CTO Finance team assumes responsibility for negotiating the budget, a budget negotiation fee will be built into the study budget in order to pass through the cost to the sponsor. The CTO will then invoice the study team for this fee after the contract has been executed.) Should an individual from the PI's department opt to take the lead on the budget negotiations, this individual will be asked to forward their initial draft proposed budget to the CTO Finance Manager prior to beginning negotiations with the study sponsor.

D. **Post-Award Management:** The PI/study team (after consulting with a department or Dean's level school administrator if required by the PI's school or unit) informs the CTO intake coordinator as to whether they would like the CTO Finance team to assume responsibility for post-award financial management of the study. (See below for implications with regard to the Oracle project number.)

E. **Contract Negotiation: The** CTO Contract Manager will assume responsibility for negotiating the clinical trial/study agreement with the study sponsor or designee.

F. **RAPSS Funding Proposal (FP)**: The Designated Budget Negotiator will initiate creation of the Funding Proposal (FP) in RAPSS and will finalize the FP once the budget is considered final by the sponsor.

G. **Contract/Budget Finalization:** Once the CTA with the finalized budget is ready to be executed AND the study is approved by the IRB or approval is imminent, the CTO Contracting Manager forward the executable version to the Executive Director, Research Contract Services via DocuSign or by email for signature. The CTO Contract Manager will upload a copy of the Fully Executed CTA with the budget to OnCore Financials Console once available.

H. **Document upload to RAPSS:** Once the CTA is finalized, the designated budget negotiator will upload the Fully Executed CTA with the final budget to the RAPSS Funding Proposal (FP) and ensure that the FP been fully and accurately completed before routing the FP for department approval as appropriate. The RAPPS FP comment section should include a statement to indicate that the "*DR# is not applicable as this was routed via OnCore"* and should also note "*that the CTA is fully executed."*

I. By default, RAPPS will assign processing of the Award (AWD) to the Grant Specialist assigned to Department.

Considerations for Oracle Project Number and Project funds flow: The level of CTO involvement in post-award financial management of the study will drive the decision of whether the Oracle Project # will be established under the CTO/Rutgers Institute for Translational Medicine and Science (RITMS) vs. under the PI's School and Department. Specifically, if the CTO assumes responsibility for post-award financial management of the study, the Project # will be set up under the CTO/RITMS UDO. Under these circumstances, the CTO finance manager will craft a written agreement with the PI based on the negotiated budget for the study. This agreement will itemize fees which are to be returned to the PI or his/her department to compensate for investigator and study team time and effort as appropriate. These fees will then be credited back to the PI or his/her department on a periodic basis as funds are received from the study sponsor. Note: These arrangements may require departmental chair and/or dean's finance office approval, depending on the school or unit. Note also that, when the FP is created, the Designated Budget Negotiator will add the PI's key departmental contact where prompted to "select team members to have read-only rights" and will then select RITMS as the "submitting department."

RAPSS Funding Proposal – The Designated Budget Negotiator is responsible to ensure the following:

- Project title in RAPSS: must match the formal protocol title as listed in OnCore. (200-character limit)
- Display title in RAPSS: List OnCore Protocol #, name of sponsor and short title from OnCore. (100-character limit)
- Section 1.05: Add the CTO or Department/Unit Pre-Award Contact depending on who is responsible for budget negotiation and financial oversight.
- Section 1.05: Add the CTO or Department/Unit Post-Award Contact depending on who is responsible for post award financial oversight. (For example, if this is an RWJMS study and post-award finance will be the responsibility of the RWJMS Research Support Team (RST), the individual assigned to the PI's department from the RST will be added here.)
- Section 1.09: Read/edit rights should be extended to key department contacts, including the PI and other appropriate school or department staff members working on behalf of the PI.
- Section 3.0 (Research Department Determination): Select the department which has agreed to assume responsibility for post award financial management of the study.
- FP budget estimate should be based on the low estimate accrual targets provided by the study team in OnCore and a conservative calculation of the amount to be earned for each participant (i.e. without consideration of possible invoiceable costs or other unknowns.) (Note, however, that if a study receives cash receipts in excess of the budget established by the FP, a modification within Oracle will need to be requested.)
- If Section 13.0 (Budget Periods) was not completed with respect to Budget period/Target Direct and Target Indirect funds anticipated, add these estimates as "comments" to the award setup team (i.e. specifically, in dollar figures, what portion of the total budget represents direct vs. indirect costs with the budget period provided.)
- Upload a copy of the fully executed CTA to the FP section in RAPSS.

Additional Details on RAPSS FP & Awards Set-up Processes:

- Funding proposals for any studies conducted through the CTSA Treatment Innovation Network (TIN,) regardless of the Principal Investigator's department, will always be under the RITMS/CTO UDO.
- Once the Principal Investigator submits the Funding Proposal it is routed for approvals in the usual manner (i.e. if under CTO, it will be routed through RITMS for approval; if under the school, it will be routed as per school policy.)
- The Research and Sponsored Programs (RSP) Grant specialist (GS) will be automatically assigned through RAPSS; The GS will submit the FP to the RFS Award set-up team as per current process.
- Award set-up is conducted as per current RSP current process.

Requests for Clinical Trial Agreement Amendments:

A. The study team will submit any requests for contract and/or budget amendments to the CTO team via a Change Review submission in the ePRMS console in OnCore.
B. The study team will upload all documents pertaining to the change (including the proposed contract and budget amendment, the sponsor's amended protocol version, any memo or correspondence detailing the summary of changes, etc.) in the ePRMS console in OnCore.
C. The designated budget negotiator or contract negotiator will add ALL contract amendments (whether there is an impact on the budget or not) to the Award module in RAPSS by e-mailing the specialist within RAPSS and attaching all relevant documents related to the amendment.
D. The designated budget negotiator or contract negotiator will upload the FE contract amendment with budget modifications to the OnCore Financials Console.

Documentation in OnCore:

The designated budget negotiator will enter both the RAPSS FP# and Oracle project # into the OnCore PC console as the internal account # under the "Management" tab. (ex: FP000XXXXx/8XXXXX).

6. Resources

For more information about these processes, please visit the CTO website: https://njacts.rbhs.rutgers.edu/clinical-trials-office/

You may also e-mail your inquiry to clinicaltrials@rbhs.rutgers.edu