For JHU Internal Use Only

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Clinical Research Contracting (CRC)

Contract Process FAQ and Tips

APPLICABILITY: All contracts for clinical research with material or monetary support from a commercial entity.

PURPOSE: Provide SOM research personnel with the information they need to ensure contracts for their studies will be processed and finalized by the CRC as quickly as possible.

QUESTIONS? Submit to CRCinquiry@jh.edu

KEY TIPS

The most critical steps you can take to reduce contracting-related delays are:

I) Submit the contract request to CRC via the required method:
   a) NDAs only: Email to SOMNDA@jh.edu (see Section 1 below)
   b) All other contract types: Upload all required documents and information to FIBI (see Section 5 below)

II) Ensure all information submitted to the NDA mailbox or FIBI as above is complete, accurate, and matches the information in eIRB (same PI, same project title, same sources of support, etc.).

III) Promptly inform the CRC of any updates to the information submitted.

IV) Submit the contract proposal record to FIBI as soon as you have all information required by FIBI. Do not wait until the IRB approves the study or the budget is final.

V) Following these instructions will help ensure a fast, efficient, contracting process.

FREQUENTLY ASKED QUESTIONS

NON-DISCLOSURE AGREEMENTS (NDA) (AKA CONFIDENTIALITY OR CONFIDENTIAL DISCLOSURE AGREEMENTS, ETC.)

1) A company/organization sent me an NDA to sign. What should I do?
2) I think JHU already has an NDA with a particular company/organization. Do I need yet another NDA to discuss a new project with the same company/organization?
3) What can I expect after I submit my NDA request to the CRC?
4) As JHU faculty/staff, what are my obligations under the NDA?

ALL CONTRACTS OTHER THAN NDAS (CLINICAL TRIAL, MATERIAL TRANSFER, COLLABORATION AGREEMENTS, ETC.)

5) I need to get a contract in place for a study/project that has commercial support (e.g., company will provide drugs, devices, equipment, etc.). What do I do?
6) Will submitting a request to CRSS for the budget trigger contract review by the CRC?
7) Do I need to submit a Statement of Work (SOW) to FIBI? If so, what information must be in the SOW?
8) What I can expect from the CRC and other party/CRO after I submit my contract request to FIBI?

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1) A COMPANY/ORGANIZATION SENT ME AN NDA TO SIGN. WHAT SHOULD I DO?

a) Do not sign the NDA (or any other contract) until CRC staff has reviewed it and asked you to sign.

i) Only authorized JHU officials can sign research contracts (including NDAs) on behalf of JHU; faculty also sign to acknowledge their responsibilities for a given project but faculty may not sign on behalf of JHU.

b) Submit the NDA request to SOMNDA@jh.edu, making sure to:

i) Provide a brief but detailed description of the "purpose" of the discussions;

ii) Identify the timeline and/or deadlines for getting the NDA in place;

iii) Identify the PI/lead faculty member under which the NDA should be filed (only one name permissible);

iv) Enclose a copy or summary of relevant emails or other communications regarding the subject matter;

v) Enclose an editable version of the other party's NDA template *or* else indicate that the CRC needs to provide a JHU template;

vi) Provide the full name of the other party and contact information for negotiations;

vii) Indicate whether JHU is sharing confidential information, receiving confidential information, or both

viii) Provide the name and JHED ID of any JHU personnel other than the PI/lead (such as a co-investigator or research manager/study coordinator) who should receive MyRAP record updates.

c) IMPORTANT NOTES

i) The SOMNDA@jh.edu address is for all SOM research NDA requests, regardless of whether they are with commercial or non-commercial parties, or whether they are for clinical or pre-clinical projects; there is ONE address for all SOM research NDAs and there is no need to submit NDA requests to the ORA or CRC Sponsored Projects Specialist assigned to your department/division.

ii) NDAs are only for sharing information to allow for preliminary discussions; an NDA should not be used to transfer patient data or materials or to perform a research project or provide services. Consult with the CRC about what type of agreement would be appropriate for such purposes.

2) I THINK JHU ALREADY HAS AN NDA WITH A PARTICULAR COMPANY/ORGANIZATION. DO I NEED YET ANOTHER NDA TO DISCUSS A NEW PROJECT WITH THE SAME COMPANY/ORGANIZATION?

a) PROBABLY

i) Consult with the CRC every time you have a new project to discuss even if you think JHU already has an NDA on file that will suffice. NDAs are usually project-specific, so chances are you'll need an NDA for each new project.

ii) Even if you have a broad NDA, it might have expired.

b) About "Master" NDA Agreements

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i) CRC does not have any master agreements that are independently effective; these masters only include terms and conditions, but they must be applied to a *specific engagement*, with a specific faculty PI, for a specific project. This also applies to master research and clinical trial agreements.

(1) These *specifics* are detailed in a short, "mini" agreement that is signed each time a particular project will be discussed or pursued. Under Master NDAs, such a mini-agreements might be referred to as a "Notice of Disclosure", "Transfer Notice", or the like. Likewise, under master research agreements, you might see those mini agreements being referred to as "Task Orders", "Work Orders", "Protocol Agreements", etc.

ii) This system allows CRC to maintain clear records of what has been disclosed to whom; it is important for JHU to document this information in the event of any subsequent dispute.

3) WHAT CAN I EXPECT AFTER I SUBMIT MY NDA REQUEST TO THE CRC?

a) You can expect to receive an email within 24 hours (excluding weekends & holidays) confirming receipt and creation of a MyRAP record.

b) The MyRAP record identifiers, including the CRC file name and MyRAP ID#, will be shared with you and/or your team.

c) The CRC is increasing its use of MyRAP; MyRAP should be your first "go-to" resource for information about the status of your NDA or other agreement.

d) The NDA will be assigned to a negotiator within 24-48 hours after initiation. That negotiator will be the point of contact with the sponsor throughout the negotiation process.

e) The NDA negotiator will document in MyRAP the transitioning of the agreement through each step of the negotiation process. These updates will be in the form of comments and can be accessed by logging into your MyRAP account and accessing the matter in your dashboard or by searching the unique identifiers provided at intake.

f) The timeline for negotiation varies and depends on multiple factors (e.g., new sponsor, involvement by a third-party CRO, current volume of contracts under negotiation by the CRC, etc.).

g) If, at any time during the intake/negotiation process questions or concerns arise, send an email to SOMNDA@jh.edu.

4) AS JHU FACULTY/STAFF, WHAT ARE MY OBLIGATIONS UNDER THE NDA?

a) Read and understand the terms once finalized. Ask the CRC if you do not know what a term means.

b) Only share the information the other party sends you under the NDA to those within JHU who have a "need to know" for the project.

c) Do not share any information you receive from the other party to the NDA with anyone outside of JHU without checking with the CRC first.

d) The obligation of confidentiality exists only for the period specified in the NDA, which is a legally binding contract. Make sure you know what this period is.

e) If any of the following occur, contact your CRC negotiator before you take any action:

i) The other party/CRO informs you that the NDA does not require signature from an authorized JHU signatory.

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ii) Someone outside of JHU asks to see the confidential information you received from the other party to the NDA.

(1) Example: The CRC signed an NDA with a pharmaceutical company so your team can discuss with that company whether or not it will provide its drug for a JHU investigator-initiated study. Your team is thinking about engaging another institution to serve as an additional investigative site ("subsite") and that subsite asks you to send them the Investigator's Brochure (IB) or other information the pharmaceutical company provided to you. Do not send that potential subsite the IB or any other information you received from the company without first discussing the matter with the CRC.

**This is just one example; your circumstances may be different. When in doubt, send an email to CRCinquiry@jh.edu.

iii) The other party asks you to destroy or return the confidential information it provided to you.

iv) An attorney or representative from the other party contacts you about matters that seem legal in nature.

v) If you believe you or a member of your team may have made a disclosure of confidential information that maybe you should not have made.

5) I NEED TO GET A CONTRACT IN PLACE FOR A STUDY/PROJECT THAT HAS COMMERCIAL SUPPORT (E.G., COMPANY WILL PROVIDE DRUGS, DEVICES, EQUIPMENT, ETC.). WHAT DO I DO?

a) Obtain the contract template

i) Most sponsors/supporters require that we use their template; ask them to provide a template if they have not already done so. If the other party does not have a template or asks to use a JHU template instead, add a note to FIBI so that the CRC knows it must provide one.

ii) Do not send the other party any templates or contracts.

(1) This includes but is not limited to templates from the OCT or ORA websites or templates from other projects (whether or not the other project was with the same entity). The ORA will handle all aspects of negotiation. The template that is appropriate will vary from project to project. The CRC will customize a template based on the nature of the project.

b) Submit using the FIBI system (all contracts except NDAs)

i) The record in the FIBI system is called a Proposal Development or "PD" record. Once the complete PD is received and accepted by CRC, the CRC Sponsored Projects Specialist will create a contract file in MyRAP and a CRC contract reviewer will be assigned.

ii) Do not submit contract requests to the CRC via email (except for NDAs, which should be submitted directly to SOMNDA@jh.edu).

iii) Until the CRC has a complete FIBI PD for a contract that has been approved by your department and CRC, there is no contract file and your contract is not in the queue for review. It is critical to get your study contract submitted via FIBI in order to ensure a prompt contracting process. Emailing study or contract documents to CRC staff does not mean CRC has a contract file, and does not mean that a reviewer has been assigned.

iv) CRC is glad to provide advice and informal comments about contracts before receiving the FIBI PD, especially in situations where there is a truly urgent need. However, the general process is that contract negotiations commence only upon the receipt and approval of the FIBI PD.

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v) Make sure all information submitted in FIBI, including the information in the Supplemental Information Sheet (SIS), is complete and accurate.

(1) The CRC relies heavily on all information in FIBI, including the information in the SIS, when it determines how best to handle a particular agreement and what the appropriate contract terms will be.

vi) Send an email to CRCinquiry@jh.edu if you have questions that must be answered before you can submit the contract to FIBI.

c) WHEN should I submit my contract request to FIBI?

i) As soon as you have all FIBI-required documents & information.

ii) Do not wait until the study has been approved by the Johns Hopkins Medicine IRB (IRB).

iii) Do not wait until the budget has been finalized.

iv) Ideally, the protocol review by the IRB, budget negotiation, and contract negotiations should all proceed in parallel (and not one after the other).

d) WHO collects the information required to be submitted to FIBI?

i) Departmental staff are responsible for obtaining the required information for all agreements submitted for review. CRC can help with the process by clarifying what is necessary, but we cannot get these materials for you.

ii) Please note that although information about the proposal was submitted with the application/FIBI PD, the department staff must obtain all follow-up information requested by CRC staff to assure that the proposal continues to move through the process as quickly as possible.

e) WHAT information do I need to submit to FIBI?

i) For all contracts:

(1) Editable version of the contract (Word version preferred)

(2) Budget (draft is OK)

(a) Starting April 29, 2024, study teams will no longer need to prepare or submit internal budgets to FIBI. Internal budgeting matters will be managed through the OnCore system.

(3) Protocol (or IRB file #) and/or SOW (see Section 7 below)

(4) Supplemental Information Sheet

(5) Other, as applicable (can be added as a note in FIBI or summarized in a separate document)

(a) Add a note that includes the name of any CRC negotiator that is already familiar with or has already assisted you with preliminary matters.

(b) If the other party to the contract is not funding the project, provide the name of the funding entity OR the number of the department account that will be used to fund the project.

(c) If there are any other entities involved in the same project – providing funding, material support, or receiving any data/specimens – provide the name of such entities and describe their roles.

ii) Special circumstances:

(1) Amendments:

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(a) Provide the eIRB Change in Research (CIR) number that corresponds to the amendment (include in a comment) and provide the CIR approval letter from the IRB if already approved.

(b) Example: If the budget is being amended due to a protocol amendment, provide the CIR number that corresponds to the protocol amendment.

(2) All contracts except those for company/sponsor-initiated clinical trials:

(a) SOW, unless the protocol on file with the IRB contains all of the information specified in the UIDP guidance (see section 7, below).

6) WILL SUBMITTING A REQUEST TO CRSS FOR THE BUDGET TRIGGER CONTRACT REVIEW BY THE CRC?

a) NO. Requests for contract review must be submitted to FIBI. This includes contract amendments.

b) Agreement on an updated/revised budget is not the same thing as a contract amendment. An amendment to the budget will need to be memorialized in a contract amendment approved by CRC and signed by both parties.

7) DO I NEED TO SUBMIT A STATEMENT OF WORK (SOW) TO FIBI? IF SO, WHAT INFORMATION MUST BE IN THE SOW?

a) YES, an SOW is required UNLESS the IRB protocol includes the information required under section 7(f) below; however, the CRC would prefer that teams include all information listed in section 7(f) in the IRB protocol, including detailed information about all transfers; most sponsor-initiated protocols include all of the necessary information, but many investigator-initiated protocols, especially those on "eForm" templates, do not.

b) Also known as a "work scope", the Statement of Work (SOW) describes what the JHU faculty PI or staff will do and what the company will do; the SOW should provide detailed information about all transfers – funds, materials, data, specimens, etc. – in either direction.

c) The CRC relies heavily on the information in the SOW when deciding what terms to negotiate in the contract

d) Investigators should review the contract before it is submitted to FIBI to see if an SOW is attached.

e) It is up to the JHU investigator and sponsor (or other outside entity) providing support to work together and agree upon the content of the SOW before the SOW and other required information is submitted to FIBI.

f) Content

i) The CRC strongly encourages research teams to follow the guidance on drafting SOWs that was established by the University-Industry Demonstration Partnership (UIDP), which is available here.

(1) Deliverables versus Tasks

(a) All SOWs must contain a clear and unambiguous description of the deliverables and tasks to be performed by each party. The descriptions must be detailed enough so that it can be determined whether the requirements were met.

(b) Deliverables are not tasks; rather, they are items such as reports and particular data and results that must be delivered by one party to another.

ii) No conflict between the SOW and IRB Protocol

(1) The CRC will add a term to the contract that specifies JHU will comply with the IRB protocol; however, the other party will want to include a term that specifies JHU will comply with the SOW (which will be attached to the contract). It is therefore imperative that there is no conflict between the SOW and IRB protocol; the IRB protocol must control if there is a conflict between it and the SOW.

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(2) If the CRC perceives a conflict between the IRB file and/or protocol on the one hand and SOW on the other, the CRC might send (or ask the study team to send) the SOW to the IRB so that the IRB can make its own determination about whether a conflict exists. If the IRB perceives a conflict, the study team will need to (i) update the IRB protocol/file and/or SOW, (ii) obtain approval of the required changes from the supporter of the study, and (iii) send the CRC (a) an updated draft of the supporter-approved SOW and/or (b) the updated IRB protocol or applicable IRB Change in Research number. From the CRC's perspective, it would best for your team to ensure the IRB protocol contains all information that, per the UIDP guidance referenced in Section 7(f)(i) above, should be in the SOW (such that there would be no need for a separate SOW).

8) WHAT I CAN EXPECT FROM THE CRC AND OTHER PARTY/CRO AFTER I SUBMIT MY CONTRACT REQUEST TO FIBI?

a) <u>What you can expect from the CRC</u>

i) Once the FIBI record is submitted and approved by your departmental staff – for some divisions this may include multiple levels of approval before reaching CRC—a CRC Sponsored Projects Specialist will review the record.

(1) FIBI submissions that do not contain all required information will be rejected and returned to your departmental/divisional team for correction.

ii) The CRC Sponsored Projects Specialist who handles your department will create a contract file and a corresponding MyRAP record, and the new file will be triaged and assigned to a CRC negotiator.

(1) All FIBI submissions received by CRC are assigned on a first-come, first-served basis to an associate the following Monday afternoon after CRC representatives analyze and triage the request.

(2) Any urgent requests must be noted and described in the SIS with specific information about the need for urgency. CRC will contact your team to follow up about urgent requests.

iii) Once assigned, the CRC negotiator will perform an initial assessment of the contract within a few days of it being assigned. The results of the assessment will be noted in MyRAP.

iv) Once assigned, the CRC negotiator will endeavor to send their first set of comments and proposed changes to the contract to the other party within 10 business days of the date the contract is assigned.

v) Comments will be added to MyRAP every time a draft is provided by the other party or sent out by the CRC negotiator.

vi) The CRC is increasing its use of MyRAP; MyRAP should be your first "go-to" resource for information about the status of your NDA or other agreement.

vii) If you have questions that cannot be answered by reviewing the MyRAP record, please send an email to the CRC Sponsored Projects Specialist who handles your department or CRCinquiry@jh.edu.

b) <u>What you can expect from the other party/CRO</u>

i) It may take the other party – especially if the other party is or is working with a CRO – several weeks to respond to JHU's proposed changes to a contract. In some cases, it may be a month or more; this is not unusual.

ii) The other party may contact the study team directly, without informing the CRC, to indicate that a draft provided by JHU was accepted or approved by that other party. The other party may even send and ask the study team to sign a PDF of the contract that the other party claims is final.

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(1) Do not sign any contracts (NDA or otherwise) that are provided by anyone other than a CRC staff member. Unless otherwise instructed by the CRC when the particular contract at issue has been finalized, it will be the CRC that sends you the CRC-approved version that can be signed.

9) HOW DOES TIMING WORK WITH RESPECT TO REVIEW AND EXECUTION OF THE CONTRACT, BUDGET NEGOTIATIONS, AND IRB REVIEW AND APPROVAL?

a) CRC contract review, IRB protocol review, and CRSS budget development should proceed in parallel.
   i) Do not wait for the budget to be finalized to submit the contract proposal record (PD) to FIBI.
   ii) Do not wait for the IRB to approve the study to submit the contract proposal record (PD) to FIBI.

b) The CRC can begin reviewing and negotiating a contract before the study has been submitted to the IRB; however, absent special circumstances like the ones listed immediately below, the CRC will not execute (sign) a contract until the project has been approved by the IRB (and the budget has been finalized).
   i) Circumstances under which the CRC might sign a contract before the project has been approved by the IRB:
      (1) The project work scope includes developing the protocol or performing some other work that must be completed before the project can be approved by the IRB;
      (2) The company must commit funds by a certain date that will pass before the IRB is likely to approve the study (this often happens at the end of the sponsor's/supporter's fiscal year); or
      (3) JHU or the other party has a deadline by which the contract must be executed or else JHU or the other party is likely to lose/withdraw support or approvals for the project (such as clinical studies with a limited number of sites).

c) If any of the circumstances in 9(b) above apply to your contract, please do the following:
   i) Add a note in FIBI and the SIS that explains the circumstances.
   ii) If 9(b)(i) applies, make sure the SOW, if required (see section 7 above), clearly shows that JHU will be performing work that must be completed before the IRB can approve the study. The budget should show how much JHU getting paid for that portion of the project.

10) WHAT CONTROLS THE ROUTING OF CONTRACTS TO CRC VS. THE ORA-MRB?

a) If a proposal has a direct commercial sponsor AND is clinical research, then it will be processed by CRC.

b) If a proposal has a prime commercial supporter whose terms are flowed down to JHU through a subcontract AND is clinical research, then it will be processed by CRC (even if the JHU contract is from another university/hospital).
   i) Example: JHU will be an investigative site for a study sponsored by an investigator at ABC University. A pharmaceutical company is providing funding and/or the study drug to ABC, and in turn, ABC will pass along funds/materials to JHU. Because funding and/or the study drug would flow in to JHU from ABC, the contract between JHU and ABC would be a subcontract from ABC to JHU (not a sub from JHU to ABC). Some of the terms in the ABC-JHU contract will have been "flowed down" to JHU from the pharma company; in other words, some of terms in the JHU-ABC contract would be the same if the contract were directly between JHU and the pharma company instead. The contract between ABC and JHU would therefore be negotiated by CRC, not the ORA subawards team and not the ORA-MRB.

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c) If a project has a commercial partner, the funding is from a federal sponsor, and the federal sponsor will arrange the supply of drug to JHU (JHU not dealing with the commercial partner directly), the underlying contract will be processed by the ORA-MRB office, as these are fundamentally federal awards (e.g., Small Business Innovation Research - SBIR/STTR awards).

d) When a commercial sponsor/supporter is providing drug directly to JHU, the drug supply agreement with that commercial sponsor/supporter will be processed by CRC, regardless of the study funding source.

11) MY CONTRACT IS CALLED A "MATERIAL TRANSFER AGREEMENT" (MTA) BUT IS REALLY FOR A COLLABORATIVE RESEARCH PROJECT, AND NOT MERELY FOR RECEIPT OF MATERIALS FROM AN (OTHERWISE DISINTERESTED) ACADEMIC COLLABORATOR. WHAT DO I DO?

a) If the project has any funding, a defined work scope, any deliverables (other than the materials), or an intention to jointly publish, the underlying contract should probably be negotiated by CRC.

   i) Consult with the CRC for guidance.

b) If you answer "yes" to any of the following questions, the contract would be negotiated by CRC, ORA-MRB, or the ORA subawards team (as applicable).

   i) Is the contract for a sponsor-controlled research study? Consult with the CRC.

   ii) Is the project a funded or unfunded collaborative study between Johns Hopkins School of Medicine and the provider of the materials? Consult with the CRC.

   iii) Does the research involve patients or protected health information, clinical testing or procedures, or drug/device testing in humans or any planning/lab/clinical service in support of such clinical research? Consult with the CRC.

c) JHU has policies that govern human subjects research and such policies must be reflected in applicable contracts; therefore, contracts that pertain to human subjects research are more complicated and take more time to negotiate than a simple MTA that involves receipt or provision of materials from an otherwise disinterested collaborator.

Resources

- ORA website: https://ora.jhmi.edu/
- Office of Clinical Trials: https://www.hopkinsmedicine.org/research/resources/offices-policies/office-clinical-trials/
- Johns Hopkins Medicine Research; Offices and Policies: https://www.hopkinsmedicine.org/research/resources/offices-and-policies

CRCinquiry@jh.edu

Use this email when you are not sure whom to contact

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