

What controls the routing of Agreements with Commercial Sponsors to ORA Fells Point?

To track the progress of a research agreement from the time it is received in the Office of Research Administration (ORA) until it is finalized and scanned to Sponsored Projects Shared Services, you must go to: <https://myrap.jhu.edu>; log in once with your JHED ID user name and password for access and to establish a MyRAP (**My Research Agreement Place**) account. **MyRAP works in tandem with COEUS.**

NOTE:

- ▶ If a proposal has a direct commercial sponsor AND is clinical research, then it will be processed at Fells Point.
- ▶ If a proposal has a prime commercial sponsor whose terms are flowed down to JHU through a subcontract AND is clinical research, then it will be processed at Fells Point.
- ▶ If a project has a commercial partner (e.g. drug supply arranged by NIH) BUT the funding is from a federal sponsor, then it will be processed at the MRB. (e.g. SBIR).
- ▶ Drug supply agreements with commercial sponsors for JHU clinical trials will be processed at Fells Point.

1. What information is needed for CDA's / Confidentiality Agreements / Nondisclosure Agreements:

No COEUS PD is required for review of a Confidentiality Disclosure Agreement (also called CDA or Non-Disclosure Agreement or NDA). A MyRAP record will be generated by ORA for these agreements.

For the review of a Confidentiality Disclosure Agreement:

- ▶ Email an editable version of the document to the Fells Point Sponsored Project Specialists: Jared Nipper (jnipper@jhmi.edu) and Josh Reynolds(jreyno29@jhmi.edu);
- ▶ Provide the contact information for the Sponsor; and
- ▶ Identify the purpose and your timeline.

2. What information is needed for CTA's / Clinical Trial Agreements / Clinical Study Agreements:

These agreements must be submitted via the COEUS system with the following documents uploaded:

- ▶ Editable version of the contract document (*preferably MS Word*);
- ▶ Supplemental Information Sheet for Commercial Agreements (aka the "SIS")
(available here: <http://www.hopkinsmedicine.org/Research/ora/Forms/index.html>);
- ▶ Proposed budget (draft is OK; does not need to be final; see Sec 6 below for details); and
- ▶ Study protocol or Scope of Work (*IRB application # may be listed instead of a copy of protocol*).

The resulting record in the system is called a Proposal Development or "PD" record. Once the complete PD is received and accepted by ORA, the Sponsored Projects Specialist will create a contract file in MyRap and a contract reviewer can be assigned.

Until ORA has a complete COEUS PD for a CTA, there is no contract file and your contract is not in the queue for review. It is critical to get your study CTA's submitted via COEUS in order to ensure a prompt contracting process. Emailing CTA documents to ORA staff does not mean ORA has a contract file, and does not mean that a reviewer has been assigned.

What controls the routing of Agreements with Commercial Sponsors to ORA Fells Point?

An IRB approval is needed before the contract can be executed (signatures obtained), unless the contract work scope includes developing the protocol and then submitting it to the IRB. To avoid unnecessary delays, the Prospective Reimbursement Analysis (PRA), budget development, Institution Review Board (IRB), and contract submission should be worked on simultaneously. ORA does not need an IRB approval or a final budget for you to submit a contract with a commercial sponsor for review.

ORA is happy to provide advice and informal comments on CTA's before receiving the COEUS PD, especially in situations where there is a truly urgent need. However, the general process is that contract negotiations commence upon the receipt and approval of the COEUS PD.

3. What information is needed for contract amendments:

Contract Amendments must be submitted via a COEUS PD (be sure to Include the *Master Proposal*#) with the following documents uploaded:

- ▶ Editable version of the Amendment;
- ▶ Supplemental Information Sheet for Commercial Agreements form (see link above);
- ▶ Budget, if applicable (draft is OK; does not need to be final);
- ▶ Study protocol or Scope of Work (if it has changed) (include updated IRB info where applicable)

4. Who obtains the required information?

- ▶ Departmental staff are responsible for obtaining the required information for all agreements submitted for review. ORA can help with the process by clarifying what is necessary, but we cannot get these materials for you.
- ▶ Please note that although information about the proposal was submitted with the application/COEUS PD, the department must obtain all follow-up information requested by ORA staff to assure that the proposal continues to move through the process as quickly as possible.

What controls the routing of Agreements with Commercial Sponsors to ORA Fells Point?

5. Information needed to complete the COEUS PD Summary:

- ▶ Decide if you want to create a new proposal, base it on a template, or copy an existing proposal.
- ▶ Select the COEUS Proposal Type: *New, Renewal, Resubmission, Task Order, Continuation, Negotiation Only* (used for unfunded commercial agreements such as MTA's or 'Master' framework agreements), *Pre-Application, Internal Application, Administrative Action* (used to amend an existing award), *JHU Limited Submission*; or *Revision* (used to revise a proposal which has not been awarded).
- ▶ Enter the COEUS Activity Type: *Organized Research; Instruction; Other Sponsored Activity; or Clinical Research*. A record must be coded as "Clinical Research" to ensure routing of the PD to Fells Point.
- ▶ Award Type: *Grant; Contract; Cooperative Agreement; Clinical Trial; Fixed Fee; Sub grant; or Subcontract*.
- ▶ Principal Investigator and Co-Investigators.
- ▶ Responsible Cost Center number.
- ▶ Sponsor.
- ▶ Sponsor grant/contract number, if known.
- ▶ Master IPN, if not a new proposal.
- ▶ Human Subjects IRB # and date of protocol approvals applicable to the proposal.
- ▶ Period of performance dates.
- ▶ Amount of the proposal request, if applicable.
- ▶ Link to Export control questions if applicable:
http://prcoeus.hosts.jhmi.edu/orisite/oris_web/Documents/user_guides/Coeus%20Compliance%20Questions%207_12_11.pdf.
- ▶ For guidance on the full disclosure of a conflict of interest as well as disclosure and professional committee contact the Office of Policy Coordination at:
<http://www.hopkinsmedicine.org/Research/OPC/index.html>.
- ▶ For COEUS help, consult the guidelines and other information on the ORA website:
<http://www.hopkinsmedicine.org/Research/ora/Forms/index.html>.
- ▶ SEE ALSO the COEUS Proposal Development Module for Research Administration:
http://jhuresearch.jhu.edu/COEUS/JHU_Research_Admin_Approval_Guide.pdf.

What controls the routing of Agreements with Commercial Sponsors to ORA Fells Point?

6. Budgets

- ▶ In all budgets, consider whether the costs are allowed by JHU and the Sponsor. Specifically, costs must be reasonable/necessary, allocable, consistently applied, and in conformance with JHU policy and the terms of the award.
- ▶ Determine the appropriate Facilities and Administration (F&A) rates, also known as Indirect Cost (IDC) rates or 'overhead'. Refer to the following website for current rates:
<http://www.hopkinsmedicine.org/Research/ora/handbook/appendixc.html>
- ▶ A draft budget is needed to initiate contract review, but a final Sponsor budget and internal budget will be needed to complete the contract negotiation; contract negotiations should proceed in parallel with budget negotiations.
- ▶ Clinical Research Support Services (CRSS) is available to assist with budget preparation; please add a comment to the COEUS PD if CRSS is negotiating the project budget; as long as it is clearly indicated in the PD that CRSS is handling the budget, then there is no need to include a draft budget in your COEUS submission. Contact CRSS:
CRSS@jhmi.edu

7. Statement of Work

- ▶ Also known as a “work scope”, the SOW describes what the JHU Faculty PI or staff will do. The SOW is not always a summary of the whole proposal. For many projects, the IRB protocol is the SOW, so all you need to do is include the IRB submission number.
- ▶ Based on the statement of work, you and the ORA reviewers should be able to determine whether the budget is appropriate.
- ▶ Do not wait for IRB approval to submit contracts to ORA.

8. IRB Approvals

- ▶ Please be aware that ORA can *review* a proposal without current IRB approval, but we must have the approval in order to *fully execute* the contract for account set-up. If available, please upload the most current approval document(s) related to the proposal to the COEUS PD; if approval is issued after submission of the COEUS PD, please let your ORA contact know this, as we do not receive notification directly from IRB.

9. Things to be aware of...

- ▶ The PI and each Co-Investigator on the project needs to be listed as a team member on the IRB, and all other approved protocols related to the research proposed in the agreement.
- ▶ Be careful when using the “copy – paste” features from a prior submission to complete subsequent documents. It is easy to submit documents with outdated information if this is

What controls the routing of Agreements with Commercial Sponsors to ORA Fells Point?

done too quickly and not carefully proof-read. Please read your documents and update ALL information, as needed.

- ▶ Provide requested information in a timely manner; and be sure to send complete documents.
- ▶ Ensure consistency in documentation and accuracy when referencing COEUS PD, MyRAP, PI's, Project Titles, IRB numbers, etc. in communications.
- ▶ The final contract and the final Informed Consent must be consistent, especially in regard to payment of subject injury costs and use of study subjects' PHI and biological samples.

10. Who do I contact in ORA if I have questions?

Once the proposal is submitted to ORA, you can check the MyRAP record for updates on the proposal's review and progress; the MyRAP record displays the ORA staffer who is the current "owner" of each proposal. Should you have questions prior to submission to ORA, you can contact the Sponsored Projects Specialist assigned to your department. The department assignments for the Specialists are posted on the ORA website:

http://www.hopkinsmedicine.org/Research/ora/ORA_Deptl_Assignments.html