

## How Do I Submit Contracts and Other Research Agreements to the ORA in the Miller Research Building (MRB)?

First, follow the procedures\* to register the Principal Investigator and **you** in MyRAP, the system used to track the progress of a research agreement from the time it is received by ORA until it is finalized and scanned to Sponsored Projects Shared Services.

\*Go to this link to login and register a MyRAP account: <https://myrap.jhu.edu>

### NOTE:

- ▶ If the 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 the 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 MRB ORA Sponsored Project Specialist assigned to your department
- ▶ Provide the contact information for the Sponsor; and
- ▶ Identify the purpose and your timeline.

### 2. What information is needed for Other Contracts or Research Agreements? The "ORA 6-Pack"?

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

- ▶ For an **initial or original** agreement:
  - ▶ Editable version of the Agreement (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, when applicable

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- ▶ Statement of Work or Scope of Work
- ▶ IRB/IACUC approval or application number (and other applicable compliance, like ISCRO)

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.

Until ORA has a complete COEUS PD for an agreement, there is no contract file and your contract is not in the queue for review. It is critical to get your COEUS PD submitted in order to ensure a prompt contracting process. Emailing agreement documents to ORA staff prior to your submission of the COEUS PD does not mean ORA has a contract file.

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, 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 agreements 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 Agreement (preferably MS Word))
- ▶ Supplemental Information Sheet for Commercial Agreements (aka the "SIS")  
(available here: <http://www.hopkinsmedicine.org/Research/FMIP/>)
- ▶ Proposed Budget, when applicable
- ▶ Statement of Work or Scope of Work, if it has changed
- ▶ Updated IRB/IACUC info (and other applicable compliance, like ISCRO)

### 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.

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- ▶ For commercial sponsors, there is a required Supplemental Information for Commercial Agreements form which must be completed and uploaded in order for your proposal to be reviewed.
- ▶ 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.
- ▶ While most information is electronic, if you are delivering any related paper (hard copy) materials to ORA, *please make sure* that you indicate PD # on the envelope or folder.

### 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*. Please note that records coded as "Clinical Research" will route the PD to Fells Point, not to the Miller Research Building (MRB).
- ▶ Award Type: *Grant; Contract; Cooperative Agreement; Clinical Trial; Fixed Fee; Sub grant; or Subcontract*.
- ▶ Principal Investigator and Co-Investigators
- ▶ Responsible Cost Center number
- ▶ Sponsor
- ▶ Type of Proposal
- ▶ Sponsor grant/contract number, if known
- ▶ Master IPN, if not a new proposal
- ▶ Human Subjects IRB#, Animal IACUC #, and date of protocol approvals applicable to the proposal
- ▶ Period of performance dates
- ▶ Amount of the proposal request, if applicable
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- ▶ 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](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](http://jhuresearch.jhu.edu/COEUS/JHU_Research_Admin_Approval_Guide.pdf).

### 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.
- ▶ Consider whether the costs are allowed under the terms of the RFA or RFP
- ▶ 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>

### 7. Statement of Work (SOW)

- ▶ Also known as a “work scope”, the SOW describes what the JHU PI or staff will do. The SOW is not always a summary of the whole proposal.
- ▶ Based on the statement of work, you and the ORA reviewers should be able to determine whether the budget is appropriate.

### 8. IRB and IACUC approvals

- ▶ ORA can *review* a proposal without current IRB or IACUC approval, but we must have the approval in order to *fully execute* the contract for account set-up. Please upload to the COEUS PD your current approval document(s), related to the proposal.
- ▶ To avoid unnecessary delays, the IRB or IACUC approval and contract submission should be worked on simultaneously. ORA does not need an IRB or IACUC approval for you to submit a contract with a commercial sponsor for review.

### 9. Things to be aware of...

## **How Do I Submit Contracts and Other Research Agreements to the ORA in the Miller Research Building (MRB)?**

- ▶ The PI and each Co-Investigator on the project needs to be listed as a team member on the IRB, IACUC, and all other approved protocols related to the research proposed in the agreement.
- ▶ Please be very careful when using “copy – paste” features from a prior submission to complete subsequent documents. It is easy to submit documents with outdated information if this is done too quickly and not carefully proof-read. Please read your documents and update ALL information, as needed.
- ▶ Please 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.

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

Once the proposal is submitted to ORA, please 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 Miller Research Building (MRB) Specialists are posted on the ORA website:

[http://www.hopkinsmedicine.org/Research/ora/ORA\\_Deptl\\_Assignments.html](http://www.hopkinsmedicine.org/Research/ora/ORA_Deptl_Assignments.html)

The MRB ORA Specialists are:

- |                    |                    |
|--------------------|--------------------|
| ▶ Jenifer DeLeaver | ▶ Arlette Langer   |
| ▶ Mary Deloatch    | ▶ Angela Mellerson |
| ▶ Celeste Hartman  |                    |