

INSTRUCTIONS FOR COMPLETING SUPPLEMENTAL INFORMATION SHEET
FOR COMMERCIAL AGREEMENTS

INTRODUCTION

When to Complete an SIS:

Complete an SIS if the agreement: Is a contract where a commercial sponsor is providing materials, funding and/or equipment. This includes agreements for project that are:

~ clinical research involving at least one commercial sponsor (ORA Pratt St);

~ clinical research in support of identified consortia activities involving at least one commercial sponsor where JHU is the coordinating site (ORA at MRB); and

~ non-clinical activities (e.g. pre-clinical or bench science) involving at least one commercial sponsor (ORA at MRB).

An SIS is not needed if the agreement: Is a non-disclosure agreement (also known as a secrecy agreement; confidential disclosure agreement, CDA, or NDA).

Provide Contact Info: Provide the name, phone number, and email address of the person with whom the ORA reviewer needs to negotiate the agreement.

Notes:

OPTIONAL: provide the same information for a second point of contact.

I. **Description:** There are two ORA offices - ORA at Pratt Street and ORA at Miller Research Building ("MRB"). The workscope of the project will determine which ORA office will review the agreement.

Notes:

ORA at Pratt Street

ORA at Pratt Street reviews agreements for projects that are: 1) clinical research **and** 2) involve at least one commercial sponsor.

"Clinical research" means research that involves patients or PHI, or clinical testing or procedures, or drug/device diagnostic testing in humans or any planning/lab/clinical service in support of such clinical research. Note that "clinical research" is broader than "clinical trials."

To ensure proper routing of the agreement to ORA at Pratt Street, select "Clinical Research" in the "Activity Type" field and "Clinical Trial" in the "Proposal Type" field in the COEUS Proposal

Development (“PD”) record. All PD records coded with an Activity Type of “Clinical Research” will be sent to ORA at Pratt Street. See blue arrow below.

Start Date:

Proposal Type:

Activity Type:

Sponsored Award Type: Organized Research
Instruction
Other Sponsored Activity
Clinical Research

Sponsor:

Prime Sponsor:

Sponsor Proposal No:

ORA at MRB

In addition to grants and non-commercially sponsored activities such as projects sponsored by non-profit or government entities (e.g. Gates Foundation or NIH), ORA at MRB reviews agreements involving:

- ~ commercially-sponsored non-clinical activities (e.g. pre-clinical or bench science);
- ~ agreements for commercial clinical research that are in support of identified consortia activities where JHU is the coordinating site; and
- ~ commercial non-clinical professional practice or consulting.

To ensure proper routing of the agreement to ORA at MRB, make a selection **OTHER THAN** “Clinical Research” in the “Activity Type” field in the PD record (ex: “Organized Research, Instruction, Other Sponsored Activities”). **A selection of the Activity Type “Clinical Research” will route the record to ORA at Pratt St.** See blue arrows below.

Start Date:

Proposal Type:

Activity Type:

Sponsored Award Type: Organized Research
Instruction
Other Sponsored Activity
Clinical Research

Sponsor:

Prime Sponsor:

Sponsor Proposal No:

II. **Description:** Knowing what items will be provided to JHU under the agreement will help ORA properly address any pertinent contractual issues, such as any related rights and responsibilities of each party with respect to the items provided.

Notes:

Materials such as drugs/medical devices

If drugs/medical devices are provided, first make sure that there is a commitment on JHU's part to conduct specific research. If no such commitment exists, then contact JH Tech Ventures (formerly known as JH Tech Transfer) for review of this agreement.

Next, if drugs/medical devices are provided, make sure to indicate whether such drugs/medical devices are investigational in **Section VI of the SIS**. If JHU is to purchase any items in connection with the agreement (such as medical devices), the purchase of those items will be addressed in a purchasing agreement negotiated by JHU Shared Services.

Funding

If no funding is provided under this agreement, identify in **Section III of the SIS** the source of funding for the PI's effort.

Equipment

If the sponsor is providing any equipment, the agreement must address the parties' rights and obligations relating to the use, storage, maintenance, return, and ownership of such equipment.

Other

The agreement must address sponsor's provision of other items, such as: software license, survey instruments (ex: questionnaires), license to intellectual property, etc.

III. **Description:** Some projects involve other parties, related agreements, and/or rights and obligations. Knowing about these related aspects will help ORA properly address any pertinent contractual issues.

Notes:

All terms of such agreements and/or rights and obligations must be consistent, and not conflict.

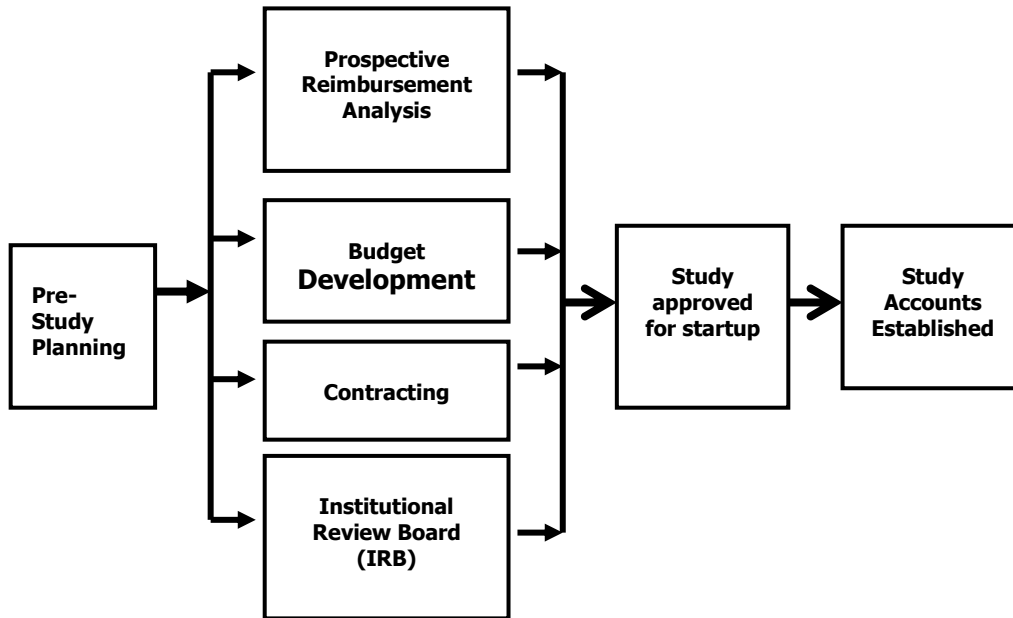
IV. **Description:** A complete COEUS submission MUST include A-C, and D as applicable.

Notes:

ORA encourages concurrent term and budget negotiation and IRB approval process

ORA encourages the negotiation of the contract terms, the negotiation of the budget (as applicable), and IRB approval process (as applicable) to occur **concurrently**.

The diagram below shows the flow of processes in a commercially-sponsored clinical study agreement.



** Prospective Reimbursement Analysis ("PRA") is a comprehensive analysis performed by ORA's Clinical Research Support Services ("CRSS") to identify standard of care and research patient care services provided to clinical trial patients. The PRA incorporates Medicare coverage principles. CRSS provides expertise in clinical research patient care coverage analysis, comprehensive budget development, and budget negotiations with corporate sponsors.

For more information on PRAs and/or CRSS, contact CRSS at: CRSS@jhmi.edu

V. **Description:** Whether a project is sponsor-initiated or investigator-initiated, and whether an investigational drug or device is involved, determines which rights and obligations must be addressed in the agreement in accordance with JHU's institutional policy. Therefore, accurately completing this section is very critical to help ensure that the agreement includes contractual provisions consistent with JHU's institutional policy.

Notes:

Please take the time to fully and **accurately** complete this section. Doing so will tremendously help ORA to negotiate this agreement efficiently.

Tip: If the protocol was co-developed by the sponsor and JHU **and** there is an IND/IDE:

- The project is sponsor-initiated if the sponsor holds the IND/IDE; and
- The project is investigator-initiated if the investigator holds the IND/IDE

VI. **Description:** If any portion of the work will be done at another JHU site, or at a JHU affiliate site, please check the “yes” box, and complete the site information for **each** location. The information provided will help ORA determine whether additional contractual issues exist (ex: involvement of such site(s) may require changes to the prime agreement, and/or trigger a subcontract or side agreement).

VII. **Description:** This section must be completed if a student (including fellows, residents, undergraduates and/or graduates) will participate as study team members.

Notes:

Students are not bound by obligations that apply to employees

As non-JHU employees, students are not bound by the confidentiality obligations and assignment of intellectual property obligations that apply to JHU employees. Therefore, any students participating on a study team must sign an agreement binding them to these obligations. To enable ORA to draft these agreements, for each student, list the student’s name, his/her department, and his/her mentor.

VIII. **Description:** MyRAP is a web-based application that allows an authorized user to look up the status of agreements as they are being reviewed, negotiated and processed by ORA. Authorized users cannot edit MyRAP records. The PI is granted access to view his/her agreement(s) in MyRAP. Other individuals (such as study team members/study coordinators/staff) can also gain access to view a PI’s MyRAP records upon request in the SIS, provided that the PI approves of such individual(s) gaining access.

Notes:

Additional Team Members

List the name(s) of additional study team member(s) who need to gain access to view the agreement in MyRAP.

Access can be granted: 1) for one agreement only, or 2) for all agreements for a particular PI.

**** Unless otherwise requested in the SIS, a study team member whose name is listed in this section will be granted access to all agreements for the PI named in the corresponding COEUS PD.**

IX. **Description:** Use this space to communicate any additional information that may help ORA in its review and negotiation of the agreement.