

## SUPPLEMENTAL INFORMATION SHEET FOR COMMERCIAL AGREEMENTS

PI: \_\_\_\_\_ SPONSOR: \_\_\_\_\_

PROJECT TITLE: \_\_\_\_\_

**SPONSOR CONTACT(S) FOR CONTRACT NEGOTIATION**

Name _____ _____ Name _____ _____	Phone _____ e-mail _____ Phone _____ e-mail _____
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**I. Which ORA office will negotiate this agreement? Check only one:**

**(ORA at Pratt Street (formerly Fells Point)) Clinical Research Involving a Commercial Sponsor**, defined as: commercial clinical 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:** To ensure proper routing of the agreement to ORA at Pratt Street, select “Clinical Research” in the “Activity Type” field in the COEUS Proposal Development (“PD”) record \*\*

**(ORA at MRB) Other Research** (anything other than commercial clinical research)

**\*\* Note:** To ensure proper routing of the agreement to ORA at MRB, select the appropriate Activity Type (excluding “Clinical Research” in the “Activity Type” field in the COEUS Proposal Development (“PD”) record. **The Activity Type “Clinical Research” is used only for those agreements being reviewed in the Pratt Street Office.\*\***

**II. What items will be provided to JHU under this agreement? Check all that apply:**

Materials provided by sponsor **with a commitment to conduct specific research** (such as drugs/medical devices)

**\*\* Note:** if there is no such commitment, contact JH Tech Ventures (formerly known as JH Tech Transfer) for review of this agreement \*\*

Funding provided by sponsor

Equipment provided by sponsor. Where will the equipment be stored (if known)? \_\_\_\_\_

Other (licenses, data, etc.). If this box is checked, explain: \_\_\_\_\_

**III. Are there any other pending or executed agreements or awards related to this project? (examples: other sources of funding for PI effort / study team effort, other material support, a third party collaboration by another sponsor) If yes, identify sponsor/type of award:**

\_\_\_\_\_  
 \_\_\_\_\_

**IV. Include the following documents in the COEUS submission:**

- A. A draft copy of contract in Word format
- B. Statement of work. If applicable, include IRB number. **NOTE:** IRB number can be provided in lieu of a statement of work
- C. Other relevant documents (examples: invention disclosure, etc.)
- D. Draft budget (as applicable)

**V. Protocol/Study Information**

A. If the project involves human subjects research, is the project sponsor-initiated, or investigator-initiated?

Sponsor  Investigator

B. If human subjects are involved:

Investigational drug/device involved?  Y

N

If yes, IND/IDE held by:  Sponsor

JH Investigator

Other: \_\_\_\_\_

**JHU-SOM-ORA Supplemental Information Sheet for Commercial Agreements (continued)**

**VI. Will any portion of the work be done at a JHU affiliate site, including JH CRN sites (such as Anne Arundel Medical Center, Reading Health System, Inova Health System, Greater Baltimore Medical Center, Peninsula Regional Medical Center, Allegheny General Hospital), Kennedy Krieger Institute, F.M. Kirby Center, Howard County General Hospital, Suburban Hospital, Sibley Memorial Hospital, Johns Hopkins Singapore, Cardiovascular Specialists of Central Maryland, and Johns Hopkins Applied Physics Laboratory (“APL”)? If yes, provide the information requested below for each site.**

\*\* ORA will use information provided to determine whether additional contractual issues exist.

Y                      N

Site name:	Subsite Investigator(s) name(s)	Will vertebrate animals be used at site?	Are human subjects involved at site?
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>	Yes <input type="checkbox"/> No <input type="checkbox"/>

**VII. Will fellows, residents, undergraduate and/or graduate students participate as members of the study team?**

Y                      N

If yes, provide the information requested below for each student.

\*\* Students must **adhere to JHU’s policies pertaining to the conduct of clinical research**, including the duty to assign rights to intellectual property arising out of the study to JHU. ORA will draft agreements to be signed by student and mentors.

Student Name	Department	Student’s Mentor

**VIII. (OPTIONAL) List additional study team members who need to gain access to MYRAP**

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**IX. (OPTIONAL) Include any additional information you would like to share with ORA regarding this agreement.**

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