# **IND/IDE Supplemental Form**

*This form is required for all planning phase applications submitted for institutional approval of an IND/IDE submission. Planning phase applications submitted to the JHM IRB without this form or with an incomplete form will be returned. NOTE:* single patient treatment and emergency use protocols are excluded from the Investigator-held INDs/IDEs policy.

# Section 1: General IND/IDE Information

1. Anticipated scope of this IND/IDE [Please check one]:

[ ]  Only one protocol is likely to be conducted under this IND/IDE

[ ]  Multiple protocols are likely to be conducted under this IND/IDE

1. Provide the source/entity of all **Monetary Support** for the work to be conducted under this IND/IDE:
2. Provide the source/entity of all **Material Support** for the work to be conducted under this IND/IDE:
3. Will this IND/IDE application involve JHU manufacturing of investigational product? (This does not include compounding by IDS.)

[ ]  Yes, complete **Section 2** [ ]  No

1. Will this IND/IDE application involve JHU manipulation (e.g. mixing, formulating, counting, compounding, etc.) after initial product manufacturing?

[ ]  Yes, answer questions below [ ]  No

* 1. Have you contacted IDS directly?
		1. If so, who was your IDS pharmacist contact?
		2. If not, describe the service IDS will need to provide
		3. Identify the campus location where the final product will be administered.
1. If a non-commercially, available compound is being used, has Certificate of Analysis (CoA) been obtained?

☐ Yes [ ]  No

If yes, upload a copy to **Section 3 of the Planning Phase Application, Item 2**

1. If additional components (empty capsules, excipients or placebo product) are used to compound the IND drug, are CoA also obtained for these items?

☐ Yes [ ]  No

If yes, upload a copy to **Section 3 of the Planning Phase Application, Item 2**

1. Will this IND/IDE support Multisite studies?

[ ]  Yes, complete **Section 3** [ ]  No

1. If you as the IND/IDE holder **are not a JHU licensed physician**, list below the assigned medical monitor for the study who is a U.S. Licensed, JHHS credentialed Medical provider. If you are a JHU licensed physician, this section may be left blank:
	* 1. Name of Medical Monitor:
		2. Department:
		3. Credentials:
		4. Email address:
2. Does the protocol contain a description of the plan for management of investigational product/devices to be supported by this IND/IDE? (This plan should include but is not limited to accountability, handling and storage of the investigational products.)

[ ]  Yes [ ]  No

* 1. If Yes, list the protocol section # (Include specific page numbers where this information may be found within the protocol):
	2. If no, provide a summary of your plans for product/device management:
1. Will your investigational product/device to be supported by this IND/IDE involve radiopharmaceuticals or radiation emitting products?

[ ]  Yes, answer questions below [ ]  No

* 1. Have you contacted the PET Center directly, for management of the product/device?
		1. If yes, who is your PET Center contact?
	2. If not, describe the service the PET Center will need to provide and identify the campus location where the final product will be administered:

\* Radiotracer Development for New Investigational New Drug Application (IND) is per agreement. Please contact Robert F. Dannals, Ph.D. PET Chemistry Director, Professor, Radiology, Division of Nuclear Medicine and Molecular Imaging. (Email: rfd@jhu.edu).

1. Please provide a description of the resources that you/your research team have available to support the planned work under this IND/IDE.
	1. Regulatory Staff with sufficient expertise.
	2. Study coordinator with data management expertise.
	3. If applicable, lab personnel for collection of correlative samples.
2. Does the Investigational drug or Investigational device for which the IND/IDE application will be submitted include any University proprietary information or intellectual property (either licensed or unlicensed)?

[ ]  Yes [ ]  No

* 1. If yes, please indicated the JHTV disclosure number (e.g., C12345) of all University proprietary information and/or intellectual property supporting the Investigational drug or Investigational device:

*\* (Please note: JHU’s Policy GOV033 Conflict of Interest and Conflict of Commitment (“*[*COI Policy*](https://policies.jhu.edu/doc/fetch.cfm/DqwggusL)*”) outlines interests that may restrict and/or prohibit individuals from serving as the Sponsor-Investigator of human subjects’ research related to their interests. For questions regarding your arrangement email the Office of Outside Activities (OOI) at* *policy@jhmi.edu**.*

# Section 2: Manufacturing

*This section is required if JHU will be have a role in manufacturing of the investigational product/device that is subject of this IND/IDE application.* Please complete Section 2a for IND applications and complete Section 2b for IDE applications:

## Section 2a: Manufacturing Requirements for IND Applications

1. Review and acknowledge all applicable statements in reference to the manufacturing planned under this IND application by selecting the corresponding check boxes.

[ ]  For any Phase 1 clinical investigations conducted under this IND application, drug will be prepared in accordance with the principles of cGMP and the manufacturing processes outlined in the corresponding IND. ­­­­­­­­­­­­­­­

[ ]  For any Phase 2 or 3 clinical investigations conducted under this IND application, drug will demonstrate strict compliance with the FDA’s current Good Manufacturing Practice (cGMP) regulations at 21 CFR Parts 210 and 211 (or 21 CFR Part 212 for Positron Emission Tomography radiopharmaceuticals).

1. What facility will the investigational product be manufactured in (choose option below) [Check all that apply]

[ ]  A JHU CLIA certified lab

 Enter Lab Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Other

 Name the JHU facility responsible for manufacturing: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Johns Hopkins will require that any JH facility or laboratory that will engage in manufacture of investigational drugs (with the exception of IDS facilities that perform compounding within the scope of their pharmacy license, or CLIA certified labs operating within the scope of their CLIA certification) will be subject to pre-qualification and at least annual audits, performed by a qualified individual selected by or approved by the* Office of Clinical Trials (OCT)*.*

*Pre-qualification requests may be submitted to the OCT,* *IND/IDE Regulatory Program**.*

1. Have you contacted the above-named facility or laboratory to provide manufacturing of the investigational product under this IND application?
	* 1. If yes, who is your contact?
		2. If not, describe the service the manufacturing facility or laboratory will need to provide:
2. Please point to the section of the protocol/Investigator’s Brochure where the manufacturing plan is described [Enter section name and page numbers]: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Section 2b: Manufacturing Requirements for IDE Applications

1. Review and acknowledge all applicable statements in reference to the manufacturing planned under this IDE application by selecting the corresponding check boxes.

[ ]  The JHU facility/laboratory that will be engaged in manufacturing of investigational devices for this IDE application will operate in strict compliance with the FDA regulations related to device manufacturing establishment registration, as set forth in 21 CFR Part 807.

[ ]  The JHU facility/laboratory that will be engaged in manufacturing of investigational devices for this IDE application will operate in strict compliance with all FDA regulations and guidance applicable to the specific type of device, including both physical devices and regulated software

1. What facility will the investigational device be manufactured in (choose option below) [Check all that apply]

[ ]  A JHU CLIA certified lab

 Enter Lab Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Other

 Name the JHU facility responsible for manufacturing: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Johns Hopkins will require that any JH facility or laboratory that will engage in manufacture of investigational devices will be subject to pre-qualification and at least annual audits, performed by a qualified individual selected by or approved by the OCT.*

*Pre-qualification requests may be submitted to the OCT,* *IND/IDE Regulatory Program**.*

1. Have you contacted the above-named facility or laboratory to provide manufacturing of the investigational product under this IND application?
	* 1. If yes, who is your contact?
		2. If not, describe the service the manufacturing facility or laboratory will need to provide:
2. Please point to the section of the protocol/Investigator’s Brochure where the manufacturing plan is described [Enter section name and page numbers]: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Section 3: Multi-Site Activities

*This section is required if the IND/IDE application will support multisite studies. Please do not complete this section if all planned activities under this IND/IDE will be conducted at JHU only.*

1. Please describe the plan for monitoring of all sites where the studies supported by this IND/IDE will be conducted [Please note, if this information is contained within the protocol, you may provide the protocol section and page numbers where this information may be located below]:
2. Please identify the monitoring program that will be responsible for monitoring of all sites: *Monitoring of other sites must be carried out through an appropriately qualified contract research organization or through an appropriately qualified monitoring program pre-approved by the OCT (e.g. the Sidney Kimmel Cancer Center trial monitoring unit). Pre-approval requests may be submitted to the OCT,* *IND/IDE Regulatory Program**.*
3. Please identify the plans for use of a single IRB for any multisite research supported by this IND/IDE application. Please indicate if you intend to request the JHM IRB serve as the sIRB for multisite research and if so, confirm you have [submitted a reliance request](https://www.hopkinsmedicine.org/institutional_review_board/about/agreements/).

Please note: Use of a single IRB is required for all federally-funded research.

1. Will the study require shipping of Investigation Drug/Device to participating sites? If so, provide the plan for shipping of Drug/Device.