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| **Supplemental Form:** **International Research**  This document is intended to be a supplement to the eIRB application and protocol to collect additional information that is not provided elsewhere. This is not an exhaustive list of all the activities Hopkins may have. Additional details may be provided in the protocol. | | | | | | | | | |
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| **I. HOPKINS ROLE/FUNDING -** *Specify what roles Johns Hopkins will have in this study (****Check all that apply****):* | | | | | | | | | |
| Johns Hopkins is the prime awardee of federal funding for this research | | | | Johns Hopkins is the Data and/or Clinical Coordinating Center for this study  Johns Hopkins study team is responsible for design of protocol/study | | | | | |
| Johns Hopkins will only analyze data.  *Please select the type(s) of data that will be analyzed:* | | | | Johns Hopkins study team will be performing (onsite or remotely): | | | | | |
|  | De-identified dataset  Limited dataset  Identifiable dataset (e.g., includes names, MRN, addresses) | | | Recruiting  Consenting  Determining participant eligibility and/or ability to continue participation in the study | | | | | Data collection  Delivering study interventions  Safety oversight (including assessment of safety/adverse events) |
| Johns Hopkins study team will provide oversight for the study and/or training of the study personnel | | | | | | | | | |
|  | With access to participant identifiers  Without access to participant identifiers | | | | | | | | |
|  | Other activities not covered above. Please explain:  Click or tap here to enter text. | | | | | | | | |
| **II. LOCATIONS** | | | | | | | | | |
| Will there be a local PI(s)? If yes, please describe the PI’s qualifications related to this research. If no, what is the plan for oversight of in-country research activities (e. g., for student-based projects)  Click or tap here to enter text. | | | | | | | | | |
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| **Location (e.g., country, province, state, etc.)** | | | **Facility (e.g., Academic Health Center, doctor’s office, public clinic, etc.)** | | | | | **Will in-person research activities take place here? (Y/N) (If the in-person activities are not conducted at the site, please explain where they will be conducted)** | |
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| **III. LOCAL LEGAL/REGULATORY REQUIREMENTS** | | | | | | | | | |
| Explain/identify any unique country or local regulatory requirements that apply to the conduct of this study at the international site(s) (e.g., use of a Legally Authorized Representative for informed consent; please see [guidance](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/international.html) for more examples). Briefly describe any steps that you have taken to adhere to the requirements and point to any applicable sections in the protocol, consent form, and/or eIRB application. | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | |
| **IV. LOCAL ETHICS REVIEW** *- Address the following requirements for each country where the research will be performed.* | | | | | | | | | |
| 1. | Documentation of approval by a local IRB/Ethics Committee or equivalent reviewing body is REQUIRED for:  (1) all greater than minimal risk studies; OR (2) for minimal risk studies, when such review is required by local laws or regulations. | | | | | | | | |
|  | Upload this documentation in the eIRB application section 20, item 2: | | | Local IRB/EC approval document uploaded in section 20, item 2  Pending:  Local IRB/EC approval is dependent on JHM IRB approval | | | | | |
| 2. | For minimal risk research where there is no local requirement for IRB/Ethics Committee review, there are two options to provide information about local context: | | | | | | | | |
|  | **OPTION 1** (preferred): If there is a local IRB/EC or other equivalent review body (e.g., Ministry of Health), please obtain and upload the approval documentation in eIRB application section 20, item 2. | | | **OPTION 2:** If there is no local IRB, the JHM IRB requires that an independent consultant with relevant local expertise review the project. Please upload the [Consultant Letter](https://www.hopkinsmedicine.org/institutional_review_board/forms/international-research-consultant-letter-example.pdf). | | | | | |
|  |  | Local IRB/EC equivalent reviewing body approval document uploaded in section 20, item 2 | |  | | Consultant Form uploaded in section 20, item 2 | | | |
| **V. OTHER PERMISSIONS** - *Answer the following questions for each country where the research will be performed.* | | | | | | | | | |
| In addition to a local IRB/EC approval: | | | | | | | | | |
| 1. | Are any national or regional regulatory approvals (e.g., FDA equivalent, Ministry of Education) required for this study? If yes, please list the names of the entities that provide approval and upload the approval document in eIRB application section 20, item 2. | | | YES. National/regional regulatory approval document(s) uploaded in section 20, item 2.  List of entities that provide approval: Click or tap here to enter text.  Not applicable  Pending:  Regulatory approval is dependent on JHM IRB approval  ***PLEASE NOTE: JHM IRB may not grant final approval until all required permissions/ approvals are obtained.*** | | | | | |
| 2. | Are any other approvals required to conduct the research in-country (e.g., facility permissions, research permits, etc.)? If yes, please list the names of the entities that provide approval and upload the approval document in eIRB application section 20, item 2. | | | YES. Other approval document(s) uploaded in section 20, item 2.  List of entities that provide approval: Click or tap here to enter text.  Not applicable  **I attest that I will ensure all required local approvals will be secured prior to initiation of the research at the applicable local site** | | | | | |
| **VI. CULTURAL/RELIGIOUS/POLITICAL CONSIDERATIONS** | | | | | | | | | |
| Please describe if any cultural/religious/political expectations or norms impact the conduct of the study (e.g., consent process, recruitment, any study procedures, remuneration) and how you will address them. For example, certain members of the household or community leaders may be expected to consent on behalf of others. Please mark “N/A” if not applicable | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | |
| **VII. REMUNERATION** | | | | | | | | | |
| Please provide justification for the remuneration amount and the plan for payment (e.g., paying the head of household).  Please explain why the amount and the plan is reasonable based on local standards (e.g., in relation to average local household income) and will not create undue influence. | | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | | |
| **VIII. LANGUAGE** - Which of the following applies to your study? | | | | | | | | | |
|  | We plan to target non-English speaking participants  We will not enroll non-English speaking participants. | | | We do not plan to target, but may include a non-English speaking participant | | | | | |
| **IX. VULNERABLE POPULATIONS** | | | | | | | | | |
| 1. | Apart from the vulnerable populations already identified in eIRB (e.g., children, pregnant women), are there any other vulnerable populations included in this study that are unique to the location/locality/country (e.g., refugees or a religious minority), and if so, what is being done to protect those vulnerable populations? | | | | | | | | |
|  | Click or tap here to enter text. | | | | | | | | |
| 2. | If this information has been already submitted, please identify the location/document that contains the information (e.g., protocol, supplemental documents) in eIRB. | | | | | | | | |
|  | Click or tap here to enter text. | | | | | | | | |
| **X. CONSENT** | | | | | | | | | |
| 1. | Review the “[JHMIRB International Research Consent Requirements](https://www.hopkinsmedicine.org/institutional_review_board/forms/jhmirb_international_research_consent_requirements_instructions.pdf)” and confirm that you have included the required consent elements in your consent form/script(s) | | |  | YES  Not applicable. Please explain: Click or tap here to enter text. | | | | |
| 2. | Indicate which of the following applies to your study per the local IRB/Ethics Committee requirement: | | |  | We only require the local IRB’s approval stamp on consent form(s)  We only require the Johns Hopkins IRB’s approval stamp on consent form(s)  We require approval stamps from both the local IRB and the Johns Hopkins IRB on consent form(s) | | | | |
| **XI. HIPAA** | | | | | | | | | |
| Will you transfer any identifiable health information to the U.S.?  If yes, please ensure that the [International HIPAA language](https://www.hopkinsmedicine.org/institutional_review_board/forms/HIPAA_statement_for_international_research_form.docx) is included in your consent form(s). | | | | | | | | | |
| YES. International HIPAA language is included in consent form(s) | | | | | | | NO | | |
| **XII. ATTESTATIONS** | | | | | | | | | |
|  | I have reviewed and agree to abide by relevant local laws, regulations, and guidelines. Examples include, but are not limited to:   * [GDPR](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/GDPR_application_research_settings.pdf) and other applicable privacy laws; * Laws/regulations on investigational drugs and devices; * Any applicable requirements on radiation; * Any applicable requirements Import/export of biospecimens; | | | | | | | | |