Single IRB Application Checklist

Use this checklist as a guide to fulfill the requirements of a Single IRB application. This checklist is **not** all-inclusive. It is intended to highlight sections of the eIRB application that are relevant to Single IRB studies.

Please Note: *You must receive confirmation of JHM IRB's willingness serve as the sIRB for your study before you submit your eIRB application.*

- ☐ General Information, Question 9 [*What kind of study is this?*] should indicate "**Multi-site study**".

- ☐ General Information, Question 10 [*Will your [JHM] IRB act as the single IRB of record for other participating sites?*] should indicate "**Yes**".

- ☐ General Information, Question 25 [*Study Team Members*], sub-question 6.0 should be answered "**Yes**" for any individuals who should have the ability to create and manage participating site [pSite] applications, which is the mechanism used to onboard sites in eIRB2.

- ☐ Protocol Information, Question 2.0 should include a multisite protocol [*Outside Sponsor OR Investigator-Initiated*]. **An eForm protocol is not acceptable**. It is recommended [*not required*] that you use one of the following protocols as a sample protocol or another similar template to build your multisite protocol. The following recommendations were taken from: https://www.nccih.nih.gov/grants/toolbox:

    - **NIH-FDA Phase 2 and 3 Protocol Template**
    - **Protocol Template for Behavioral and Social Sciences Research**
    - **NCCIH Protocol Template**

- The multisite protocol should contemplate all research activities to occur at both Johns Hopkins site and all pSites. If Johns Hopkins will serve as the lead/coordinating center, the protocol must also follow the JHM IRB Guidance where JHU will serve as a Coordinating Center: https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/coordinating.html

  If you do not intend to include a "Coordinating Center" section in your protocol and intend to address these elements throughout the protocol, it is recommended that you add a shorter, abbreviated section and point to the references in the other sections of the protocol where the specific details are included. This way, the IRB knows you've covered the material as there is a specific section that references it, and you have a guide to where in the protocol the rest of the information is located.

- Additionally, the protocol should identify JMH IRB as the sIRB for the study and provide a description of JHM IRB's role as the sIRB. Example:
    - *Johns Hopkins Medicine is serving as the single IRB for this study for all domestic sites. It is the preference of Johns Hopkins Medicine IRB to use the SMART IRB reliance agreement as the basis of reliance. The SMART IRB master reliance agreement was created to harmonize and streamline the IRB review process for multisite studies. It enables reliance on a study-by-study basis, clearly defines roles and responsibilities of relying institutions and reviewing IRBs, and eliminates the need to sign reliance agreements for each study [e.g., a non-SMART IRB agreement]. Sites that will rely on JHM IRB are still responsible for conducting a local context review prior to the start of research at their site and for following any local and institutionally required policies as it applies to research at their site [e.g., reporting of unanticipated problems].*

☐ Study Location: pSites should **not** be included in Section 10 of the parent eIRB application. pSites will be added via a pSite application following IRB approval of the parent application.

☐ Written Consent: *If you are using a written consent process,* a master consent form [**Part 1**] should be created for the study. **A Johns Hopkins consent form template is not acceptable**. It is recommended that you use the NCCIH Informed Consent Document Template as a sample consent form template **or** another similar template that includes the required consent elements to build your master consent form. *You are permitted to use the Johns Hopkins consent form template only for reference to required, site-specific language*. **This master template consent form cannot be edited by sites.**

Master Consent Form [Part 1]: The master consent form should cover the primary components of the study [procedures, risks, benefits, study purposes, etc.] and should include the following language on page 1:

- *You are being asked to take part in a research study. This is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study this informed consent form includes two parts. The first part of this document includes information that applies to all study sites. The second part of the consent form includes information specific to the study site where you are being asked to enroll.*

The master consent form must begin with a concise and focused presentation of the information that is most likely to assist a subject in understanding why s/he might or might not want to participate. This part of the consent must be organized and presented in

a way that facilitates comprehension. See the JHM IRB guidance on key information when drafting this section.

If Johns Hopkins is an enrolling site, a Johns Hopkins Site -Specific Consent Information [SSCI] addendum [**Part 2**] should also be included in your initial application. Any JH site-specific language should be included in the JH SSCI form – not in the master template consent form.

Site-Specific Consent Information [SSCI] Template [Part 2]: Site-specific required language [e.g., site-specific procedures, payments, research-related injury, HIPAA authorization language, signature lines] should be condensed in the Site-Specific Consent Information [SSCI] Form [**Part 2**].

Upon IRB approval, a JHM IRB Consent Form Specialist will combine the master consent form [Part 1] and JH SSCI template [Part 2] to create a site-specific consent form for JH. The same consent form building process will occur for pSites via the pSite onboarding process, which occurs after the initial IRB study is approved].

- **Oral Consent**: *If your study will include oral consent*, *oral assent or written assent,* you should create a master version of these documents. These documents do not have to follow the Master + SSCI format used for written consent. You should submit:

    - Master versions of these documents to allow for site customization [e.g., site name, site PI contact information] and
    - JH-specific versions [*if Johns Hopkin is an enrolling site]*.

- **Recruitment Information**: Recruitment documents should be created for broad use but also allow for site customization [e.g., space to add a sticker with local contact information]. Sites will have the opportunity to provide site-specific recruitment documents during their onboarding process, if needed. Additional guidance can be found here: https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/study_subject_recruitment.html

- **IRB Waiver of HIPAA Privacy Authorization [HIPAA Form 4**]: Per the terms of the Reliance Agreement, JHM IRB will serve as the Privacy Board will make determinations as required by and in compliance with the HIPAA Privacy Rule for use and disclosure of PHI for the Research, including waivers of, or alternations of authorizations. If Johns Hopkins or any participating site will require a waiver of HIPAA authorization to enable identification and screening of potential participants via review of EMR data as part of the recruitment plan, upload a completed HIPAA Form 4.

- **PI Responsibilities Attestation**: When JHM is serving as the single IRB, it is solely responsible for the oversight of the study and reviewing the study materials to determine if the study, as proposed, meets the criteria for approval under the federal human subjects protections regulations. Relying organizations retain responsibility for ensuring all local ancillary reviews required to conduct the research at this site are completed and for ensuring that any local requirements are communicated to the single IRB. In order to facilitate this process, each PI of a single IRB study must be aware of their roles and responsibilities when serving as the PI of a single IRB study. This attestation must be reviewed, signed and uploaded to Section 20.2.