GUIDE 633: Protocol Review Guidance for External Sites in Multi-Site Research

To assist the University of Hawaii IRB in providing appropriate review of research conducted at an external site, the researchers are asked to work with the ceding institution’s IRB to provide documentation for the following items.

Items 1 – 9 should be provided by the overall project PI, the specific site PI or the external site project point of contact. Items 10-13 will likely need to be provided by the relying institution’s IRB point of contact.

1. Protocol Title:

2. Site name

Site Investigator (Site PI)

Name:

Email:

Phone:

Site PI’s Point of Contact (POC)

Name:

Email:

Phone:

3. Are there any site-specific **ancillary reviews** that could impact the IRB review and/or approval at your site and need to be addressed by the reviewing IRB?

* 1. If yes, what is the current overall status of review and approval by the applicable ancillary committee(s)?

4. Are there any changes required to the study plan related to the **available resources** at your site? If yes, provide details.

5. Do local/site specific requirements or state laws stipulate requirements for enrolling vulnerable populations at your site that differ from those described in the protocol or associated documents? If yes, provide details.

6. Do local/site specific requirements or state laws stipulate requirements for how data will be accessed and/or stored at your site that differ from those described in the protocol or associated documents? If yes, provide details.

7. Dolocal/site specific requirements or state laws stipulate requirements for your site’s initial contact and/or recruitment plan that differ from those described in the protocol or associated documents? If yes, provide details.

8. Given the nature of this particular research study, is there any **local context**  (i.e., any additional factors particular to this study site or the community, such as community attitudes, ethnic diversity, language, etc.) that may contribute to the acceptability of this research in your area? If yes, provide details.

9. Will **drug and/or device storage** be managed centrally by a pharmacy at the organization?

10. Did the organization determine there is a relevant individual or institutional financial **conflicts of interest (COI)** for this protocol? If yes, provide the name and contact information for the appropriate POC for questions related to the determination and/ or local management plan.

11. Do all individuals at the institution who are involved in this protocol have the appropriate credentials and/or qualifications, and meet the institution’s standards for **eligibility to conduct research**?

12. If the protocol is silent on initial contact and/or recruitment, describe any institutional requirements.

13. Does the institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects for this protocol?

Notes:

**Ancillary Reviews**. The Reviewing IRB will **only** need information related to ancillary reviews that (1) may have an impact on the review and approval, and that is not already known to the IRB, (2) may affect the conduct of the study at the Relying Institution, or (3) would change the site-specific informed consent document.

**Available Resources.** Provide details of any differences in locally available resources that should be considered by the Reviewing IRB (e.g., different provisions for ensuring necessary medical or professional intervention or equipment will be provided in the event of adverse events or unanticipated problems involving subjects; exclusively using MRI, no PET; all imaging will be standard of care; only MDs will obtain consent).

**State Laws and Local Requirements**. If there are additional state laws and/or local requirements that should be considered by the Reviewing IRB (e.g., mandatory reporting to state health authorities, child abuse reporting, child pregnancy results), please provide details.

**Local Context**. To help with the Reviewing IRB’s determination to serve in such a capacity and to appropriately orient the Reviewing IRB to the Relying Institution, please provide a basic overview of the local community (i.e., cultural, demographic, and economic characteristics, languages spoken, and local educational and/or literacy concerns, and religious, social, and political considerations) as it relates to the protocol being reviewed. This will help the Reviewing IRB ensure that appropriate methods are in place for conducting research within the Relying Institution’s community.

**Drug and Device Storage.** If not managed centrally by a pharmacy at the organization, provide study-specific information about plans for storage, handling, and dispensing of drugs and medical devices. If managed centrally by the organization, no additional information is needed for each study.

**Qualifications of Investigators/Study Staff.** The regulations at 21 CFR 56.107(a) require that an IRB “ be able to ascertain the acceptability of the proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice...” In addition, the regulations at 21 CFR 56.111 require that an IRB determine that the proposed research satisfies the criteria for approval, including that “...risks to subjects are minimized...[and] reasonable in relation to anticipated benefits, if any, to subjects...” To fulfill these responsibilities, the Reviewing IRB needs information about the qualifications of the investigator(s) to conduct and supervise the proposed research.

In cases where the Reviewing IRB does not have experience with an investigator or institution, the IRB will need additional information to readily determine that the clinical investigator (and study staff) are appropriately qualified to conduct and supervise the proposed research. In these situations, the IRB should be able to obtain a statement confirming the investigator’s (and study staff’s) qualifications from an administrator of the Relying Institution. For example, for proposed research to be conducted at a hospital where only credentialed hospital staff may conduct research, the Reviewing IRB relies on the Relying Institution to confirm the credentialing for the Site PI and local study team members.

**HIPAA**. Because each institution may interpret preparatory research provisions differently, and because some researchers may be considered employees or members of a covered entity while others are not, the Reviewing IRB will require confirmation on whether a Relying Institution will require a HIPAA waiver to disclose protected health information and allow the Site PI and/or study team to contact and recruit individuals into the study.