PROTOCOL-SPECIFIC DOCUMENT

To Collect Institutional Requirements from Relying Institutions

Institutional, Local, and State Requirements Working Group of the SMART IRB Harmonization Steering Committee

July 2018

Harmonized: This document underwent a review and input process from February 2017 to July 2018 and has now been finalized.

INTRODUCTION

Purpose

The SMART IRB Protocol-specific Document captures institutional information that is **specific** to a given protocol. A Reviewing IRB may use this document to (1) collect applicable institutional, local, and state requirements, and to (2) document how the IRB has reviewed and approved a protocol for the Relying Institution.

Instructions

1. The Relying Institution's SMART IRB POC should work with their Site Investigator (Site PI) and/or designated study team point of contact (Site PI's POC) to identify and record the appropriate responses (and sub-responses) to each question. ***The Site PI and Site PI's POC should complete items 1-16 and then forward the document to their institution's SMART IRB POC, who should verify items 1-16 and complete items 17-20.***
    a. Complete each text box, as applicable.
    b. Select **one** appropriate response from each drop-down list.
    c. For each "yes" response, provide additional details, as applicable.
2. The Relying Institution's SMART IRB POC will share the completed Protocol-specific Document with the proposed Reviewing IRB's SMART IRB POC and discuss any points requiring clarification, updating responses as needed.
3. The Reviewing IRB should retain a copy of the completed Protocol-specific Document.

NOTE

- **Site PI's POC**. A Site PI's POC should be a member of the study team who is familiar with how the study will be conducted at the Relying Institution. This individual is not the Relying Institution's SMART IRB POC.
- **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.
    - A "no" response does not indicate that "no ancillary reviews were needed"; it only indicates to the Reviewing IRB that there is no additional information from an ancillary review that is needed for their review and approval. For example, if a radiation safety committee review is required at the Relying institution and the IRB has taken into account all radiation risks and disclosures in the informed consent document, the site-specific ancillary review would not impact the IRB review (i.e., a "no" response to ancillary reviews would be appropriate). In this example, confirmation that the radiation safety committee review has been completed prior to study initiation at the site would remain a responsibility of the Relying Institution and would be independent of the IRB review.
    - In the above example, if the Reviewing IRB has not considered the radiation risks and disclosures in the informed consent document, and this is required by the ancillary committee at the Relying Institution, the site-specific ancillary review would impact the IRB review (i.e., a "yes" response to ancillary reviews would be appropriate). If the Relying Institution responds "yes", the Reviewing IRB must be provided the following information:

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- Indicate whether the ancillary review has been completed or is pending.
- If the ancillary review is pending, indicate the anticipated date of review. It is recommended that the Relying Institution secure an outcome of the review prior to submitting the SMART IRB Protocol-specific Document. If the review is pending, the Relying Institution will need to work with the Reviewing IRB to determine an appropriate mechanism by which an update can be provided.
- Provide the details of the information that the Reviewing IRB will need to conduct their review, either in the text field provided or as an attached document.
- If there is more than one site-specific ancillary review that would impact the IRB review, use the text field to indicate for each review whether it is pending or complete.

- **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.
- **Conflicts of Interest (COI)**. If the Relying Institution has a COI review process, the Relying Institution's SMART IRB POC must also provide the Reviewing IRB with the following information, as applicable:
    - Determination that no individual or institutional financial COI was identified.
    - Determination that an individual or institutional financial COI was identified, but has been eliminated as part of the institution's review and management process. Details of the conflict and how it was eliminated should be attached or provided in the appropriate text box.
    - Determination that an individual or institutional financial COI was identified and a management plan has or will be developed. Details of the conflict and associated management plan should be attached or provided in the appropriate text box.
    - If the Relying Institution has identified a COI, the Relying Institution's SMART IRB POC should provide the Reviewing IRB with the name and contact information for an individual at the Relying Institution who is knowledgeable about the institution's COI review process and the details of any management plan. In most cases this will be an individual other than the Relying Institution's SMART IRB POC.

  If a Relying Institution does not have a COI review process, indicate "N/A". The Reviewing IRB will determine if they are capable of conducting the review and developing a management plan, if applicable.

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- **Qualifications of Investigators/Study Staff.** As outlined in the document, "IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE is Needed" (FDA Guidance): 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.

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A Relying Institution's SMART IRB Point of Contact (POC) should complete this form in conjunction with the local study team. The Site PI and Site PI's POC should complete items 1-16 and then forward the document to their institution's SMART IRB POC, who should verify items 1-16 and complete items 17-20.

1. Protocol Title

2. Site Name

Site Investigator (Site PI)

3. Name

4. Email

5. Phone

*Site PI's **point of contact (POC)***

6. Name

7. Email

8. Phone

9. 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?

   ○ Yes ○ No

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

      ○ Pending ○ Complete

   b. If yes, provide details (i.e., outcome, anticipated date of review) or attach documentation.

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10. Are there any changes required to the study plan related to the **available resources** at your site?

    ○ Yes ○ No

    a. If yes, provide details.

11. Do local requirements or state laws stipulate requirements for enrolling vulnerable populations at your site that differ from those described in the protocol or associated documents?

    ○ Yes ○ No ○ N/A (no vulnerable populations to be enrolled)

    a. If yes, provide details.

12. Do local 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?

    ○ Yes ○ No

    a. If yes, provide details.

13. Do local 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?

    ○ Yes ○ No

    a. If yes, provide details.

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14. Do local requirements or state laws stipulate any other requirements for the implementation and/or conduct of the protocol at your site that differ from those described in the protocol or associated documents?

    ○ Yes ○ No

    a. If yes, provide details.

15. 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?

    ○ Yes ○ No

    a. If yes, provide details.

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

    ○ Yes ○ No ○ N/A (no protocol-directed drugs or devices)

    a. If no, provide details.

17. Did the organization determine there is a relevant individual or institutional financial **conflicts of interest (COI)** for this protocol?

    ○ No
    ○ Yes and the COI has been eliminated
    ○ Yes and a management plan has been developed
    ○ N/A organization does not have a COI review process

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a. If yes, provide summary of conflict and management plan, or attach documentation.

b. If yes, provide the name and contact information for the appropriate POC for questions related to the determination and/or local management plan.

18. 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**?

    ○ Yes ○ No

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

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

    ○ Yes ○ No

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