SMART IRB

STUDY-SPECIFIC DOCUMENT

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

Introduction

Purpose

The SMART IRB Study-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 (Relying Institution PI) and/or designated study team point of contact (Relying Institution PI's POC) to identify and record the appropriate responses (and sub-responses) to each question. ***The Relying Institution PI should complete as many items as possible then forward the document to their institution's SMART IRB POC, who will verify all items.***
   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 Study-specific Document with the proposed Reviewing IRB, and update this document throughout the history of the study.
3. The Reviewing IRB should retain a copy of the completed Study-specific Document.

Notes

- **Local (Context) Considerations.** 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, 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.
- **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 Relying Institution PI and/or study team to contact and recruit individuals into the study.

A Relying Institution's SMART IRB Point of Contact (POC) should complete this form in conjunction with the local study team. The Relying Institution PI should complete as many items as possible then forward the document to their institution's SMART IRB POC, who will verify all items.

1. Protocol Title

2. Site Name

Relying Institution Investigator (Relying Institution PI)

3. Name:

4. Email:

5. Phone:

*Relying Institution PI's **point of contact (POC)***

6. Name:

7. Email:

8. Phone:

9. Will the study be implemented differently at your site due to a limited role (e.g., your site serves as a data analysis center or biospecimen repository)?

☐ Yes ☐ No

If yes, provide details.

10. Do any of the site's study team members have financial conflict of interests (COIs) related to this study?

- [ ] No
- [ ] Yes, and a management plan has been developed.
- [ ] To be determined; COI review will be performed by the Reviewing IRB.
- [ ] For federal agencies: The Agency or Department engaged in this study has completed COI analyses required by its procedures (based on federal law and policy) and participation of its investigator(s) in the research is permissible.

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

If yes, provide the name and contact information for the appropriate POC (e.g., Research Integrity Officer) for questions related to the determination and/ or local management plan.

11. The Relying Institution PI/Relying Institution confirms that all resources are available to conduct our portion of the study.

- [ ] Yes
- [ ] No

If yes, please describe:

12. Relying Institution PI/Relying Institution confirms that any drugs/devices used for this research study will be stored and managed as described in the study plan and in compliance with my institution's policy.

- [ ] Yes
- [ ] No

13. Relying Institution PI/Relying Institution confirms that all individuals conducting the research are qualified to perform any tasks delegated to them, have received adequate training on how to conduct the delegated tasks, were provided with an adequate understanding of the study, and that the Relying Institution has adequate resources to carry out this research study.

☐ Yes ☐ No

14. Does your state law, local law, or institutional policy require that the recruitment at your site be implemented differently from what is outlined in the study plan?

☐ Yes ☐ No

If yes, describe in detail the difference that must be implemented at your site:

15. Does your state law, local law, institutional policy, **or standard of care (routine care) or local practice** require that the study be implemented differently at your site than from what is outlined in the study plan?

☐ Yes ☐ No

If yes, describe in detail the difference that must be implemented at your site:

16. Does your state law, local law, or institutional policy require that the **consent process, use of a short form, and translation of consent form** be implemented differently at your site than from what is outlined in the study plan?

☐ Yes ☐ No

If yes, provide details.

17. Does your local/state laws or institutional policy impact or require changes to what is outlined in the study plan for any of the following populations?

- **Minors** (For example, your site may differ: assent process, pregnancy testing in minors, wards of state, emancipated minors, who is able to assess the capacity to consent, etc.)
  Yes No N/A (no minors to be enrolled)

  If yes, describe in detail the difference that must be implement at your site:

- **Adults with impaired decision-making capacity and their legally authorized representative (LAR)** (For example, your site may differ: who can obtain informed consent, who serves as an acceptable LAR, identifying capacity to consent, etc.)
  Yes No

  If yes, describe in detail the difference that must be implement at your site:

- **Pregnant persons**
  Yes No

  If yes, describe in detail the difference that must be implement at your site:

- **Prisoners** (For example, your site may differ categories of research in which prisoners may participate.)
  Yes No

  If yes, describe in detail the difference that must be implement at your site:

- **Other** (ex. Students, employees, etc. Your site may differ in who can conduct studies on students or employees.)
  Yes No

  If yes, describe in detail the difference that must be implement at your site:

18. Is there anything additional related to state law, local law, or institutional policy that impacts this particular study (e.g. AI policy)?
Yes No

If yes, please describe:

19. Does your institution have any **required language** that must be incorporated into the **consent form**? For example: compensation in the event of research-related injury, pregnancy testing in minors, or genetic testing.
Yes No

If yes, please describe the sections that must be altered and include the required consent language for this study:

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

☐ Yes ☐ No

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

☐ Pending ☐ Complete

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

21. Is the Relying Institution a HIPAA Covered Entity?

☐ Yes ☐ No

If yes, will you require the Reviewing IRB to serve as Privacy Board:

☐ Yes ☐ No

If you are accessing PHI and requesting a partial or full waiver/alteration of HIPAA authorization, explain how your request meets the following criteria:

- Use or disclosure of PHI involves no more than a minimal risk to the privacy of participants
- Research could not be practicably conducted without the waiver and access to PHI
- Researcher has a plan to protect the PHI from improper use and disclosure
- Researcher has a plan to destroy identifiers at the earliest opportunity