INSTITUTIONAL PROFILE

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 Institution Profile captures institutional information that is **independent** of a specific protocol. An institution's SMART IRB Point of Contact (POC) should complete this profile to (1) document institutional, local, and state requirements that would apply to **all** protocols, so that a potential Reviewing IRB may refer to this profile (in conjunction with a completed SMART IRB Protocol-specific Document) during the ceding and review of a specific protocol; and, if applicable, to (2) document information about the institution and its IRB(s) so that potential Relying Institutions may refer to this profile when determining whether to cede IRB review to the institution for a protocol.

Instructions

1. An institution's POC should record the appropriate responses (and sub-responses) to each question.
    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. An institution's POC should update the information on this form as needed to ensure accuracy.

NOTE

- **Institution Name(s)**. Because a Reviewing IRB may not be familiar with your institution, it is important to include all alternate names, abbreviations, and acronyms by which the institution may be known to avoid confusion and/or potential delays in approvals or correspondence.
- **Components.** When listing all components under your institution's FWA, indicate in the text field if the components are considered separate legal entities.
- **HIPAA.** A Reviewing IRB must know whether a Relying Institution is a covered entity under HIPAA for research activities to determine whether HIPAA regulations will apply for the institution. If your organization is a hybrid entity, where only some components and/or research activities are covered by HIPAA, mark this response as "Yes" and provide details regarding the hybrid status in the next question. A Reviewing IRB will need to know the following for any Relying Institution that must apply HIPAA:
    - Whether the institution will **always** require a stand-alone HIPAA authorization.
    - Whether the institution will **always** require a combined HIPAA authorization and informed consent document.
    - Whether the institution will leave the determination of a stand-alone or combined HIPAA authorization to the Reviewing IRB for a specific study.
- **HIPAA Details**. List any components under your FWA that are covered entities under HIPAA for research activities. If your organization is a hybrid entity, where not all components are covered by HIPAA, provide a specific listing of the components considered part of the covered entity. If collecting PHI at your institution is only subject to HIPAA in certain situations describe them here (e.g., research conducted in a clinical setting).
- **Short Form Consents.** You should indicate any institutional policy on the use of short forms for non-English speaking individuals (i.e., short forms are not used at all, short forms are not allowed for certain languages (e.g., Spanish), short forms

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are only allowable for minimal risk research). Potential Reviewing IRBs will use this information when determining if they have the capacity to serve as a Reviewing IRB for your institution.

- **Minors and Consent.** In addition to knowing the age of majority in a Relying Institution's state, a Reviewing IRB should be informed of specific situations when minors can consent for themselves (e.g., some states allow un-emancipated minors to consent to STD treatment/research).
- **State Laws and Local Requirements.** Provide details for any additional state laws and/or local requirements that would be applicable to **all** protocols, (e.g., IRB reporting requirements for all studies). If the state laws and/or local requirements would only apply to certain protocols (e.g., mandatory reporting to state health authorities, child abuse reporting, child pregnancy results), do not include this information in your SMART IRB Institutional Profile; instead, provide this information to the Reviewing IRB for an applicable protocol via the SMART IRB Protocol-specific Document.
- **Flexibility.** Many institutions have implemented flexibility options with regard to review and approval of research at their institutions. Examples of flexibility include declining to apply the regulations to non-federally funded research by "unchecking the box," establishing additional exempt categories, extending IRB approval dates, and/or expanding expedited review categories. If your institution has implemented flexibility options, provide details for the Reviewing IRB.
- **IRB Policies.** If your institution is willing to serve as a Reviewing IRB for another institution, it is important to identify how Relying Institutions may access your IRB policies (e.g., website links, upon request from the Relying Institution).
- **OHRP or FDA Investigations/Inspections.** A potential Reviewing IRB Institution should provide any publicly-available information related to investigations or inspections of the IRB that may be relevant to or influence another institution's decision whether to rely upon that IRB. Do not include information related to investigations or inspections of individual investigators at the IRB's institution.
- **Default HIPAA Privacy Board Allocation.** It is anticipated that a Reviewing IRB will also serve as the Privacy Board for all Relying Institutions; therefore, the answer to this question has been defaulted to "yes." If this is not the case for your institution/IRB, change the response to "no."
- **Review of Study Personnel.** Because processes for handling the review of study personnel can vary widely among Reviewing IRBs, it is important that potential Relying Institutions are aware of the process for any IRBs that require all study personnel be reviewed and approved by the Reviewing IRB.

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All institutions should complete this form and update it as needed to ensure accuracy.

SECTION 1. This section should be completed by any institution that may cede review to an external Reviewing IRB. A potential Reviewing IRB will review and consider the information in this section during the ceding process.

1. Name of Institution

2. List all other names by which the institution is known.

3. List all organizations that are considered components under this institution's FWA.

4. Is your institution a covered entity under HIPAA for research activities? ○ Yes ○ No

5. If applicable, provide any institution-specific details regarding HIPAA activities that may be relevant to the Reviewing IRB.

6. If your institution and/or components are a covered entity, what are the HIPAA authorization/informed consent document requirements?

7. What is your institution policy on use of short form consents for non-English speaking individuals?

8. What is the age of majority in your state?

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9. What is your institution's interpretation of state law regarding when minors in your state can consent for themselves?

10. Describe any broad laws or institutional requirements that would be applicable to all protocols reviewed on behalf of the institution.

11. Has your institution implemented flexibility options with regard to review and approval of research at your institution (e.g., have you "unchecked the box")? ○ Yes ○ No

12. If Yes, provide details.

SECTION 2. This section should be completed by any institution that may serve as a Reviewing IRB. A potential Relying Institution will review and consider the information in this section during the ceding process.

13. Is your institution willing to serve as an IRB of record (Reviewing IRB) for other institutions? ○ Yes ○ No

14. Name of the institution's IRB(s)

15. How will the institution's IRB policies be made available to Relying Institutions?

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16. In the past five years, have there been any letters of findings from OHRP or FDA as a result of investigations or inspections of the institution's IRB? ○ Yes ○ No

17. If yes, please explain.

18. As a Reviewing IRB, would you be willing to serve as the Privacy Board for other institutions? ◉ Yes ○ No

19. Will the institution's IRB(s) require a listing, review, and/or approval of all study personnel from each Relying Institution?

○ Yes ○ No

20. If yes, please describe how this will be provided, reviewed, and updated.

21. Please indicate how your institution has assessed the quality of its IRB/HRPP?

22. If other, please describe.

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