Institutional Profile

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.
    1. Complete each text box, as applicable.
    2. Select **one** appropriate response from each drop-down list.
    3. 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.

Notes

- **Institution Name(s).** Because other institutions 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.

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- **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 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 Study-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 publiclyavailable 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.

Institutional Profile

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

Institution Legal Name
President and Fellows of Harvard College (Harvard University)

List all other names by which the institution is known.
Harvard University Area Harvard University

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

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The Harvard University Area is comprised of the Faculty of Arts and Sciences, John F. Kennedy School of Government, Harvard Graduate School of Education, Harvard Law School, Harvard Divinity School, Harvard Graduate School of Design, Harvard University Health Services, Radcliffe Institute for Advanced Study, Harvard School of Engineering and Applied Sciences, and Harvard Business School

Identify any affiliations this site has, such as university, clinic, or hospital.

a. If any of the sites are within a network or system, identify all sites with separate Federal Assurances (Please note that sites with separate Federal Assurances require separate SMART IRB accounts).

Does your state law or institution require you to apply the Common Rule to all studies?
Yes

Does your state law or institutional policy require you to apply any of the subparts (B, C, or D) of the HHS regulations at 45 CFR part 46 that provide additional protections for certain populations in research to all studies, when applicable?
Yes

If yes, indicate the subpart(s) your institution applies:
Harvard University has elected to apply the standards for federally funded or supported research to non-federally funded or supported research, excluding a strict application of the cooperative research requirement, which assessed by case.

Are there any local considerations (i.e., customs, beliefs, values, or practices of a distinct subject population(s)) that a Relying Institution could expect to be included in the research?

Provide any additional information that may affect the IRB's review of your institution. Some examples may be California Bill of Rights, Virginia law that requires application of the Common Rule to all research, restriction of any vulnerable populations, etc.
HIPAA:
Harvard University Area is a hybrid entity wherein only the Harvard University Health Services is a covered entity. Harvard University Area will always require a stand-alone HIPAA authorization.

STATE LAW/UNIVERSITY POLICY:
1. MA State Law has requirements for the use of Fresh Human Fetal Tissue and Embryonic Stem Cells Reference:
a. MA Biotechnology Law: https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111L
b. MA "Section 12J":
https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12j
2. MA State Law has requirements regarding recording:
a. https://malegislature.gov/Laws/GeneralLaws/PartI/TitleIII/Chapter30A/Section20
3. MA State Law has requirements regarding Child Abuse Reporting/Mandated Reporters:
https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVII/Chapter119/Section51A
4. MA State Law has requirements regarding Confidential Birth Information:

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https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter111/Section67E
Harvard University Policies:
5. Policy on the Use of Harvard Names and Insignias:
https://trademark.harvard.edu/policy-on-use-of-harvard-names-and-insignias

MINORS:
Under DHHS and FDA regulations “children” are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Subpart D of the DHHS must be applied if and only if an individual involved in the research meets this definition. When research is conducted in Massachusetts all individuals under the age of 18 years meet this definition with the following exceptions:
1. Emancipated minors, defined as individuals who meet one of the following criteria, do not meet the DHHS and FDA definition of “children”: (M.G.L. c. 112 § 12F)
a. Married/widowed/divorced;
b. A parent;
c. A member of the armed forces;
d. Living apart from parents and managing his or her own finances; or
e. In the case of a female, pregnant or believes herself to be pregnant, unless the procedures involved in the research include abortion as described below.
2. Individuals under the age of 18 when the research procedures are limited to:
a. Diseases dangerous to the public health;
b. Drug dependency (but not alcohol dependency).
c. Pregnancy, unless the procedures involved in the research include abortion as described below.
Exception: If the research procedures involve abortion, a female under the age of 18 who is not and has never been married meets meet the DHHS and FDA definition of “children.” (M.G.L. c. 112 § 12S)

SHORT FORM:
The short form consent is typically used when the potential participant does not speak English and there is not enough time to translate the English version of the approved consent document into a language the potential participant understands.
Requirements for Use
The investigator must provide the following to the IRB for review:
• A written summary of what is to be said to the participant or the participant's legally authorized representative. The summary must include all of the required and appropriate elements in Section 7: Elements of Consent Disclosure in the “WORKSHEET: Criteria for Approval (HRP-314)”. The PI may use the English version of the IRB approved informed consent document.
• The short form document that will be signed by the potential participant.
• Confirmation that:
o The oral presentation will be conducted in a language understandable to the participant.
o The person obtaining consent is authorized by the IRB.
o There will be a witness to the oral presentation (this cannot be the same person who is obtaining consent). If the participant does not speak English, the witness should be fluent in both English and the language of the participant. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

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o The short form will be signed by the participant and the witness.
o The written summary will be signed by the witness and the person actually obtaining consent.
o A copy of the oral summary and the short form will be given to the participant.
Responsibilities Afterward
The request to use the short form consent process is typically made because time is of the essence. As such, the IRB prioritizes the review of these requests in order to avoid denying a patient an opportunity to participate in research. However, once the participant is enrolled, the investigator is expected to adhere to the IRB's standard requirements
for non-English speaking participants. This includes providing the IRB (in a timely fashion) with the plan for ensuring that ongoing communication with the participant is in a language understandable to the participant the following. Please see “SOP: Informed Consent Process for Research (HRP-090)” for a complete overview of the consent process, including the short form consent process.

Identify the age of majority for your state or territory. For federal agencies or departments, please indicate the applicable age of majority.
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Is your institution willing to serve as an IRB of record (Reviewing IRB) for other institutions?
Yes

Name of the institution's IRB(s).
IRB00000109 Harvard U Faculty Arts & Science IRB #1 IORG0000074

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

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