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
Children's Hospital Orange Co (CHOC)

List all other names by which the institution is known.
1. DBA: CHOC & CHOC Children's 2. Academic and Research Affiliations with: School of Medicine University of Irvine, CA (UCI) 3. Parent Company: Rady Children's Health

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List all organizations that are considered components under this institution's FWA.
Research occurring at CHOC under CHOC's FWA. Oversight is with the local IRB at CHOC. The FWA covers both CHOC and Children's Hospital at Mission.

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?
No

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?
No

If yes, indicate the subpart(s) your institution applies:

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?
CHOC is located in an ethnically diverse community. CHOC provides the following translations of short form consent documents and HIPAA authorizations: Spanish, Vietnamese, Chinese, Arabic, Korean and Farsi. Study teams should consider resources available to provide for full translations of consent documents for studies that are greater than minimal risk.

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.
Our local IRB does not allow for enrollment of wards of the court in Research, except under special circumstances. Per the California Health and Safety Code, Protection of Human Subjects in Medical Experimentation Act (Sections 24170–24179.5): the experimental subject's bill of rights be provided, written in a language in which the subject is fluent to all research subjects in medical experiments.

In order to meet the signature requirement the Bill of Rights should be inserted into the consent document and the form must include language such as, "You have been given a copy of this consent form and the Human Research Participant's Bill of Rights to keep". CHOC will provide template to be used.

The default age for solicitation of assent is seven (7) years of age but younger or older limits may be chosen based on the nature of the study and the expected capacity for the prospective subject(s) to understand the purpose of the research, the nature of the procedures and the ability to express their voluntary approval or disapproval to participate. This requirement is based on California Health and Safety Code Sec. 111530. CHOC has developed an assent form template specific to the 7-11 years of age group to meet age appropriate comprehension level and generally requires use of this template, which will be

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provided. Our local IRB does not allow for enrollment of wards of the court in Research, except under special circumstances. Per the California Health and Safety Code, Protection of Human Subjects in Medical Experimentation Act (Sections 24170–24179.5): the experimental subject's bill of rights be provided, written in a language in which the subject is fluent to all research subjects in medical experiments. In order to meet the signature requirement the Bill of Rights should be inserted into the consent document and the form must include language such as, "You have been given a copy of this consent form and the Human Research Participant's Bill of Rights to keep". CHOC will provide template to be used.

In order to avoid compliance errors, CHOC incorporates assent forms into the consent document, CHOC will provide template. CHOC standard authorization form required in order to meet California Confidentiality of Medical Information Act requirements. Must be a separate document from informed consent document and in 14 pt. font. CHOC will provide document to be used. All other local requirements can be found on the CHOC IRB Reliance Consent Checklist.

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?
No

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