Institutional Profile

Site Name: San Francisco General Hospital Medical Center

Last modified date: 10/12/2018

ABOUT THE INSTITUTIONAL PROFILE
The IREx IP contains basic information about your institution that another institution might use to determine if they feel comfortable relying on, or serving as the Reviewing IRB for, your institution. The IP can also be used by IRBs and study teams to better understand one's institutional processes and requirements when using reliance. This information will be visible to other users in IREx and publicly available as a downloadable PDF on the IREx Website here. This information is for general review purposes only. It may not be accurate and may be subject to change, withdrawn or revised at any time without notice. The Institutional Profile is not intended to serve as a complete record of an Institution's study-specific local considerations.

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Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>San Francisco General Hospital Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00000315</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2019-10-23</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Pediatrics, transplant, oncology, emergency medicine, infectious disease</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Yes</td>
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Section 2: SITE-SPECIFIC LOCAL CONTEXT
This information may be helpful for a Reviewing IRB to understand when considering whether to serve as the Reviewing IRB for your organization. Additional, study-specific information will be requested when a Reviewing IRB is reviewing a specific study for your site (e.g., COI, investigator training, study-specific consent requirements, state law or institutional requirements). However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).

To what state laws is your institutions subject?
List other names by which your institution is known. ZSFG, SFGH,

Age of majority in your state? 18

What circumstances affect age of consent in your state? For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment

- Emancipated minors
- Self-Sufficient minors
- Care related to the prevention or treatment of pregnancy
- Minors, 12 years or older, seeking care for: 1. Outpatient mental health treatment or counseling, excluding drugs 2. Care related to the diagnosis or treatment of reportable infectious, contagious, or communicable/sexually transmitted diseases 3. Care provided to the victims of sexual assault or rape

Do you have any state or local laws or institutional policies that require RECORD KEEPING for longer than federal law requires under the Privacy Rule or Common Rule? No

Do you require specific language in your consent form to describe what requires mandatory reporting to authorities? No

Does your site require a site-specific logo appear on consent forms and/or recruitment documents? No

Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects? Yes

Does the site have a posted policy for the following? NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.

- Consent Process for those with Impaired Decision-Making Capacity
- Use of short forms for non-English speaking individuals
- Translation of consent forms for non-English speaking individuals

Does your IRB require HIPAA authorization forms be a separate document from the Informed Consent Form? Yes

Please enter your specific consent form language regarding payment for research-related injury. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the UCSF IRB Committee on Human Research at 415-476-1814.

Please enter your specific consent form language regarding costs to participants to participate. [For studies in which the sponsor pays all costs:] No. The sponsor has agreed to pay for all procedures associated with this research study; you or your insurer will not be billed. [For studies where subjects
may be responsible for some costs: Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.

Please upload your template HIPAA Authorization language.

Do you have any additional HIPAA Authorization language template documents? Yes

Please upload additional template HIPAA Authorization language documents

**LOCAL CONTEXT: Component Sites**

As the FWA-holder of a component site, you are responsible for providing the relevant local considerations for component sites here, in the Institutional Profile, and for specific studies, as requested by the Reviewing IRB. **If your component sites have information that differs from that provided in the previous section, specify the site and what differs below.**

Do you have a component site on your FWA? No

**Section 3: LOCAL INSTITUTIONAL REQUIREMENTS FOR INVESTIGATORS WHEN RELYING ON ANOTHER IRB.**

These steps occur BEFORE the study is approved by the Reviewing IRB:

- How should an investigator request to cede review to an external IRB? For example, should they email the IRB? Is there a specific person at the IRB? Should they just submit the request via your local IRB system (as outlined in the questions below)?

  - If the request is at grant application stage, the study team should request a single IRB consultation from the UCSF IRB. If the funding has been awarded, the UCSF PI should submit an application through the iRIS system. The PI should be provided with a protocol at this stage.

Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely? Yes

Select all documents that must be submitted along with the reliance request package or reliance application

- Protocol
- Local consent form(s)
These steps occur AFTER the study is approved by the Reviewing IRB: Indicate below what documentation and events are submitted to your local IRB when relying on an external IRB.

Should your investigator submit any of the following to your HRPP when ceding review to another institution? If checked, you will be asked to detail what should be submitted.

- Local amendments (personnel modifications)
- Final report

What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review?

Personnel change, funding change, ancillary review changes such as COI, and radiation safety as applicable.

What should be submitted for final reports?

The UCSF PI should fill out the close out report in our local iRIS system.

Who at your institution should be contacted if a Lead IRB wishes to report an unanticipated problem, a determination of serious or continuing non-compliance, or a suspension or termination?

<table>
<thead>
<tr>
<th>Name</th>
<th>Laurie Herraiz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:laurie.herraiz@ucsf.edu">laurie.herraiz@ucsf.edu</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(415) 514-9246</td>
</tr>
</tbody>
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**Section 4: The Study-Specific Reliance Plan**
The questions below have been harmonized with the [SMART IRB Agreement Implementation Checklist](#) and serve as your reliance preferences when serving as the IRB of record for other sites.

If you decide to serve as the Reviewing IRB in IREx, when you create the study, these preferences will appear as the basis for your SSRP. You may edit your responses for the study or for one (or more) sites, if requested, at your discretion.

Is your institution willing to serve as the IRB of Record for other institutions? If yes, more information on your reliance preferences/requirements will be collected below.

- No