Institutional Profile

Site Name: Stanford University

Last modified date: 10/15/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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.

Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>Stanford University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00000935</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2020-12-20</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>00000348 00000349 00000350 00000351 00004593 00004947 00005136 00006208</td>
</tr>
<tr>
<td>Is the IRB AAHRPP accredited?</td>
<td>Yes</td>
</tr>
<tr>
<td>Does your institution REQUIRE institutions to be AAHRPP accredited in order to serve as their IRB of Record (all the time)?</td>
<td>It depends</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Panel 3 and 7 prisoner studies Panel 1 gene transfer Panel 3 stem cells</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</td>
</tr>
<tr>
<td>Additional Comments</td>
<td>The University is outside of the covered entity. Most research done in the University is under our SBER IRB (Panel 2).</td>
</tr>
</tbody>
</table>

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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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 institution subject?

- CA

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.

In California, minors may consent to participation in research without parental or guardian permission if legally emancipated and in certain treatment circumstances. An "emancipated minor" may consent to participation in any type of research. In addition, for research involving treatment certain un-emancipated minors may consent to research involving specific types of medical treatment, including: 1. Outpatient mental health treatment for a minor 12 years or older when certain criteria are met, 2. Hospital, medical or surgical care related to prevention or treatment of pregnancy for minors (any age), 3. Medical care related to diagnosis/treatment of a communicable reportable disease or condition, 4. Hospital, medical or surgical care related to rape for a minor 12 years or older, 5. Hospital, medical or surgical care related to sexual assault but must attempt to contact parent/guardian unless reasonably believe involved, 6. Care for alcohol or drug abuse.

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your IRB require HIPAA authorization forms be a separate document from the Informed Consent Form?</td>
<td>No</td>
</tr>
<tr>
<td>Please enter any special formatting your IRB requires for HIPAA authorization forms?</td>
<td>CA Regulations require HIPAA to be font size 14</td>
</tr>
<tr>
<td>Please enter your specific consent form language regarding payment for research-related injury.</td>
<td>Industry Sponsored or Funded Projects Option 1: Use this language if the industry sponsor or funder is paying for medical care costs incurred as a result of research-related injury: All forms of medical diagnosis and treatment - whether routine or experimental - involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, care will be provided to you. You will not be responsible for any of these costs. If you receive Medicare benefits, and if the sponsor of this study pays for any study-related treatment, complications or injuries, personal information about you, your treatment, and your participation in this study will be provided to the sponsor, who is required by law to provide it to Medicare. You do not waive any liability rights for personal injury by signing this form. Other Funding or No funding Option 2: Use this language for: A. Projects with federal funding (i.e., NIH funding), Stanford Departmental funding, gift funding, medical scholars funding and projects with pilot or other internal funding. B. Industry funded projects when the industry funder/sponsor is not paying for medical care costs incurred as a result of research-related injury. In these situations, the study must be reviewed and approved by the Risk Assessment Committee (RAC). For information on RAC application, please contact your contract officer. All forms of medical diagnosis and treatment - whether routine or experimental - involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits.</td>
</tr>
</tbody>
</table>
program. You will be responsible for any associated co-payments or deductibles as required by your insurance. If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital. You do not waive any liability rights for personal injury by signing this form.

Please enter your specific consent form language regarding costs to participants to participate.

Include the following if there is no treatment involved and there will be no additional costs to the participant due to their participation in the research: There is no cost to you for participating in this study, other than basic expenses like transportation and the personal time it will take to come to all of the study visits. OR Include the following paragraphs if there might be additional costs to the participant due to their participation in the research: If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. You will also be responsible for any co-payments and/or deductibles as required by your insurance. Participation in this study is not a substitute for health insurance.

Please upload your template HIPAA Authorization language.

Do you have any additional HIPAA Authorization language template documents? No

**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.

**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)?

Contact Stanford IRB: Sanskruti (Sans) Rayate, IRB Reliance Manager at sans.rayate@stanford.edu or 650-736-9024

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)
- Serious or continuing non-compliance
- Unanticipated problems
- 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?

Change of Stanford Protocol Director/Stanford personnel Changes in funding Changes in Conflict of Interest Changes to research radiation exposure

What should be submitted for serious or continuing non-compliance?

Protocol event report submission required per Stanford's regular reporting requirements for these type of events, i.e. possibly serious/continuing noncompliance, unanticipated problems. Copy of the IRB of record's determination/notice and any supplemental documents related to event.

What should be submitted for unanticipated problems?

Protocol event report submission required per Stanford's regular reporting requirements for these type of events, i.e. possibly serious/continuing noncompliance, unanticipated problems. Copy of the IRB of record's determination/notice and any supplemental documents related to event.

What should be submitted for final reports?

Close the sIRB application in our eProtocol 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?

Name
Anastasia Doherty

Email
anastasia.doherty@stanford.edu
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