Institutional Profile

Site Name: Cedars Sinai Medical Center

Last modified date: 04/06/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Cedars Sinai Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA#00000468</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2018-04-09</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
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</tbody>
</table>
| IRB Registry Number(s) | IRB00000209 Cedars-Sinai Med Ctr IRB #1  
IRB000000734 Cedars-Sinai Med Ctr IRB #2  
IRB00001319 Cedars-Sinai Med Ctr IRB #3  
IRB00005641 Cedars-Sinai Med Ctr IRB #4 - SCROC/IRB IRB00008568 Cedars-Sinai Med Ctr IRB #5 Rapid Activation |
| Is the IRB AAHRPP accredited? | Yes |
| Does your institution REQUIRE institutions to be AAHRPP accredited in order to serve as their IRB of Record (all the time)? | It depends |
| Describe any board specialties of your IRB. | One hybrid Stem Cell Oversight (SCRO IRB) - however, we do not allow reliance for stem cell protocols |
| Is your institution a covered entity? | Yes |
| Additional Comments | Cedars-Sinai will serve as Privacy Board for all reliance collaborations. |
**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.

Examples of situations for which individuals under the age of 18 would not be considered children include: i. Where the individual has been determined by a court or by State or Federal law to be an "emancipated minor". ii. In accordance with California Family Code Section 7002, a minor is only emancipated if he or she has entered into a valid marriage, is on active duty with the armed forces of the United States, or has received a declaration of emancipation from a court. iii. A minor is not automatically considered emancipated by way of being pregnant. iv. California Law, Health & Safety Code Section 6925, states that a"minor may consent to medical care related to the prevention or treatment of pregnancy." In addition, Health & Safety Code, Section 626 states that if "a minor of 12 years of age or older has come into contact with any infectious, contagious, or communicable disease of the type which must be reported to the local health officer, or sexually transmitted disease, the minor is able to consent hospital, medical, and surgical care related to the diagnosis or (clinical) treatment of the disease." Applying the principle of these laws, the IRB may approve investigators to obtain minor's "consent" to participate in certain types of research (e.g., pregnancy-related protocols, blood donation, HIV testing, or HCV testing) based on considerations of the nature of the study, the risks and benefits, and the potential ethical concerns. v. California Law, Health & Safety Code Section 1607.5, states that a minor 17 years of age or older may consent to blood donation. Therefore, minors may consent to participation in research involving blood donation, assuming the research involves no additional treatments or...
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? Yes, I will insert language in text box

Please insert the language required to be used around mandatory reporting to health authorities. If you test positive for HIV, your name and test results will be reported to the local and state health departments in accordance with California law. Researchers are required under California law to disclose information about you, without your consent in incidents such as child abuse, and intent to harm yourself or others.

Does your site require a site-specific logo appear on consent forms and/or recruitment documents? Yes

Please upload the logo

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. See Appendix A Cedars-Sinai Informed Consent Form Template Inserts

Please enter your specific consent form language regarding costs to participants to participate. See Appendix A Cedars-Sinai Informed Consent Form Template Inserts

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.

Do you have a component site on your FWA? No

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

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

1. Collaborating investigators meet to decide how each institution will be involved in the protocol and to determine which institution may qualify as the Reviewing IRB. 2. The investigator completes a summary of the collaboration, CSMC Request to Rely on an External IRB Questionnaire, to document what research activities will take place at Cedars-Sinai. The completed form should be emailed with the protocol to irb@cshs.org. 3. The CSMC investigator consults with IRB administration regarding the proposed decisions related to who will serve as the Reviewing IRB. 4. The designated IRB administrator will discuss with collaborating IRBs to make a final determination on which IRB will serve as the Reviewing IRB and notify the Lead PI. 5. The CSMC investigator will create a reliance submission in the CSMC IRB Webridge system. 6. The Reviewing IRB completes its review and issues approval with a contingency that the CSMC IRB accepts the submission as approved. All IRB application reviews will be conducted at the Reviewing IRB using their established forms and processes. 7. CSMC IRB identify and address local context issues before issuing a final acknowledgment notice to initiate the study at CSMC and releasing consent/recruitment documents approved for use at CSMC. All applicable ancillary reviews must be completed before final acknowledgement may be released. 8. The CSMC relying investigator must comply with continuing review, amendment, and post approval submission requirements as outlined in CSMC IRB policy.

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.

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
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| 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. | • Study-wide amendments (protocol or consent form modifications)  
• Local amendments (personnel modifications)  
• Continuing review  
• Serious or continuing non-compliance  
• Unanticipated problems  
• Serious adverse events  
• Adverse events  
• Final report |
| What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review? | CSMC IRB Webridge Amendment submission Revised protocol Revised ICF CSMC reconsent cover memo, as applicable per local policy |
| What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review? | All local amendments |
| What should be submitted at continuing review? | Approval letter from Lead IRB and entry of updated approval period |
| What should be submitted for serious or continuing non-compliance? | CSMC IRB Webridge Safety/Other Report submission Applicable supporting documents |
| What should be submitted for unanticipated problems? | CSMC IRB Webridge Safety/Other Report submission Applicable supporting documents |
| What should be submitted for serious adverse events? | CSMC IRB Webridge Safety/Other Report submission Applicable supporting documents |
| What should be submitted for adverse events? | CSMC IRB Webridge Safety/Other Report submission Applicable supporting documents |
| What should be submitted for final reports? | CSMC IRB Webridge Continuation (Closure) submission Sponsor confirmation of ok to close CSMC site |
| 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: Keren Dunn  
Email: Keren.Dunn@cshs.org  
Phone Number: (310) 423-3783 |

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.

Yes