Institutional Profile

Site Name: Rady Children’s Hospital & Health Center

Last modified date: 05/15/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

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Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>Rady Children’s Hospital and Health Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00000021</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2020-10-06</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>n/a</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Yes</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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
List other names by which your institution is known.

Rady Children's Hospital - San Diego
Rady Children's Institute for Genomic Medicine

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.
15 year olds may consent to medical care in some circumstances. 12 years olds may consent to mental health services in some circumstances 12 years olds may consent to treatment for infectious diseases in some circumstances.

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?

No

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.

- We do not have a posted policy for any of these

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

No

Please enter any special formatting your IRB requires for HIPAA authorization forms?

see information under FWA components

Please enter your specific consent form language regarding payment for research-related injury.

see information under FWA components

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

See information under FWA components

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?

Yes

What is the name of this component site?

Rady Children's Hospital - San Diego
Please indicate which questions you will answer about this component. Please only include those questions for which this component's answers differ from those for the FWA-holding site.

- Applicable State Laws
- Age of majority
- Circumstances affect age of consent
- Record Keeping
- Mandatory Reporting
- Informed Consent Documents and Policies
- HIPAA Templates
- Subject Injury Language

### Applicable state laws

**CA**

<table>
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<tr>
<th>Age of majority:</th>
<th>18</th>
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**Circumstances affecting age of consent:** For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment. 15 year olds may consent to medical care in some circumstances. 12 years olds may consent to mental health services in some circumstances 12 years olds may consent to treatment for infectious diseases in some circumstances.

**Do 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

**Is specific language required in their 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 it is reasonably foreseeable that the study will have access to or collection of information that Federal, State, and/or local laws/ regulations require or may require to be reported to other officials and the study includes investigator(s) who is/are a "mandated reporter" of child abuse, please use the following:"

"Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities." [If the study includes investigator(s) who is/are not a "mandated reporter" of child or elder abuse, please use the following:] "We may need to report information about known or reasonably suspected incidents of abuse or neglect of a child including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may report such information to the appropriate authorities."

**Does the site have a posted policy for the following?**

- We do not have a posted policy for any of these
<table>
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<tr>
<td>Please enter the specific consent form language regarding payment for research-related injury.</td>
<td>Parent Consent WHAT IF YOUR CHILD IS INJURED IN THE STUDY? [For industry-sponsored studies:] If your child is injured as a direct result of being in this study, treatment will be available. The costs of such treatment will be covered by the University of California, Rady Children's Hospital - San Diego, or the study sponsor [must be named], depending on a number of factors. The University, Rady Children's Hospital - San Diego, and the study sponsor [must be named] do not normally provide any other form of compensation for injury. You may call the UCSD Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your child's rights as a research subject, or to report research-related problems. [For grant-sponsored or PI-initiated studies:] If your child is injured as a direct result of participation in this research, Rady Children's Hospital - San Diego or the University of California will provide any medical care needed to treat those injuries. Neither Rady Children's Hospital - San Diego nor the University will provide any other form of compensation to you if your child is injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your child's rights as a research subject or to report research-related problems. Adult Consent: WHAT IF YOU are INJURED IN THE STUDY? [For industry-sponsored studies:] If you are injured as a direct result of being in this study, treatment will be available. The costs of such treatment will be covered by the University of California, Rady Children's Hospital - San Diego, or the study sponsor [must be named], depending on a number of factors. The University, Rady Children's Hospital - San Diego, and the study sponsor [must be named] do not normally provide any other form of compensation for injury. You may call the UCSD Human Research Protections Program Office at</td>
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858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject, or to report research-related problems. [For grant-sponsored or PI-initiated studies:] If you are injured as a direct result of participation in this research, Rady Children's Hospital - San Diego or the University of California will provide any medical care needed to treat those injuries. Neither Rady Children's Hospital - San Diego nor the University will provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems. Adolescent Assent: WHAT IF YOU ARE INJURED IN THE STUDY? If you are injured or become ill as a direct result of this research study, you will be provided with medical care.

| Do you have another component site on your FWA? | Yes |
| What is the name of this component site? | Rady Children's Institute for Genomic Medicine |

Please indicate which questions you will answer about this component. Please only include those questions for which this component's answers differ from those for the FWA-holding site.

- Applicable State Laws
- Age of majority
- Circumstances affect age of consent
- Record Keeping
- Mandatory Reporting
- Informed Consent Documents and Policies
- HIPAA Templates
- Subject Injury Language

Applicable state laws: CA

Age of majority: 18

Circumstances affecting age of consent: For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment. 15 year olds may consent to medical care in some circumstances. 12 years olds may consent to mental health services in some circumstances 12 years olds may consent to treatment for infectious diseases in some circumstances.

Do 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

Is specific language required in their 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 it is reasonably foreseeable that the study will have access to or collection of information that Federal, State, and/or local laws/regulations requires or may require to be reported to other officials and the study...
includes investigator(s) who is/are a "mandated reporter" of child abuse, please use the following:]
"Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities." [If the study includes investigator(s) who is/are not a "mandated reporter" of child or elder abuse, please use the following:] "We may need to report information about known or reasonably suspected incidents of abuse or neglect of a child including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may report such information to the appropriate authorities."

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<tr>
<td>Please enter the specific consent form language regarding payment for research-related injury.</td>
<td>You should call your child's doctor and the study team if you think your child was injured as a result of being in this study. Your study team's telephone number is at the end of this consent form. If your child is injured because of this study, your child will receive medically necessary care from Rady Children's Hospital. The Rady Children's Hospital will bill you or your insurance for these services just like any other medical care. Rady Children's Institute for Genomic Medicine does not have funds set aside to pay research participants if the research results in injury. By signing this form, you, or your child, are not giving up any legal rights. You may also call (enter IRB name and contact information) for more information about your child's rights as a research subject or to report research-related problems.</td>
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<td>Do you have another component site on your FWA?</td>
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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:

| 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)? | Request is submitted to local IRB Sehily Jaimes is the reliance IRB analyst, hrpp@ucsd.edu |
| 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)  
• Other |
| Please specify what other documents must be submitted | Signed Application Face Sheet HIPAA Authorization and HIPAA Waiver Form Study Approval Letter |

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. | • 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? | amended protocol (redline and clean versions) and amended consent forms (redline and clean versions). Approval letter from Lead IRB Amendment Cover Letter |
| 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 in Key personnel request forms |
| What should be submitted at continuing review? | renewal approval letter any renewal documents submitted to the reviewing IRB |
| What should be submitted for serious or continuing non-compliance? | Reviewing IRB determination Letter. Any documents submitted to the reviewing IRB. |
What should be submitted for unanticipated problems? Reviewing IRB determination Letter. Any documents submitted to the reviewing IRB.

What should be submitted for serious adverse events? Reviewing IRB determination Letter. Any documents submitted to the reviewing IRB.

What should be submitted for adverse events? Reviewing IRB determination Letter. Any documents submitted to the reviewing IRB.

What should be submitted for final reports? Reviewing IRB determination Letter. Any documents submitted to the reviewing IRB.

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 Dr. Anthony Magit
Email hrpp@ucsd.edu
Phone Number (858) 246-4777

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