Institutional Profile

Site Name: The Methodist Hospital dba Houston Methodist

Last modified date: 08/12/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Houston Methodist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00000438</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>1923-02-13</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00005005 IRB00006784 IRB00010841</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>Biomedical</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
To what state laws is your institution subject?

- TX

List other names by which your institution is known.
The Methodist Hospital d/b/a Houston Methodist

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 minor

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?
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?
No

Please enter any special formatting your IRB requires for HIPAA authorization forms?
Information about use and disclosure of HIV is required in the authorization if applicable to the study.

Please enter your specific consent form language regarding payment for research-related injury.
If you are injured as a direct result of this study, medical care is available. In general, no long-term medical care or financial compensation for research-related injuries will be provided by Houston Methodist. You do not waive (give up) any legal rights by signing this informed consent form.

Please enter your specific consent form language regarding costs to participants to participate.
What is the cost of participating in this study? The sponsor/study will cover the cost of (specify types of research procedures / treatments that will not be charged to the participant. Ex., additional CT scans,
the device). The cost of the (ex. Surgery, hospital stay, usual care for your diagnosis and follow-up) will be your /your insurance company's responsibility. The study team will review a list of procedures with you that show which are standard of care and which are research only. Unless a procedure is listed as 'research' you should expect that you and/or your insurance company will be responsible for payment of items and services. You will be responsible for your normal co-payments and co-insurance/deductibles. If you have questions about the cost of participation, ask for more information before deciding to participate in the study.

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? Yes

What is the name of this component site? Methodist Hosp Rsch Inst d/b/a Houston Methodist

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 . None

Do you have another component site on your FWA? Yes

What is the name of this component site? Methodist Hlth Ctrs d/b/a Houston Methodist Sugar

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 . None

Do you have another component site on your FWA? Yes

What is the name of this component site? Methodist Hlth Ctrs d/b/a Houston Methodist Willowbrook Hospital, Houston TX

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 . None
<table>
<thead>
<tr>
<th>Do you have another component site on your FWA?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the name of this component site?</td>
<td>o San Jacinto Methodist Hospital d/b/a Houston Methodist San Jacinto Hospital, Baytown TX</td>
</tr>
<tr>
<td>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.</td>
<td>• None</td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>o Methodist Hlth Ctrs d/b/a Houston Methodist West Hospital, Houston TX</td>
</tr>
<tr>
<td>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.</td>
<td>• None</td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>o Houston Methodist St John Hospital Clear Lake TX</td>
</tr>
<tr>
<td>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.</td>
<td>• None</td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>o Houston Methodist St. Catherine Hospital, Katy TX</td>
</tr>
<tr>
<td>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.</td>
<td>• None</td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>o Houston Methodist The Woodlands Hospital, The Woodlands TX</td>
</tr>
<tr>
<td>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.</td>
<td>• None</td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>No</td>
</tr>
</tbody>
</table>

**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 a email is required to initiate the process. Followed by a local IRB application to provide information needed to approve reliance.
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  

Documentation of external IRB approval when available / before site initiation

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.

| Study-wide amendments (protocol or consent form modifications)  
| Local amendments (personnel modifications)  
| Continuing review  
| Serious or continuing non-compliance  
| Unanticipated problems  
| Final report |

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  
| Final report |

What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review?  

approval letter from Lead IRB + revised documents

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

approval letter from Lead IRB + revised documents

What should be submitted at continuing review?  

approval letter from Lead IRB + revised documents

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

We ask that the investigator to submit report of serious or continuing noncompliance concurrently with the report to the external IRB. This includes a description of the event.

What should be submitted for unanticipated problems?  

We ask that the investigator to submit report of UPIRSOs concurrently with the report to the external IRB. This includes a description of the event and investigators rational for UPIRSO determination.

What should be submitted for final reports?  

A copy of the external IRB closure.

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: Mary Clancy  
Email: mkclancy@houstonmethodist.org
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