Institutional Profile

Site Name: University of Texas Houston Health Science Center

Last modified date: 11/15/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

| Institution                                      | The University of Texas Health Science Center at Houston |
| Federalwide Assurance (FWA) #                   | FWA00000667                                              |
| FWA Expiration Date                             | 2022-10-12                                               |
| Does your institution have an internal IRB?     | Yes                                                      |
| IRB Registry Number(s)                          | IRB00000308 IRB00003763 IRB00004604 IRB00008445         |
| 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.     | Biomedical Research                                      |
| Is your institution a covered entity?           | Yes                                                      |

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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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

- TX

List other names by which your institution is known.  

UTHealth, UT-H, UTHSC-H

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. Pregnant minors are considered emancipated for the duration of their pregnancy. After birth, the minor retains the ability to make medical decisions for the child, but must have parental permission for research concerning themselves.

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?  

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

NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.

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

No

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

1) When the study has no provision for treatment: If you suffer an injury as a result of taking part in this research study please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, necessary facilities, emergency treatment and professional services will be available to you, just as they are to the general community. You should report any such injury to <insert PI name and phone number> and to the Committee for the Protection of Human Subjects at 713-500-7943. You will not give up any of your legal rights by signing this consent form. 2) When the study
is sponsor initiated, and there is a provision of
treatment (please note that this language is mandatory
for pharmaceutical company sponsored protocols): If
you suffer any injury as a result of taking part in this
research study the sponsor of this study, <insert
sponsor's name>, will pay for reasonable and
necessary medical expenses if the injury is a direct
result of taking the study medicine or undergoing
study procedures, and not due to the natural course of
any underlying disease or treatment process. You
should report any such injury to <insert PI name and
phone number> and to the Committee for the
Protection of Human Subjects at 713-500-7943. You
will not give up any of your legal rights by signing this
consent form.

| 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? | Memorial Hermann Health System |
| 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? | Harris Health System |
| 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 . | • Subject Injury Language |

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

In the event of injury resulting from this research, the University of Texas Health Science Center at Houston and/or the Harris County Hospital District (name of Hospital District facility or facilities) are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment and professional services will be available to you, just as they are to the general community. You should report any such injury to
<insert PI name and phone number> and to the Committee for the Protection of Human Subjects at 713-500-7943. You will not give up any of your legal rights by signing this consent form. When the study is sponsor initiated, and there is a provision of treatment (please note that this language is mandatory for pharmaceutical company sponsored protocols): If you suffer any injury as a result of taking part in this research study the sponsor of this study, <insert sponsor's name>, will pay for reasonable and necessary medical expenses if the injury is a direct result of taking the study medicine or undergoing study procedures, and not due to the natural course of any underlying disease or treatment process. You should report any such injury to <insert PI name and phone number> and to the Committee for the Protection of Human Subjects at 713-500-7943. You will not give up any of your legal rights by signing this consent form.

| Do you have another component site on your FWA? | Yes |
| What is the name of this component site? | Houston Health Department |
| 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? | City of Houston Fire Department |
| 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? | 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)?

The PI must submit an application for review with the protocol and lead site consent. The application has a section to indicate a request to rely on another IRB.

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
- Other

Please specify what other documents must be submitted

If at a component hospital, there is an additional hospital application to complete.

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?

approval letter from Lead IRB + revised documents

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

A report of what occurred and the corrective action plan.

What should be submitted for unanticipated problems?

A report of what occurred and the corrective action plan.

What should be submitted for final reports?

Study closure report.

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: Sujatha Sridhar
Email: Sujatha.Sridhar@uth.tmc.edu
Phone Number: (713) 500-3622

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