Institutional Profile

Site Name: Central Texas Neurology Consultants

Last modified date: 07/13/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>Central Texas Neurology Consultants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00026572</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-02-20</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>No internal IRB</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- TX
**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. Minors can consent to treatment by a physician or dentist when the minor is:
- On active duty with armed services.
- 16 years old or older and residing apart from parent, managing conservator or guardian and managing his or her own financial affairs.
- Unmarried and pregnant and consenting to treatment related to pregnancy other than abortion.
- Unmarried and the parent of a child and has actual custody of that child and consents for treatment of the child.
- Consenting to diagnosis or treatment of an infectious, contagious, or communicable disease that is reportable to the Texas Department of State Health Services.
- Consenting to examination or treatment for chemical addiction, dependency, or any other condition directly related to chemical use.
- Consenting for counseling for suicide prevention, chemical addiction or dependency, or for sexual, physical, or emotional abuse.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
<td>No</td>
</tr>
<tr>
<td>Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?</td>
<td>No</td>
</tr>
<tr>
<td>Does your site require a site-specific logo appear on consent forms and/or recruitment documents?</td>
<td>No</td>
</tr>
<tr>
<td>Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects?</td>
<td>No</td>
</tr>
<tr>
<td>Does the site have a posted policy for the following? <strong>NOTE:</strong> Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.</td>
<td>• We do not have a posted policy for any of these</td>
</tr>
<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 your specific consent form language regarding payment for research-related injury.</td>
<td>Central Texas Neurology Consultants does not offer any compensation for research-related injury.</td>
</tr>
</tbody>
</table>

**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
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)?

Our site does not have a local IRB.

**Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely?**

No

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.

- None--we do not require any submission when ceding review

**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: Lori Mayer, DNP
Email: lorimayerdnp@gmail.com
Phone Number: (512) 218-1222

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