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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>University of Tennessee Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA#00002254</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2020-07-31</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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 institutions subject?
### List other names by which your institution is known.

University Health System, Inc.

### 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.

A minor at age 16 can consent for behavioral health treatment.

### 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?

Yes

### Please describe how long you are required to keep your records.

Under Tennessee law, the patient medical record must be kept for ten years from the last professional contact with the patient. The medical record for minors must be kept for one year after they reach the age of majority or ten years after the last patient contact, whichever is longer.

### 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?

N/A

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

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment. You are not waiving any legal rights or releasing the University of Tennessee Medical Center or its agents from liability for negligence. In the event of physical injury resulting from research procedures the University of Tennessee Medical Center does not have funds budgeted for compensation either for lost wages or for medical treatment. In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this 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? 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)?

UTMC has no internal 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.

- 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?

Approval letter and 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 and revised documents

What should be submitted at continuing review?

Approval letter and revised documents

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

Details of non-compliance occurrences and resolution
<table>
<thead>
<tr>
<th>What should be submitted for unanticipated problems?</th>
<th>Details of unanticipated problems and resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>What should be submitted for serious adverse events?</td>
<td>Details of serious adverse events and resolution</td>
</tr>
<tr>
<td>What should be submitted for adverse events?</td>
<td>Details of adverse events and resolution</td>
</tr>
<tr>
<td>What should be submitted for final reports?</td>
<td>Enrollment, deviations, SAEs.</td>
</tr>
</tbody>
</table>

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?

<table>
<thead>
<tr>
<th>Name</th>
<th>Janet Parkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:jparkey@utmck.edu">jparkey@utmck.edu</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(865) 305-6194</td>
</tr>
</tbody>
</table>

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.

| Is your institution willing to serve as the IRB of Record for other institutions? | No |