Institutional Profile

Site Name: University of Tennessee Health Science Center

Last modified date: 09/16/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

<table>
<thead>
<tr>
<th>Institution</th>
<th>University of Tennessee Health Science Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00002301</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2022-12-03</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000070 IRB00000071 IRB00000072 IRB00000073</td>
</tr>
<tr>
<td>Is the IRB AAHRPP accredited?</td>
<td>No</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>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Biomedical Research</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- AR
- MS
- TN

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.

1. Minors who are parents. A minor may consent to the treatment of their own children TCA 63-6-229.
2. Contraceptives. Medically acceptable contraceptive procedures, supplies, and information shall be available to each person regardless of age. However, a physician can refuse to provide them for medical reasons. TCA 68-34-104.
3. Sterilization. A minor can consent to sterilization procedure if the minor is married TCA 68-34-108.
4. Juvenile drug users. A physician may treat a juvenile drug user without parental consent but may notify the juvenile's parent of such treatment TCA 63-6-220.
5. Emergency. If a physician has a reasonable medical belief that emergency treatment should not be delayed, such physician can treat the minor without parental consent if treatment is necessary to save the minor's life or prevent further deterioration of the condition. Such treatment shall be commenced only after a reasonable effort is made to notify the minor's parents or guardians if known or readily ascertainable TCA 63-6-222.
6. Prenatal and Peripartum Care. Physicians may provide prenatal care to minors without consent from the parents or legal guardian (including pregnancy testing) and physicians may provide peripartum care, including peripartum analgesia, examine, diagnose and treat a minor without consent of the parents or legal guardian. TCA 63-6-223.
7. Sexually transmitted diseases. Physicians may examine, diagnose, and treat minors with a STD including HIV without the consent or knowledge of the parent. TCA 68-10-104.
8. Emancipated minor. An emancipated minor is defined under Tennessee law as either a minor who is married or who has received a court order freeing the minor from the care, custody, and control of the minor's parent(s) or legal guardian(s). TCA 37-10-302. Definitive proof of a minor's emancipation is a court order or valid proof of the minor's marriage.
9. Mature minor exception. In the absence of appropriate parental consent,
Tennessee courts will look to “the age, ability, experience, education, training, and degree of maturity or judgment obtained by the minor, as well as the conduct and demeanor of the minor at the time.” Cardwell v. Bechtol, 724 S.W.2d 739 (Tenn. 1987). The physician may use the "Rule of Sevens" to determine that a minor patient is a mature minor: • Under age 7 - no capacity for minor to consent to care • Age 7-14 - rebuttable presumption of no capacity to consent to care • Age 14+ - rebuttable presumption minor has capacity to consent 10. Mental Health. A child with serious emotional disturbance or mental illness who is 16 years of age or older has the same rights as an adult with respect to outpatient and inpatient mental health treatment, medication decisions, confidential information and participation in conflict resolution procedures TCA 33-8-202

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?

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

Do 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.

COMPENSATION AND TREATMENT FOR INJURY: [All studies utilizing a main consent form MUST include the statements in this section, even if you believe there is no potential for a physical or non-physical injury. If sponsors have different liability or reimbursement language, this can be added after all of UTHSC’s required liability language and can be separated by sub-headers if preferable (e.g., “UTHSC’s statements”; “Sponsor X’s statements”.) [Choose one of the following 8 paragraphs; however, if you are conducting your research at several of the
sites/organizations mentioned below, you must name all of them in each of the 3 sentences of the template paragraph, using only one paragraph. This language should NOT be edited.] You are not waiving any legal rights or releasing the University of Tennessee or its agents from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee does not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee does not provide for treatment or reimbursement for such injuries. [OR when Regional One Health is involved] You are not waiving any legal rights or releasing the University of Tennessee, Regional One Health, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Regional One Health do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and Regional One Health do not provide for treatment or reimbursement for such injuries. [OR when both Methodist & Le Bonheur are involved] You are not waiving any legal rights or releasing the University of Tennessee, Methodist Le Bonheur Healthcare, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Methodist Le Bonheur Healthcare do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and Methodist Le Bonheur Healthcare do not provide for treatment or reimbursement for such injuries. [OR when Methodist hospitals are involved] You are not waiving any legal rights or releasing the University of Tennessee, Methodist Healthcare-Memphis Hospitals, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Methodist Healthcare-Memphis Hospitals do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and Methodist Healthcare-Memphis Hospitals do not provide for treatment or reimbursement for such injuries. [OR when Le Bonheur is involved] You are not waiving any legal rights or releasing the University of Tennessee, Le Bonheur Children's Hospital, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Le Bonheur Children's Hospital do not have funds budgeted for compensation for medical treatment.
Therefore, the University of Tennessee and Le Bonheur Children’s Hospital do not provide for treatment or reimbursement for such injuries. [OR when University Clinical Health is involved] You are not waiving any legal rights or releasing the University of Tennessee, University Clinical Health, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and University Clinical Health do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and University Clinical Health do not provide for treatment or reimbursement for such injuries. [OR when UT Regional One Physicians is involved] You are not waiving any legal rights or releasing the University of Tennessee, UT Regional One Physicians, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and UT Regional One Physicians do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and UT Regional One Physicians do not provide for treatment or reimbursement for such injuries. [OR when UT Le Bonheur Pediatric Specialists, Inc. is involved] You are not waiving any legal rights or releasing the University of Tennessee, UT Le Bonheur Pediatric Specialists, Inc., or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and UT Le Bonheur Pediatric Specialists, Inc. do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and UT Le Bonheur Pediatric Specialists, Inc. do not provide for treatment or reimbursement for such injuries. [Edit the 2nd statement to indicate whether the study doctor will provide the medical treatment to subjects in case of a research related injury, provide acute treatment and refer, or just provide a referral. For example:] If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide acute medical treatment, and will provide you with a subsequent referral to appropriate health care facilities. [For all studies, include the following sentence. This language should NOT be edited:] If you are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment. [For all studies, include the following sentence. This language should NOT be edited:] No compensation will be
available to you for any extra expenses that you may have as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc. [For all studies, include the following sentence. This language should NOT be edited.] No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation. [In addition to the UTHSC statements above, if the sponsor may reimburse part or all of these costs associated with the treatment of a research related injury, indicate this and any exceptions/limitations. (You may use a separate sub-header above the sponsor statements if preferable.) For example:] If you have followed the instructions of the study doctor, [name of the sponsor] will reimburse you, your insurance company, and/or the hospital for any costs related to a research injury.

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

[Explain whether there are any costs to the subject or his/her parent/legal guardian or his/her legally authorized representative. If there are, explain whether insurance will be billed and who will pay if insurance does not.] There are no costs to you for participating in this study. [If applicable, include the following statements:] [Sponsor Name] will provide the study [drug/device] free of charge during this study. Tests and procedures that are done only for research purposes will not be billed to you or your insurance company. [OR] You or your insurance company may be billed for: • [list costs as necessary] [If some or all of the costs associated with procedures being performed for research purposes only will be billed to insurance, add:] You may want to talk with your insurance company about its payment policy for medical care or procedures performed as part of a research study. If your insurance company does not pay, you may be billed for those charges.

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.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have a component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>Boling Center for Developmental Disabilities</td>
</tr>
<tr>
<td>Please indicate which questions you will answer about this component.</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 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
• Local consent form(s)

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
• 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 and revised study 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?

Update application in IRB electronic system, and if appropriate, approval letter from Lead IRB and revised study documents

What should be submitted at continuing review?

Approval letter from Lead IRB and re-approval of
consent form

<table>
<thead>
<tr>
<th>What should be submitted for serious or continuing non-compliance?</th>
<th>A report of what occurred and a corrective action plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>What should be submitted for unanticipated problems?</td>
<td>A report of what occurred and a corrective action plan (if appropriate)</td>
</tr>
<tr>
<td>What should be submitted for final reports?</td>
<td>Study closure report</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?

Name: Cameron Barclay
Email: cbarclay@uthsc.edu
Phone Number: (901) 448-4824

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