Institutional Profile

Site Name: University of Vermont and State Agricultural College

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

<table>
<thead>
<tr>
<th>Institution</th>
<th>University of Vermont and State Agricultural College</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00000723</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2021-06-29</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>00000485</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>We have a diverse set of experience that covers across multiple disease conditions.</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</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)
To what state laws is your institution subject?

- VT

List other names by which your institution is known.

- U of Vermont & State Agricultural College
- U of Vermont
- University of Vermont
- UVM

Age of majority in your state?

18

What circumstances affect the age of consent in your state? For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment.

No state law in this regard.

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?

Yes, I will insert language in text box

Please insert the language required to be used around mandatory reporting to health authorities.

There is one exception to confidentiality that you should know about. By law, it is our responsibility to report to the appropriate authority suspicion of harm to children or to others. If appropriate add: However, we are not seeking this type of information in our study nor will you be asked questions about these issues.

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

If you are injured or become ill as a result of being in this research, The University of Vermont Health Network Affiliate hospital where you are enrolled in this research, will provide reasonable and usual medical care for that injury or illness. There will be no
cost to you if the conditions listed below apply to your injury or illness. These conditions are: 1. The investigator, in consultation with the study sponsor, determines that your injury or illness results from the research and not from your underlying condition or its usual treatment. 2. You let the investigator know about the injury or illness when you first notice it; and 3. You follow medical advice about proper treatment options for the injury or illness. If the above conditions are not met, The University of Vermont Health Network Affiliate hospital where you are seeking care, may claim payments for your medical treatment directly from the study sponsor or your insurance company when these payments are allowed. If we bill your insurance for this care, you will be responsible for any associated co-payments or deductibles. For an injury or illness that results from being in this study, The University of Vermont Health Network affiliate hospital where you are receiving care will not offer you any other payments, such as lost wages or expenses, except for your medical care. Even though you may receive medical care at no cost to you under certain conditions if you are in this study, The University of Vermont Health Network affiliate hospital and the University of Vermont do not admit to any responsibility for an injury or illness that results from being in the study. If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

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

If drugs are provided free of charge, state that if the drug becomes commercially available subjects may have to pay for it. This typically would occur in a pharmaceutical sponsored study. Clarify that standard testing/treatment will be billed to subjects or their insurance and not all expenses may be covered by their insurance, which would leave them responsible for payment.

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
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)?


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

List of key personnel, sponsor provided consent template, data management and security plan (UVM specific form), any required reliance agreements.

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
- Serious adverse events
- Other

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

PI or proxy must submit a Modification in the electronic system.

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

PI must submit Reportable New Information in the electronic system.

What should be submitted for unanticipated problems?

PI must submit Reportable New Information in the electronic system.

What should be submitted for serious adverse events?

PI must submit Reportable New Information in the electronic system.

What else should be submitted to your HRPP when ceding review?

PI must submit documentation of protocol closure. The sponsor’s correspondence in this regard is sufficient.
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>Donna Silver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:Donna.Silver@uvm.edu">Donna.Silver@uvm.edu</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(802) 656-5040</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.

No