Institutional Profile

Site Name: University of Nebraska Medical Center

Last modified date: 09/21/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>University of Nebraska Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA#00002939</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-06-27</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000670 IRB00000671 IRB00002686 IRB00007222</td>
</tr>
<tr>
<td>Is the IRB AAHRPP accredited?</td>
<td>Yes</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>It depends</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>IRB00000670 and 00000671 are adult IRBs IRB00007222 is a pediatric IRB IRB00002686 is a rapid response 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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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 institutions subject?

<table>
<thead>
<tr>
<th>State</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>NE</td>
<td></td>
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</tbody>
</table>

Age of majority in your state?

19

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. If the subject is Native American living on federal tribal lands federal law sets the age of majority at age 18. In the state of Nebraska, children who are ward of state can be included in research only if the Ward would receive direct treatment or therapy that might benefit him/her and Nebraska DHHS allows an exception to policy (390 NAC 11-002.04K)

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.

University of Nebraska requires all records be maintained for 7 years.

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
- Use of short 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 any special formatting your IRB requires for HIPAA authorization forms?

none

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

For Minimal Risk Research: “Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem or some other kind of problem as a direct result of being in this study, you should immediately contact one of the
people listed at the end of this consent form." For greater than Minimal Risk Research (not commercially sponsored): "Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form. Emergency medical treatment for this injury or problem will be available at the Nebraska Medical Center. If there is not sufficient time, you should seek care from a local health care provider. The Institution has no plans to pay for any required treatment or provide other compensation. If you have insurance, your insurance company may or may not pay the costs of medical treatment. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay for the medical treatment. Agreeing to this does not mean you have given up any of your legal rights." For Greater than Minimal Risk Research (Commercially sponsored): "Your welfare is the main concern of every member of the research team. If you are injured or have a medical problem as a direct result of being in this study, you should immediately contact one of the people listed at the end of this consent form. Emergency medical treatment for this injury or problem will be available at The Nebraska Medical Center. If there is not sufficient time, you should seek care from a local health care provider." [Insert the commercial sponsor language] "The Institution has no plans to pay for any required treatment or provide other compensation. Agreeing to this does not mean you have given up any of your legal rights."

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

In addition to a description of the financial obligations the subject will incur as a result of participating in the study and whether financial obligations will be increased as a result of procedures conducted solely for research - add the following for clinical trials...
"You will be responsible for any applicable insurance deductibles and co-payments. If you wish to speak with a financial counselor about your insurance coverage and benefits, let the investigator or other study personnel know. A contact for personal assistance will be made available for you." Alternately if there are no financial obligations to the subject then use: "There is no cost to you to be in this research study."

Please upload your template HIPAA Authorization language.
Do you have any additional HIPAA Authorization language template documents?  

| 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? | Children’s Hospital & Medical Center |
| 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? | University of Nebraska at Omaha |
| 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 |

**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 investigator must submit a request to utilize the Central IRB through our online system. With this request the investigator must also upload all documents associated with the study. If there are any questions the investigator is directed to call our office. |

| 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)  
Study contract  
Other |

| Please specify what other documents must be submitted | As applicable: Pharmacy & Therapeutics Committee Drug Registry application Clinical Trial Master Matrix Coverage Analysis IT security approval for maintaining |
social security number (for compensation/reimbursement) Recruitment

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.

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

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.

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: Bruce Gordon MD
Email: bgordon@unmc.edu
Phone Number: (402) 559-6045

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.

Yes

No