Institutional Profile

Site Name: University of Wisconsin - Madison

Last modified date: 12/05/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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 Wisconsin - Madison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00005399</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2022-08-15</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</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>The HS-IRB and MR-IRB review all human subject research protocols in accordance with applicable federal regulations, state laws, and local and university policies.</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- WI

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 NA

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.

- Sexually Transmitted/Communicable Disease testing
  Text to include when reporting is required: This study requires testing that may show you have [specify reportable disease or condition]. If the test indicates you have [disease or condition requiring reporting], we will inform you of the results of the test by [describe process for reporting results]. The results will also be placed in your medical record and reported to state or federal health officials as required by law. We can provide you with a list of resources to assist you in understanding the results. • Protocol Specifically Tests For HIV, Hepatitis B and C
  Additional text to include if the study involves HIV testing performed in Wisconsin: If you test positive for human immunodeficiency virus (HIV), the Wisconsin health department will be informed of the results. The health department may contact you to help with counseling, medical care and other services, if you need them and want them. You may be asked about sex and/or needle-sharing partners and you may be offered help notifying your partners about your positive HIV test. These are all common practices of the health department and apply to all individuals who test positive for HIV. Additional text to include if the study involves Hepatitis C virus (HCV) testing performed in Wisconsin: If you test positive for Hepatitis C virus (HCV), the Wisconsin health department will be informed of the results. The health department may contact you with resources for counseling and medical care, if you need them and want them. You may be asked about sex and/or needle-
sharing partners. These are all common practices of the health department and apply to all individuals who test positive for HCV. • Illegal Substance Use or Illegal Activities This study involves [testing for / asking questions about] illegal [substances / activities (e.g., abusive behavior, driving drunk, drug use). There is a chance that someone outside of the study could find out about the [results of the testing / answers to your questions]. If that happens, this could expose you to legal risks or damage your reputation. We will try to keep others from getting this information by [briefly describe confidentiality protections]. For studies conducted in Wisconsin that include people who could become pregnant and involve asking questions about illicit drug use or alcohol abuse, or performing toxicology tests to obtain this information, add the following: Pregnant women who abuse illegal drugs or alcohol may be reported by members of the research team to county social services under Wisconsin state law. Although this rarely happens, pregnant women found abusing drugs or alcohol to a severe degree may be placed in custody to protect the fetus. The decision to place someone in custody is made by county social services.

| 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. | • Consent Process for those with Impaired Decision-Making Capacity • Use of short 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. | COMPENSATION FOR INJURY • Please determine whether or not the sponsor will pay for research-related injuries and choose the appropriate language from the template below. What happens if I am injured or get sick because of this study? For minimal risk studies, add: Being injured during this research is very unlikely. However, accidents can happen. For all studies, include: If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people. • If it is an emergency, call 911 right away or go to the emergency room. • For non-emergency medical |
problems, [specify what subjects should do, e.g. contact the study team for instructions, contact your regular health care provider]. • Call the Lead Researcher, [name], at [phone number] to report your sickness or injury. Here are some things you need to know if you get sick or are injured because of this research: • If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs. • Your health insurance company may or may not pay for this care. • No other compensation (such as lost wages or damages) is usually available. • UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study. • By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study. For studies with an industry sponsor, add the following if the sponsor has a compensation policy: [Company X], the sponsor of this study, has a policy to pay for certain treatment costs for sickness or injury that is related to the research. [You can ask the research team for a statement of the company's policy. OR, if sponsor requires specific language about its compensation policy: The paragraph below describes [Company X]'s payment policy.] Insert language from sponsor • If you have any questions concerning [Company X]'s payment policy, the research team can help you get in touch with [Company X]. • The [University, UW Health] and our researchers have no part in [Company X]'s payment program and do not guarantee any payment by the sponsor. • Important: If the sponsor has language in their compensation for injury section that states they will only pay if a subject's insurance does not pay, include the following: If UW-Madison or UW Health determine that it would not be legal to bill your insurance for costs of your medical care or if your insurer will not cover the costs of your medical care, then those costs will be billed to the sponsor and paid as described in the sponsor's payment policy above.

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)?

https://kb.wisc.edu/hsirbs/page.php?id=17759

**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

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?**

- Serious or continuing non-compliance
- Unanticipated problems
- Final report
- Other

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

Potential unanticipated problems, subject injuries, significant subject complaints, or noncompliance that occur at UW-Madison or UW Health sites may need to be reported to the Health Sciences IRBs in addition to the reviewing IRB. Study teams should contact the HS-IRBs' Reliance Team for guidance when such an event occurs.

**What should be submitted for unanticipated problems?**

Potential unanticipated problems, subject injuries, significant subject complaints, or noncompliance that occur at UW-Madison or UW Health sites may need to be reported to the Health Sciences IRBs in addition to the reviewing IRB. Study teams should contact the HS-IRBs' Reliance Team for guidance when such an event occurs.
What should be submitted for final reports?
Submit closure report when study has been completed.

What else should be submitted to your HRPP when ceding review?
Changes in key personnel.

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  
Mike Bingham

Email  
irbreliance@wisc.edu

Phone Number  
(608) 265-9792

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**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