Institutional Profile

Site Name: Medical College of Wisconsin

Last modified date: 07/16/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

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Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>Medical College of Wisconsin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA#00000820</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2021-02-24</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>MCW/FH IRB #1 IRB00001395 MCW/FH IRB #2 IRB00001396</td>
</tr>
<tr>
<td></td>
<td>IRB00001564</td>
</tr>
<tr>
<td></td>
<td>MCW/FH IRB #4 IRB00000078 MCW/FH IRB #5 IRB00006380</td>
</tr>
<tr>
<td></td>
<td>IRB00011716</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>Yes</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).

<table>
<thead>
<tr>
<th>To what state laws is your institution subject?</th>
<th>• WI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age of majority in your state?</td>
<td>18</td>
</tr>
<tr>
<td>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</td>
<td>Per MCW General Counsel Local Context document: Age of Majority in Wisconsin Chap. 990, §990.01(3), (20) Age of Majority 18 (§990.01(3)) Emancipation By marriage unless incompetent (880.04(1))</td>
</tr>
<tr>
<td>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?</td>
<td>Yes</td>
</tr>
<tr>
<td>Please describe how long you are required to keep your records.</td>
<td>MCW Policy - 10 years</td>
</tr>
<tr>
<td>Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?</td>
<td>Yes, I will insert language in text box</td>
</tr>
<tr>
<td>Please insert the language required to be used around mandatory reporting to health authorities.</td>
<td>The following language is not pertinent to the COVET study. For studies that involve Blood Center of Wisconsin, Summary of Procedures: Include the following if research involves infectious disease testing, donating a unit of blood in any BloodCenter donor room, or undergoing apheresis. As part of the procedure for donating a unit of blood, your blood will be tested for diseases that can be passed on to other people by transfusion, including AIDS (the disease caused by the HIV virus), syphilis, hepatitis B, hepatitis C and others. If certain tests are positive, BloodCenter of Wisconsin/we will/may inform you, put your name on a list of ineligible donors, and inform certain government health agencies as required by law. Results of your blood test will be released only to authorized persons as governed by Wisconsin law. A list of persons to be notified and reasons that will cause release of your blood test is available upon request. Results of the blood test will be released to BloodCenter physicians and their assistants/ &lt;&lt;insert appropriate parties&gt;&gt;. Abnormal test results of active military personnel will be forwarded to the military medical authority of the base to which you are assigned, as required by the Department of Defense. Include the following if research involves genetic</td>
</tr>
</tbody>
</table>
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
- 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 any special formatting your IRB requires for HIPAA authorization forms?

Consent form templates available here - https://www.mcw.edu/HRPP/Forms/Consent-Form-Templates.htm MCW requires all of E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION i.e. HIPAA

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

Consent form templates available here - https://www.mcw.edu/HRPP/Forms/Consent-Form-Templates.htm MCW requires all of D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE STUDY? , exactly as in the MCW ICF template

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

Consent form templates available here - https://www.mcw.edu/HRPP/Forms/Consent-Form-Templates.htm; MCW requires the last paragraph of section D1 to be included in Costs.

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)?

Submit a Reliance Request Form, protocol/narrative, consent form, status of OCRICC discussions, status of safety committee reviews, signed PI attestation, confirmation of CITI training, and a copy of the PI's CITI certificate to MCWIRBReliance@mcw.edu

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)
- Other

Please specify what other documents must be submitted

PI Attestation for Ceded Review & Projects Form CITI training confirmation & CITI certificate from PI Safety Committee Review status as necessary Status of OCRICC review

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.

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

What should be submitted for serious or continuing non-compliance? Email notification to MCW IRB Office.

What should be submitted for unanticipated problems? Email notification to MCW IRB Office.

What should be submitted for final reports? Confirmation of final report.

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

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: Beth McDonough
Email: MCWIRBReliance@mcw.edu
Phone Number: (414) 955-4585

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