Institutional Profile

Site Name: University of Massachusetts Medical School

Last modified date: 04/26/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

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Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>University of Massachusetts Medical School, Worcester</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00004009</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2021-08-08</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000269 IRB00000270</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>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>The Committees include a wide range of medical expertise (e.g., adult and pediatric oncology, pediatrics, surgery, nursing, pharmacology, cardiology, rheumatology, emergency medicine, psychology). Each Committee has the appropriate expertise for vulnerable populations, including prisoners, pregnant women, children, economically disadvantaged, etc.</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</td>
</tr>
<tr>
<td>Additional Comments</td>
<td>UMMS is not specifically identified as a hybrid. That</td>
</tr>
</tbody>
</table>
said, while UMMS is not a covered entity, our clinical partners are. Any research that is conducted in a clinical setting is treated as though it is subject to HIPAA.

**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?

- MA

<table>
<thead>
<tr>
<th>Age of majority in your state?</th>
<th>18</th>
</tr>
</thead>
<tbody>
<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>[Link](<a href="https://www.umassmed.edu/globalassets/ccts/ccts-med">https://www.umassmed.edu/globalassets/ccts/ccts-med</a> ia/irb/updated-policies-2015/hrp-021-policy---legally-authorized-representatives-children-and-guardians.umass.pdf)</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>No</td>
</tr>
<tr>
<td>Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?</td>
<td>No</td>
</tr>
<tr>
<td>Does your site require a site-specific logo appear on consent forms and/or recruitment documents?</td>
<td>No</td>
</tr>
<tr>
<td>Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects?</td>
<td>Yes</td>
</tr>
</tbody>
</table>
| 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 any special formatting your IRB requires for HIPAA authorization forms? | We do not require special formatting and permit a compound consent and authorization. We have uploaded an additional HIPAA authorization template |
in the event a stand-alone authorization is required.

| Please enter your specific consent form language regarding payment for research-related injury. | See attached template with language for industry-sponsored and non-industry sponsored studies |
| Please enter your specific consent form language regarding costs to participants to participate. | None |
| Please upload your template HIPAA Authorization language. | |
| Do you have any additional HIPAA Authorization language template documents? | Yes |
| Please upload additional template HIPAA Authorization language documents | |

**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.**

<p>| Do you have a component site on your FWA? | Yes |
| What is the name of this component site? | Shriver Ctr |
| 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? | Marlborough Hosp |
| 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? | Clinton Hosp |
| 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? | New England Newborn Screening |
| 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 |</p>
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td></td>
</tr>
<tr>
<td>Hahnemann Campus</td>
<td></td>
</tr>
<tr>
<td>Please indicate which questions you will answer about this component.</td>
<td>• None</td>
</tr>
<tr>
<td>Please only include those questions for which this component's answers differ from those for the FWA-holding site.</td>
<td></td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>HealthAlliance</td>
</tr>
<tr>
<td>Please indicate which questions you will answer about this component.</td>
<td>• None</td>
</tr>
<tr>
<td>Please only include those questions for which this component's answers differ from those for the FWA-holding site.</td>
<td></td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>UMass Memorial Medical Center: University Campus &amp; Memorial Campus</td>
</tr>
<tr>
<td>Please indicate which questions you will answer about this component.</td>
<td>• None</td>
</tr>
<tr>
<td>Please only include those questions for which this component's answers differ from those for the FWA-holding site.</td>
<td></td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>Meyers Primary Care</td>
</tr>
<tr>
<td>Please indicate which questions you will answer about this component.</td>
<td>• None</td>
</tr>
<tr>
<td>Please only include those questions for which this component's answers differ from those for the FWA-holding site.</td>
<td></td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>Community Healthlink</td>
</tr>
<tr>
<td>Please indicate which questions you will answer about this component.</td>
<td>• None</td>
</tr>
<tr>
<td>Please only include those questions for which this component's answers differ from those for the FWA-holding site.</td>
<td></td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>MassBiologics</td>
</tr>
<tr>
<td>Please indicate which questions you will answer about this component.</td>
<td>• None</td>
</tr>
<tr>
<td>Please only include those questions for which this component's answers differ from those for the FWA-holding site.</td>
<td></td>
</tr>
<tr>
<td>Do you have another component site on your FWA?</td>
<td>Yes</td>
</tr>
<tr>
<td>What is the name of this component site?</td>
<td>Simon-Sinon Regional Cancer Center</td>
</tr>
<tr>
<td>Please indicate which questions you will answer about this component.</td>
<td>• None</td>
</tr>
<tr>
<td>Please only include those questions for which this component's answers differ from those for the FWA-holding site.</td>
<td></td>
</tr>
</tbody>
</table>
Do you have another 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)?

email irb@umassmed.edu; include a copy of the protocol, a brief description of how UMMS personnel are involved, and if available, a copy of the consent form

Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely?  
No

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
- Other

What should be submitted for serious or continuing non-compliance?  
Email notification with information provided to Reviewing IRB

What should be submitted for unanticipated problems?  
Email notification with information provided to Reviewing IRB

What else should be submitted to your HRPP when ceding review?  
Running list of local personnel via HRP-270 form available here (https://www.umassmed.edu/ccts/irb/submission/western-irb-wirb/)

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  
Allison Blodgett, PhD, CIP

Email  
allison.blodgett@umassmed.edu

Phone Number  
(508) 856-4271

**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?** | **Yes** |
| **STANDARD OPERATING PROCEDURES ("SOPs")** | **Using SMART IRB SOPs (recommended)** |
| **HIPAA DETERMINATIONS AND ACTIONS** | If one or more Relying Institution(s) are HIPAA Covered Entities, Reviewing IRB will make certain HIPAA determinations and perform certain HIPAA actions required for Relying Institution(s) to use/disclose PHI (as specified below, if applicable). |
| **HIPAA AUTHORIZATION LANGUAGE AND CONSENT FORMS** | Reviewing IRB requires HIPAA authorization language to be incorporated into the informed consent documents, unless the Relying Institution obtains agreement from the Reviewing IRB to use a separate authorization form (e.g., separate form is required by State law or institutional policy). If the Relying Institution requires a separate authorization form, the Relying Institution shall be responsible for ensuring the separate form complies with applicable requirements in the HIPAA Privacy Rule). |
| **CONFLICTS OF INTEREST** | Relying Institution(s) will perform conflict of interest analyses under their policies |
| **IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)** | Reviewing IRB will provide notifications through another party |
| **NAME OF NOTIFYING PARTY** | Principal Investigator |
| **IRB-INITIATED AUDITS/INVESTIGATIONS** | Relying Institution(s) will conduct any IRB-initiated audits or investigations |
| **IRB-INITIATED EXTERNAL REPORTING** | Reviewing IRB and Relying Institution(s) will jointly draft and submit reports to external parties |
| **CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS** | Reviewing IRB will review congruence |
| **FINANCIAL AGREEMENTS [For review costs - indemnification agreements are addressed separately below]** | Reviewing IRB/Institution will not charge Relying Institution(s) for costs of review: The Relying Institution(s) will not be responsible for financial support of the costs of review of the identified study(ies). The Reviewing IRB may charge the sponsor or other third parties for those costs. |
| **QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM("QA/QI")** | QA/QI program access required Each Participating Institution engaged in or conducting the identified study(ies) must have or have access to a human subjects research QA/QI program or service (or an
alternate means of monitoring) that can conduct and report to that institution the results of for-cause and not-for-cause audits of the institution's and its Research Personnel's compliance with human subjects protections and other relevant requirements.

**INSURANCE**

Insurance required: Each Participating Institution must maintain insurance coverage of sufficient type(s) and in reasonable amount(s) to cover its activities with respect to the identified study(ies), including coverage of its IRB/IRB members when acting as a Reviewing IRB. (State/federal agencies or instrumentalities of state/federal government may provide documentation of self-funded liability coverage or of reliance on applicable law providing immunity from or limiting liability.) Note: Participating Institutions may request from one another an insurance certificate or equivalent documentation of the relevant coverage (including any sponsor-provided coverage).

**INDEMNIFICATION**

Indemnification agreements not required: Indemnification agreements or other contractual arrangements for allocation of liability are not required with respect to the identified study(ies).