Institutional Profile

Site Name: Dartmouth-Hitchcock Clinic

Last modified date: 10/22/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Dartmouth-Hitchcock Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00027371</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-11-10</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00012031</td>
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<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>It depends</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>
<tr>
<td>Additional Comments</td>
<td>N/A</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provided in the IP will be superseded by information provided by the relying site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 institution subject?

- NH

| List other names by which your institution is known. | Mary Hitchcock Memorial Clinic |
| 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 | N/A |
| 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? | 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? 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? | HIPAA authorization should be included in consent forms. |
| Please enter your specific consent form language regarding payment for research-related injury. | Local Information: If you are injured or become ill as a result of research procedures, you will be provided with medical treatment but the following organizations do not plan to pay for this treatment. • Mary Hitchcock Memorial Hospital • Dartmouth-Hitchcock Clinic • Dartmouth-Hitchcock Medical Center • Trustees of Dartmouth College • Federal funding agency If you have any questions or concerns about the legal responsibility of these organizations, please call the Mary Hitchcock Memorial Hospital Office of Risk Management at (603) 653-1250 during normal business hours. 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. If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. [Insert the name of the institution] has no program to pay for medical care for research-related injury. [Describe any compensation available for research related injury.]

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

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 the site and what differs below.
### 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 PI must first submit a request to rely in the D-HH eIRB system. They will receive an Acknowledgement of the request to rely and be required to submit approval from the external IRB upon receipt.

**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:

- HRP-815 - Institutional Profile, which requests information from the IRB/HRPP staff regarding the HRPP or IRB (e.g., FWA, local context information, communication plan, etc.).

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.

- Study-wide amendments (protocol or consent form modifications)
- Local amendments (personnel modifications)
- Continuing review
- Serious or continuing non-compliance
- Unanticipated problems
- Final report

What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review?

All documents reviewed and approved by the external IRB and a copy of the external IRB’s approval letter.

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

Any local amendments that impact local context review should be submitted to the local IRB for review. Personnel mods should include financial interest disclosure and allow the IRB to confirm satisfaction of local training requirements.

What should be submitted at continuing review?

All local data submitted to the external IRB along with the external IRB's approval letter.
What should be submitted for serious or continuing non-compliance?
The reported event along with the external IRB's determination letter.

What should be submitted for unanticipated problems?
The reported event along with the external IRB's determination letter.

What should be submitted for final reports?
All information reported to the external IRB along with the external IRB's determination/acknowledgement letter.

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: Candi Loeb
Email: candice.m.loeb@hitchcock.org
Phone Number: (603) 650-1846

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

STANDARD OPERATING PROCEDURES ("SOPs")
Using SMART IRB SOPs (recommended)

HIPAA DETERMinations and ACTIONS
If one or more Relying Institution(s) are HIPAA Covered Entities, Relying Institution(s) will make any HIPAA determinations or perform any HIPAA actions.

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 | Reviewing IRB notifies the D-HH PI. The lead PI is responsible for notifying pSite PI's. |
| IRB-INITIATED AUDITS/INVESTIGATIONS | Plan for conduct of IRB-initiated audits or investigations will be determined on a case-by-case basis |
| IRB-INITIATED EXTERNAL REPORTING | Plan for drafting and submission of IRB-initiated external reports will be determined on a case-by-case basis |
| CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS | Another party will review congruence |
| NAME OF PARTY THAT WILL BE RESPONSIBLE FOR REVIEW | Under the revised common rule there is no longer a mandate for IRB's to conduct grant/protocol 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 | One or more Participating Institutions require an indemnification agreement: The Reviewing IRB and... |
Relying Institution will enter a separate indemnification agreement or agreements or other contractual arrangements for allocation of liability among them with respect to the identified study(ies): The executed separate indemnification agreement(s) will be maintained on file with the Reviewing IRB.