Institutional Profile

Site Name: New York University School of Medicine
Last modified date: 02/14/2020

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>New York University School of Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00004952</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2022-03-01</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00001015 IRB00001162 IRB00006676 IRB00008507 IRB00008043</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>Cancer, pediatrics, dentistry, nursing, population health,</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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 institution subject?

- NY

List other names by which your institution is known.

NYU Langone Health System

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

1) Individual who is a parent of a child, 2) All individuals under 18 years of age, if the research procedures are limited to: o HIV testing, counseling, and treatment o Outpatient mental health services o Testing or treatment for sexually transmitted diseases o Treatment or rehabilitation for alcohol or drug dependence o Abortion counseling and treatment 3) All individuals between 16 and 18 years of age, if the research procedures are limited to inpatient mental health services.

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.

The Principal Investigator and other researchers must ensure that all Research Data is maintained in accordance with NYU Langone Policy for the longer of (i) three (3) years after the final project close-out or (ii) six (6) years after any reporting, publication, presentation, or use in any grant application by the researcher of such Research Data, or self-citation of the same in such manner that may be of benefit to such researcher, except as follows: 1. Research Data arising out of sponsored research must be retained for the time period specified in an applicable Sponsored Research Agreement; 2. Research Data relating to projects subject to the review of the Institutional Review Board (IRB) must be retained until five (5) years after the completion of the project; 3. Research Data that incorporates Protected Health Information (PHI) or other pertinent human subject information (e.g., medical records, protocols, case history forms, progress reports and final reports) must be retained for the period mandated by New York State law (six years from date of discharge or three years after the patient's age of majority (18 years), whichever is longer, or at least six years after death); 4. Research Data relating to clinical trials involving an
investigational drug or device must be retained until two (2) years following the date the applicable FDA marketing application is approved or, where the investigation is discontinued, two years from the date that the FDA is notified that no marketing application will be filed; and 5. Research Data relating to a student project must be retained at least until the degree is granted or it is clear that the student has abandoned the work.

<table>
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<th>Question</th>
<th>Answer</th>
</tr>
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<tbody>
<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>Yes</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  
• 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 your specific consent form language regarding payment for research-related injury. | Compensation for Injury: [Add the following paragraph as the first paragraph of this section:] For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form. [Insert sponsor's language here.] [Add the following paragraph as the last paragraph of this section:] There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form. |
| 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

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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.

<table>
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<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have a component site on your FWA?</td>
<td>No</td>
</tr>
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</table>

**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)?
  - They should submit a study in Research Navigator (our electronic human research management system) indicating they will use an external IRB. See also: [https://med.nyu.edu/research/office-science-research/clinical-research/resources-researchers-study-teams/human-research-regulatory-affairs/external-institutional-review-boards](https://med.nyu.edu/research/office-science-research/clinical-research/resources-researchers-study-teams/human-research-regulatory-affairs/external-institutional-review-boards)

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.

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

After your HRPP has provided local reviews to the SIRB, does your IRB or HRPP require a submission of your site’s SIRB approved documents before your site is activated/enrollment can begin?

- **Yes**

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?

- Protocol and consent form modifications

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

- personnel modifications, local site modifications

What should be submitted at continuing review?

- financial disclosures, continuing review approval letter.
What should be submitted for serious or continuing non-compliance?
all related information

What should be submitted for unanticipated problems?
copy of the sIRB determination letter and regulatory reporting confirmation.

What should be submitted for final reports?
copy of the 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
Ikoa Jeschke Lopez

Email
irb-external@nyulangone.org

Phone Number
(646) 754-7412

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 other SOPs (not otherwise mandated)

NAME OR DESCRIPTION OF ALTERNATIVE SOPs
Contact SIRB

WHERE CAN PARTICIPATING INSTITUTIONS ACCESS THE SOPs
I will provide a hyperlink to the SOPs

ENTER THE URL FOR ACCESS THE SOPs

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).

<table>
<thead>
<tr>
<th>CONFLICTS OF INTEREST</th>
<th>Relying Institution(s) will perform conflict of interest analyses under their policies</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB NOTIFICATIONS (OF DECISIONS, CHANGES, LAPSES IN APPROVAL, PROBLEMS, NONCOMPLIANCE)</td>
<td>Reviewing IRB will provide notifications directly</td>
</tr>
<tr>
<td>IRB-INITIATED AUDITS/INVESTIGATIONS</td>
<td>Plan for conduct of IRB-initiated audits or investigations will be determined on a case-by-case basis</td>
</tr>
<tr>
<td>IRB-INITIATED EXTERNAL REPORTING</td>
<td>Plan for drafting and submission of IRB-initiated external reports will be determined on a case-by-case basis</td>
</tr>
<tr>
<td>CONGRUENCE OF FEDERAL GRANT APPLICATIONS/CONTRACT PROPOSALS</td>
<td>Reviewing IRB will review congruence</td>
</tr>
<tr>
<td>FINANCIAL AGREEMENTS [For review costs - indemnification agreements are addressed separately below]</td>
<td>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.</td>
</tr>
<tr>
<td>QUALITY ASSURANCE / QUALITY IMPROVEMENT FUNCTION / PROGRAM(&quot;QA/QI&quot;)</td>
<td>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.</td>
</tr>
<tr>
<td>INSURANCE</td>
<td>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).</td>
</tr>
<tr>
<td>INDEMNIFICATION</td>
<td>One or more Participating Institutions require an</td>
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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.