Institutional Profile

Site Name: Columbia University

Last modified date: 04/11/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Columbia University</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00003831</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-01-25</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00006799</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>
</tbody>
</table>

Describe any board specialties of your IRB.

The membership of each Board includes individuals with varying backgrounds who possess the appropriate professional competence to review the diverse types of protocols that are received or to provide awareness of considerations of the local community. Examples include: a) cardiologists are involved in the review of innovative cardiac surgery and device protocols; b) psychology faculty are assigned as reviewers or asked to consult on research procedures that may result in participant stress requiring intervention; c) a board devoted to oncology studies; d) another board devoted to genetic/genomic...
studies that include whole exome or whole genome sequencing (WES/WGS).

Is your institution a covered entity?  Yes

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.  The Trustees of Columbia University in the City of New York

Age of majority in your state?  18

What circumstances affect age of consent in your state?  N/A
For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment

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?  No

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 your specific consent form language  The use of the specific language below is not required,
but the language used in consent forms cannot be in
conflict with the below: Research Related Injury
Language: -For Industry Sponsored studies (Phases I-
III) involving investigational drugs or devices: “Taking
part in this research study may result in injury or
harm to you. In the event of an injury resulting from
your participation in this study, you should seek
appropriate medical care and inform the study doctor.
In the event of an emergency you should go to an
emergency room. If you are injured or harmed as a
result of participating in the study and receive medical
care through the NewYork-Presbyterian Hospital
(NYPH), a Columbia doctor, or any other health
provider, you will be sent a bill for whatever medical
care you receive. All or part of your bill may be paid by
your health insurance. If this medical care is provided
by NYPH or by a Columbia doctor, the study sponsor
may pay these providers for any reasonable medical
expenses to treat your injury. The study sponsor,
however, is not offering to pay for medical expenses
that are covered by your insurance provider or if your
injury was not caused by the study drug/device or a
study procedure. Columbia University and NewYork-
Presbyterian Hospital (NYPH) are not offering to
provide you the drug/device after the termination of
the study or to pay you for pain, worry, lost income,
the cost of your medical care or non-medical care
costs that might occur as a result of your taking part
in this study. However, you do not waive any of your
legal rights in signing this form.” -All other studies
that are greater than minimal risk [e.g., Investigator
initiated, NIH, non-profit sponsor/research
collaborator (other universities or foundations) or
industry-supported Phase IV studies involving drugs or
devices; if studies involve interventions other than
drugs or devices, insert "study intervention" for
"drug/device"] Taking part in this research study
may result in injury or harm to you. In the event of an
injury resulting from your participation in this study,
you should seek appropriate medical care and inform
the study doctor. In the event of an emergency you
should go to an emergency room. If you are injured or
harmed as a result of participating in the study and
receive medical care through the NewYork-
Presbyterian Hospital (NYPH), a Columbia doctor, or
any other health provider, you will be sent a bill for
whatever medical care you receive. All or part of your
bill may be paid by your health insurance. Columbia
University and NewYork-Presbyterian Hospital (NYPH)
are not offering to provide you the drug/device after
the termination of the study or to pay you for pain,
Please enter your specific consent form language regarding costs to participants to participate.

<table>
<thead>
<tr>
<th>Please enter your specific consent form language regarding costs to participants to participate.</th>
<th>No specific language requirements</th>
</tr>
</thead>
</table>

Do you have any additional HIPAA Authorization language template documents?

<table>
<thead>
<tr>
<th>Do you have any additional HIPAA Authorization language template documents?</th>
<th>No</th>
</tr>
</thead>
</table>

**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? Yes

What is the name of this component site? Lamont-Doherty Earth Observatory

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? Earth Institute

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? No

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**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)?

Tasha Isles Smith ts2257@cumc.columbia.edu and irboffice@columbia.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

- Other
<table>
<thead>
<tr>
<th>Please specify what other documents must be submitted</th>
<th>Online submission through Columbia's submission system</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Study-wide amendments (protocol or consent form modifications)</td>
</tr>
<tr>
<td></td>
<td>• Local amendments (personnel modifications)</td>
</tr>
<tr>
<td></td>
<td>• Continuing review</td>
</tr>
<tr>
<td></td>
<td>• Serious or continuing non-compliance</td>
</tr>
<tr>
<td></td>
<td>• Unanticipated problems</td>
</tr>
<tr>
<td></td>
<td>• Final report</td>
</tr>
</tbody>
</table>
| What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review? | "1) Once reviewed/approved by the reviewing IRB, submission through the Columbia electronic system is required. 2) Confirmation that the sIRB has reviewed and approved changes (i.e. attaching sIRB approval letter, updated sIRB stamped ICFs, etc)"
| What types of local amendments (e.g. personnel modifications) should be submitted to the local HRPP and what should be submitted when ceding review? | All local amendments should be submitted to the Columbia HRPO once approved by the reviewing sIRB. |
| What should be submitted at continuing review? | "1) Once reviewed/approved by the Reviewing IRB, submission through the Columbia electronic system is required. 2) Confirmation that the Reviewing IRB has reviewed and approved changes (i.e. attaching sIRB approval letter, updated sIRB stamped ICFs, etc)"
| What should be submitted for serious or continuing non-compliance? | "-Along with notifying the Reviewing IRB, a modification submission should be made in the Columbia electronic system notifying C of the event. - All allegations/incidences of non-compliance should be made in the Columbia electronic system."
| What should be submitted for unanticipated problems? | "-Along with notifying the Reviewing IRB, a UP submission should be made in Columbia's electronic system."
| What should be submitted for final reports? | #NAME? |
| 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 | Thresiamma Lukose |
| Email | tt2103@cumc.columbia.edu |
| Phone Number | (212) 342-2120 |
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.

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>Yes</td>
</tr>
<tr>
<td>STANDARD OPERATING PROCEDURES (&quot;SOPs&quot;)</td>
<td>Using other SOPs (not otherwise mandated)</td>
</tr>
<tr>
<td>NAME OR DESCRIPTION OF ALTERNATIVE SOPs</td>
<td>Columbia University IRB SOPs</td>
</tr>
<tr>
<td>WHERE CAN PARTICIPATING INSTITUTIONS ACCESS THE SOPs</td>
<td>I will provide a hyperlink to the SOPs</td>
</tr>
<tr>
<td>ENTER THE URL FOR ACCESS THE SOPs</td>
<td><a href="https://research.columbia.edu/sites/default/files/content/HRPO/IRB_SOP_v5.1_4.12.18_TOC_176a.pdf">https://research.columbia.edu/sites/default/files/content/HRPO/IRB_SOP_v5.1_4.12.18_TOC_176a.pdf</a></td>
</tr>
<tr>
<td>HIPAA DETERMINATIONS AND ACTIONS</td>
<td>If one or more Relying Institution(s) are HIPAA Covered Entities, Relying Institution(s) will make any HIPAA determinations or perform any HIPAA actions.</td>
</tr>
<tr>
<td>HIPAA AUTHORIZATION LANGUAGE AND CONSENT FORMS</td>
<td>Not applicable - Ceded study(ies) does not fall under HIPAA Privacy Rule regulations</td>
</tr>
<tr>
<td>CONFLICTS OF INTEREST</td>
<td>Relying Institution(s) will perform conflict of interest analyses under their policies</td>
</tr>
<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>Reviewing IRB and Relying Institution(s) will jointly draft and submit reports to external parties</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</td>
</tr>
</tbody>
</table>
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.