Institutional Profile

Site Name: Mayo Clinic

Last modified date: 09/11/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Mayo Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00005001</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2022-02-28</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000020 IRB00003294 IRB00003295 IRB00005256</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>It depends</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Our boards do not specialize, but one board has a prisoner representative for review of Subpart C studies.</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?  
- AZ  
- FL  
- MN

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.

Under Minnesota law, a person is generally considered to be a child until reaching the age of 18 years. In such instances, the child may not participate in research unless informed consent is provided by the child's parent(s) or guardian, as provided in Mayo IRB policies. While there are no research-specific exceptions for determining whether a person is a child, there are certain limited situations in which a person younger than 18 years old may become an "emancipated minor" under Minnesota law. In such cases, the person may treated the same as an adult for purposes of determining who may provide informed consent to participate in research. These situations include the following: 1. The person has been declared emancipated by a court order; 2. The person is married; 3. The person is living apart from his or her parents and managing his or her own financial affairs; 4. The person has given birth; 5. The person is seeking treatment for pregnancy and associated conditions; sexually transmitted diseases; or alcohol and other drug abuse, and the research procedures relate to those conditions.

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?  
Yes, I will insert language in text box

Please insert the language required to be used around mandatory reporting to health authorities.  
If it isn't known if you have [insert reportable disease name], you will need to have a blood test done. If your [insert reportable disease name] test result is positive you will need to have a second test done to make sure the results are the same. The researcher will tell you how to find medical help and counseling as needed, and you may not be able to take part in the study. Your
health insurer or you will have to pay for the cost of the repeat test, any follow-up medical care, or counseling. If the [insert reportable disease name] test results are positive, it is the state law that they be reported to the State Department of Health. The test results will also be put in your medical record.

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<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>No</td>
</tr>
<tr>
<td>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.</td>
<td>Consents 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</td>
</tr>
<tr>
<td>Does your IRB require HIPAA authorization forms be a separate document from the Informed Consent Form?</td>
<td>No</td>
</tr>
<tr>
<td>Please enter your specific consent form language regarding payment for research-related injury.</td>
<td>Where to get help: If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed. Who will pay for the treatment of research related injuries: Investigator initiated/Mayo funded/Extramural funded: Option (A) For studies with no prospect of direct benefit to individual subjects - Mayo Clinic offers to reimburse for treatment of research related injuries (including deductibles, co-payments and coinsurance): Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic. Option (B) For studies with the prospect of direct benefit to individual subjects - Mayo Clinic does not offer to reimburse for treatment of research related injuries, deductibles, co-payments and coinsurance: Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. Sponsor initiated and funded: Option (A) Sponsor will reimburse for treatment of research related injury,</td>
</tr>
</tbody>
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including deductibles, co-payments and coinsurance: The Sponsor [insert Sponsor name] will offer to pay for medical treatment of research-related injuries directly resulting from the proper application of the study [drug/device/procedure]. The Sponsor may not offer to pay for several reasons. The Sponsor may not offer to pay if the Sponsor concludes the injury happened because you did not follow the study directions or the injury resulted from your actions. The Sponsor may not consider the worsening of an existing health condition to be a research-related injury. In the case of injury resulting from your participation in this study, you do not lose any of your legal rights to seek payment by signing this form. Contact the Principal Investigator, who can help you obtain this reimbursement. Option (B) Sponsor will not agree to reimburse for treatment of research related injury and subject is responsible for all claims, including deductibles, co-payments and coinsurance: Care for research-related injuries will be billed in the ordinary manner to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

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

| All Study Costs Covered: You won’t need to pay for tests and procedures which are done just for this research study. These tests and procedures are: o Specify tests and procedures o List as bulleted items However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles. Drug Study with All Costs Charged to Subject: The study drug will be given to you at no cost; however, you may need to pay for the administration of the study drug. You and/or your insurance might also have to pay for other drugs or treatments given to help control side effects. You and/or your insurance will need to pay for all tests and procedures that are part of this research study. Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered. You will have to pay for any costs not covered by your insurance. Incidental Findings: If the results of tests or procedures performed for research may be useful for your health care, you may be notified. If you decide to follow up, any further medical testing will be considered part of your clinical care, and will not be paid for by the research study. Costs will be billed to you or your insurance. If you have questions about any costs to you that may result from taking part in the |
research, please speak with the Principal Investigator. If you wish, arrangements can be made for you to speak with someone in Patient Financial Services about these costs. Investigational Device: You won’t need to pay for tests and procedures which are done just for this research study. These tests and procedures are: o Specify tests and procedures o List as bulleted items You [Choose one: will / won’t] need to pay for the investigational device used in this study. You and/or your insurance will need to pay for all other tests and procedures needed for your clinical care. You and/or your insurance may also have to pay for other drugs or treatment given to control side effects. Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered. Some insurers will not pay for these costs. You will have to pay for any costs not covered by your insurance. If you have billing or insurance questions call Research Billing at the telephone number provided in the "Contact Information" section of this form. Some Tests and Procedures Paid by Study: You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are: o Specify tests and procedures o List as bulleted items However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care. These tests and procedures are: o Specify tests and procedures o List as bulleted items You will also be responsible for any co-payments and deductibles. Sponsor Covers Costs: [Name of company] is providing [name of study drug] at no cost and will also pay for: • [bulleted list that specifies what is covered, e.g., study visits, tests, and procedures done only for this research]. However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

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.

| 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)?

| 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

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.

| What should be submitted by your investigator for study-wide amendments (e.g. protocol and consent form modifications) when ceding review? | Protocol, consent form(s), approval letter, revised documents |
| 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 modification, approval letter, revised documents |
| What should be submitted for serious or continuing non-compliance? | When a UPIRTSO and/or major protocol violation/deviation occurs at Mayo Clinic, but the Mayo Clinic IRB is not the IRB of Record: 1. The Investigator must complete reporting according to the requirements of the external IRB. 2. The Investigator must report the problem or event to IRCU within five working days of becoming aware of the problem or event by completing the Reportable Event form within the Mayo Clinic IRB electronic system. 3. The Investigator must, upon receipt of the external IRB’s review and determination regarding the problem or event, submit a copy of that determination to IRCU by: a. Completing an additional Reportable Event form |
Within the Mayo Clinic IRB electronic system b. Selecting "follow-up" in section 3 of the Reportable Event form.

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?

<table>
<thead>
<tr>
<th>Name</th>
<th>Mayo Clinic principal investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:ORRS@mayo.edu">ORRS@mayo.edu</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(507) 266-0022</td>
</tr>
</tbody>
</table>

**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, 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

Mayo Clinic investigator and study team are to provide notifications to external sites.

### IRB-INITIATED AUDITS/INVESTIGATIONS

Reviewing IRB and Relying Institution(s) will jointly 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 not required: Each Participating Institution is not required to maintain insurance coverage to cover its activities with respect to the identified study(ies).

### 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).