Institutional Profile

Site Name: Henry Ford Health System

Last modified date: 03/26/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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

Section 1: GENERAL HRPP INFORMATION

<table>
<thead>
<tr>
<th>Institution</th>
<th>Henry Ford Health System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00005846</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2020-07-31</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00000253 IRB00008660</td>
</tr>
<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>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Biomedical</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Yes</td>
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</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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- MI

Age of majority in your state? 18 (unless emancipated minor)

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

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? 
NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.

- 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?

Yes

Please enter your specific consent form language regarding payment for research-related injury.

FOR PHARMACEUTICALLY SPONSORED STUDIES: You will not be responsible for costs of your medical injuries related to your participation in this study, as long as the injury is not part of the natural progression of your disease or your carelessness. We may need to know some information (like name, date of birth, Medicare insurance, claim number and/or social security number) to pay these medical expenses. In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Medical services will be offered at the usual charge. However, compensation for things such as lost wages, disability or discomfort is not routinely available. By signing this consent form, you do not give up any of your legal rights in the event of an injury. FOR NIH FUNDED, OR HFHS PHYSICIAN (SINGLE SITE) INITIATED STUDIES: There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your
medical insurance may have to pay for your medical care if you are injured as a result of participating in this study. By signing this consent form, you do not give up any of your legal rights in the event of an injury.

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

IF THERE ARE ASSOCIATED COSTS: Taking part in this study may lead to added costs to you or your insurance company. Items related to your routine medical care will not be covered. If your insurance company is billed, you may be responsible for payment of any deductibles, coinsurances and co-payments required by your insurer. Additional costs may include <insert specific costs. Be sure to include any co-pays, transportation costs, including lodging, travel, parking, etc.> You have the right to ask what it will cost you to take part in this study. If you have any questions about the costs of this study, please ask the study doctor, a member of the study staff, and/or your health care provider. IF THERE ARE NO EXTRA MEDICAL COSTS, OR IF ALL OF THE COSTS (INCLUDING THOSE RELATED TO RESEARCH INJURIES AND INSURANCE-RELATED) WILL BE BORNE BY THE STUDY SPONSORING/FUNDING AGENCY: There will be no charge to you for your participation in this study. The <investigational drug/device, study-related procedures, and study visits> will be provided at no charge. You will still be responsible for the cost of your usual ongoing medical care, including <procedures and drugs that are not required by this study>. You have the right to ask what it will cost you to take part in this study. If you have any questions about the costs of this study, please ask the study doctor, or a member of the study staff. The sponsor and/or Henry Ford Health System will pay for the tests and examinations that are required by this study and anything else that is not part of your standard medical care. While some of the tests and exams may be considered standard of care, they may or may not be covered by your medical insurance. You may be responsible for insurance co-payments. If your medical insurance does not pay for your care you may be responsible for the cost of the medical care related to your condition including but not limited to: laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization and procedures.

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? Yes
What is the name of this component site? Henry Ford Wyandotte Hosp

- None

Do you have another component site on your FWA? Yes
What is the name of this component site? Henry Ford West Bloomfield Hospital

- None

Do you have another component site on your FWA? Yes
What is the name of this component site? Henry Ford Hospital

- None

Do you have another component site on your FWA? Yes
What is the name of this component site? Henry Ford Macomb Hospital

- None

Do you have another component site on your FWA? Yes
What is the name of this component site? Henry Ford Med Ctrs

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)?

Regardless of what external IRB is being used, the HFHS IRB administrative process is as follows: 1. Submit an "External IRB Request and Authorization Form" to the HFHS IRB. HFHS IRB must approve the request prior to submitting to the intended external IRB of record. Although IRB oversight will become the responsibility of the external IRB, the HFHS IRB remains responsible for tracking studies being conducted at HFHS facilities, usage of HFHS pharmacy, PI qualifications, PI training requirements, conflict of interest, key personnel, IRDBC requirements, radioactive agent safety, and diagnostic radiology availability, consent injury and privacy language (among other items). 2. Once the "External IRB Request and Authorization Form" is approved, the PI will submit the form to the intended external IRB of record and begin that IRB's process for approval.

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)
- Study contract
- Other

Please specify what other documents must be submitted

Any other study-specific approved documents, such as questionnaires, surveys, 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.

- Local amendments (personnel modifications)
- Continuing review
- Final report

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

Key Personnel changes

What should be submitted at continuing review?

This is done by submitting a Continuation Report to the HFHS IRB and providing a copy of the Continuation approval letter.

What should be submitted for final reports?

This is done by submitting a Final Report to the HFHS IRB and providing a copy of the final report or closure 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?

<table>
<thead>
<tr>
<th>Name</th>
<th>Courtney Cloutier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:cclouti1@hfhs.org">cclouti1@hfhs.org</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(313) 874-4420</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.

No