Institutional Profile

Site Name: VHS of Michigan dba Detroit Medical Center

Last modified date: 02/12/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>VHS of Michigan dba Detroit Medical Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00002459</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2022-05-19</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Medical Medical/Pediatric Behavioral Phase 1</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 However, any information provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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 institutions subject?
  • MI
List other names by which your institution is known.

| VHS of Michigan VHS of Michigan - Detroit Medical Center VHS of Michigan - DMC Detroit Medical Center | DMC |

Age of majority in your state?

| 18 years |

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

The consent to receive medical, surgical care, treatment or services by a hospital, clinic or physician that is executed by a minor who professes to be infected with a venereal disease or HIV is valid and binding. A minor may consent to the provision of prenatal and pregnancy related health care or to the provision of health care for a child of the minor and shall be valid and binding as if the minor had achieved the age of majority. Health care means only treatment or services intended to maintain the life and improve the health of both the minor and the minor's child or fetus. The minor cannot consent for participation in research unless they meet the definitions of emancipated minors. Parental permission must be sought to enrolling minors in research, unless the research protocol meets the criteria for waiver of parental permission as set forth in 45 CFR 46.408.

| 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  
• 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.

Research Related Injuries Please note the language in this section must match the Clinical Trial Agreement (CTA)/Contract. The Sponsored Programs Administration will assist the PI with the language. [If the risks to the study are no more than minimal (i.e.,...
protocol may be expedited or exempted), this disclaimer, including the header, may be removed if IRB chair or designee concurs with its elimination.] 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. No reimbursement, compensation, or free medical care is offered by Wayne State University. TENET’s LANGUAGE FOR SUBJECT INJURY- PICK THE FIRST PARAGRAPH OR SECOND PARAGRAPH BELOW DEPENDING ON WHO IS RESPONSIBLE FOR PAYMENT If a "research related-injury" results from your participation in this research study, medical treatment will be provided at no cost to you and paid by the sponsor of the study. A "research related-injury" means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research study. You, or your medical insurance, will be responsible for other medical expenses resulting from your medical condition. OR If a "research related injury" results from your participation in this research study, medical treatment will be provided. The costs for all your medical treatment will be billed to you and/or your insurance. A "research related-injury" means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research. It is important for you to follow your physician's instructions including notifying your study physician as soon as you are able of any complication or injuries that you experienced. You will not be paid for any other injury- or illness-related costs, such as lost wages. You are not waiving any legal rights and are not freeing the sponsor, Principal Investigator, or hospital of any malpractice, negligence, blame or guilt by participating in this study. If you think that you have suffered a research related injury, contact the PI right away at [insert phone number].

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?  
Childrens' Hospital of Michigan

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?  
Detroit REceiving Hosp/University Hlth Ctr

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?  
Harper Hospital

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?  
Rehab Institute of Michigan

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?  
Sinai-Grace Hsopital

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

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 should submit the request to Wayne State University IRB via the External IRB Process. The PI should also contact the Detroit Medical Center Clinical Research Office at 313-578-2184.

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
Please specify what other documents must be submitted

VHS of Michigan Local Context Agreement

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.

- Serious or continuing non-compliance
- Unanticipated problems
- Serious adverse events

What should be submitted for serious or continuing non-compliance? Non-compliance report and relative documents

What should be submitted for unanticipated problems? Unanticipated problem report and relative documents

What should be submitted for serious adverse events? Serious Adverse Events Report and relative documents

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
Pamela Odziana

Email
podziana@dmc.org

Phone Number
(313) 578-2184

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