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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Memorial Health Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA00000081</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-10-15</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IORG00000575</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>Anesthesiology Pediatric Infectious Disease Orthopedic Surgery Pharmacology Nursing Cardiology Maternal Fetal Medicine Medical Informatics</td>
</tr>
<tr>
<td>Is your institution a covered entity?</td>
<td>Hybrid</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
To what state laws is your institution subject?

- CA

List other names by which your institution is known.

MemorialCare

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. Married with permission from individuals' parents and the court.
2. Join the armed forces with permission from individuals' parents, and the armed forces must accept individual.
3. Declaration of emancipation from a judge

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.

Per institutional policy: 30 years upon closure of study.

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.

1. there is a federal, state, or local law that requires disclosure (such as to report child or elder abuse and neglect, harm to self or others, or communicable diseases);

Does your site require a site-specific logo appear on consent forms and/or recruitment documents?

Yes

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 any special formatting your IRB requires for HIPAA authorization forms?

1. The text of this section must be in a 14-point font, in
accordance with state law (Cal. Civ. Code 56.11(a)). 2. California state law requires an end date and does not permit the use of terms such as "indefinitely" or "forever" 3. Must include a space for the date and time documentation of the participant/LAR signature given

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

What Should I Do If I Have a Research-Related Injury? Select (only) one of the appropriate injury language sections below depending on study type and funding source. OPTION 1 (NO COMPENSATION FOR INJURY AVAILABLE): If you believe the project is minimal risk, OR there is no compensation for injury offered (e.g. MemorialCare, federal grant, or other private foundation funding), include the following statement: If you think you have been hurt by taking part in this study, tell the study doctor immediately. If you require treatment because you were injured from participating in this study, treatment will be provided. You should tell the treating doctor that you are participating in a clinical trial and give them your study doctor's contact information. Your study doctor is Dr. _______________. [He/She] can be reached at [Principal Investigator Number]. The study sponsor, [sponsor/funding agency name], and your study doctor will not offer to pay for any medical diagnosis or treatment for illness or injury caused by the study. You and your insurance company will have to pay for the cost of this treatment. However, by signing this form you have not given up any of your legal rights. OPTION 2 (INDUSTRY SPONSORED): If the project is industry sponsored, the language below must be included verbatim. NOTE - If industry sponsor does not agree to this language and other language is mutually agreed upon with approval from Legal and the Executive Director of Research Administration, the contractual sponsor budget must include the cost of ICF modification approval by the IRB. If you think you have been hurt by taking part in this study, tell the study doctor immediately. If you require treatment because you were injured from participating in this study, treatment will be provided. You should tell the treating doctor that you are participating in a clinical trial and give them your study doctor's contact information. Your study doctor is Dr. _______________. [He/She] can be reached at [Principal Investigator Number]. The sponsor will pay for the diagnosis and treatment of your illness or injury if it is the direct result of your participation in the study, use of the study [drug/device], or a research procedure that was properly performed. If the sponsor pays for the treatment of your illness or injury, you may be required to provide them with some personal
information such as your social security number as they may need to report the payment to Medicare or your insurance company. No other compensation is available. However, by signing this form you have not given up any of your legal rights.

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

Costs and Research Related Injuries What are the costs of taking part in this study? INSTRUCTIONS: Include (only) one of the following cost language options below depending upon study type. If you have questions about what kind of study you have, contact MemorialCare Research Finance Office at (657) 241-3740. OPTION 1 No cost for participating, e.g., data or survey research, the following language is used: There is no cost to you for participating in this study. OPTION 2 Drug, biologic, or vaccine trial where research items/services and additional study-required safety monitoring are paid for by the study under the contract/award and all other ordinary standard of care services that the patient would have received absent participation in the study, but that is also used for Protocol data is billed to the subject/their insurance company as their ordinary care, e.g., most industry sponsored drug trials. This is the most common option for clinical drug trials (if in doubt, choose this option) all the following language is required: You will get [study drug] for no cost. [Sponsor name] will supply it. [Sponsor name] will pay for procedures done only to collect research data. You and your health insurance will be billed for the care that you would have received if you were not in the study. You may be responsible for co-pays, deductibles, and other costs not covered by insurance. Talk with your health insurance company before agreeing to be in this study. Ask them what they will and will not pay for while you are in the study. If your insurance does not pay, you will have to pay. If you have questions about the cost, ask your study team. You can also call the Research Finance Office at (657) 241-3740 to connect you with the right person in Patient Financial Services. OPTION 3 Drug, biologic, or vaccine trial where patient or patient’s insurance company pays for some or all of the administration of investigational drug and standard of care, e.g., a cancer study where the sponsor provides the chemo agent but the patient has to pay for the infusion cost. If the research is a “Qualifying Clinical Trial” where billing patient/insurance for “Routine Costs” is identified in the MHS Study coverage analysis, but the investigational drug and research-only services will be provided at no cost, all of the following language is required: You will get [study
drug] for no cost. [Sponsor name] will supply it. [Sponsor name] will pay for procedures done only to collect research data. Costs for preparation and administration of the [study drug] will be billed to you and your health insurance. You and your health insurance will also be billed for the care you would have received if you were not in the study and any additional services determined by your physician to be medically necessary for your health and not required per the research. You may be responsible for co-pays, deductibles, and other costs not covered by insurance. Talk with your health insurance company before agreeing to be in this study. Ask them what they will and will not pay for while you are in the study. If your insurance does not pay, you will have to pay. If you have questions about the cost, ask your study team. You can also call the Research Finance Office at (657) 241-3740 to connect you with the right person in Patient Financial Services.

OPTION 4 Device trial where sponsor pays for Investigational device. If this is a CMS-Approved IDE study billing patient insurance for the "Routine Costs" identified in the MHS Study coverage analysis, but the investigational device and research-only services will be provided at no cost, all of the following language is required: You will get [study device] for no cost. [Sponsor name] will supply it. [Sponsor name] will pay for procedures done only to collect research data. You and your health insurance will be billed for the [describe device procedure/surgery], care you would have received if you were not in the study, and any additional services determined by your physician to be medically necessary for your health and not required per the research. You may be responsible for co-pays, deductibles, and other costs not covered by insurance. Talk with your health insurance company before agreeing to be in this study. Ask them what they will and will not pay for while you are in the study. If your insurance does not pay, you will have to pay. If you have questions about the cost, ask your study team. You can also call the Research Finance Office at (657) 241-3740 to connect you with the right person in Patient Financial Services.

OPTION 5 Device study where patient or patient’s insurance company pays for investigational device. If in doubt pick this option for your device trial. If this is a CMS-Approved Category B IDE Study for which the investigational device is not provided by the sponsor and will be billed to patient/insurance - Billing patient/Insurance for the cost of the device and the "Routine Costs" identified in the MHS Study coverage analysis, but the research-
only services will be provided at no cost, all of the following language is required: Sponsor name] will pay for procedures done only to collect research data. You and your health insurance will be billed for the [study device], the [describe device procedure/surgery], the care you would have received if you were not in the study, and any additional services determined by your physician to be medically necessary for your health and not required per the research. You may be responsible for co-pays, deductibles, and other costs not covered by insurance. Talk with your health insurance company before agreeing to be in this study. Ask them what they will and will not pay for while you are in the study. If your insurance does not pay, you will have to pay. If you have questions about the cost, ask your study team. You can also call the Research Finance Office at (657) 241-3740 to connect you with the right person in Patient Financial Services. FOR ALL OPTIONS --- If there are any procedures/visits performed for research purposes that will not be billed to the participant/participant’s insurance, these must be separately identified after the first paragraph of this section in an itemized list below. This list must match the costs in the clinical trial agreement budget. Be specific, but write in easy to understand terms. Include visit numbers when applicable to separate standard of care visits from research visits: You and your insurance company will not be billed for the activities listed below. These activities are required for study participation and are only being performed for research purposes: [list activities]

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? Long Beach Memorial Medical Center

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? | Miller Children's & Women's Hospital Long Beach
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? | Saddleback Memorial Medical Center
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? | Orange Coast Memorial Medical Center
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? | Wave Imaging LLC
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? | MemorialCare Medical Foundation
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? | MemorialCare Medical Group
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)?

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last modified 01/24/2019</td>
<td>Submit the request via our local IRB System</td>
</tr>
</tbody>
</table>

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)
- Budget template
- Study contract
- Other

Please specify what other documents must be submitted

1. IRB Deferral form with supplements depending on how items are answered. 2. Principal Investigator And Study Team Members Information. 3. Current CV for all investigators if not on file (updated every 2 years)

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)
- 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?

Local HRPP submission Personnel modifications Final closure form once closure has been completed by reviewing IRB Items local HRP would like once completed: Approval letter from lead IRB + revised documents for any type of transaction for a shadow file.

What should be submitted for final reports?

Local Closure form once lead IRB has closed study.

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>Victoria Do</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:vdo1@memorialcare.org">vdo1@memorialcare.org</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>(657) 241-3732</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