Institutional Profile

Site Name: University of Florida

Last modified date: 10/07/2019

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>University of Florida</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>FWA#00005790</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2023-12-07</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>#IRB00000335 #IRB00000336 #IRB00000337</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>IRB 01- Biomedical; IRB 02 Behavioral/Social</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 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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- FL

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. Minors who are or were married, or are legally emancipated may consent to their own treatment. Maternal health and contraceptive info and non-surgical services may be provided to minors if minor is pregnant, married or a parent, or if minor may in the opinion of the physician suffer "probable health hazards" without such services. Minors may consent to STD or HIV testing, substance abuse-related services, and some limited mental health / outpatient crisis intervention services on their own behalf.

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.

http://irb.ufl.edu/index/data/investigator-requirements-for-retaining-research-data.html

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

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

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.

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants,
nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider. You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information. The Principal Investigator will determine whether your injury is related to your participation in this study. No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence. Please contact the Principal Investigator listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

<table>
<thead>
<tr>
<th>Please enter your specific consent form language regarding costs to participants to participate.</th>
<th>No. There will be no extra cost to you for participating in this Research Study. Please note: This default costs template language is to be used for research studies that DO NOT require a Billing Compliance Review by the Office of Clinical Research (OCR) office. For more information regarding which studies require an OCR review, see <a href="http://rac.med.ufl.edu/preparation/rac_dsr_irb/rac/">http://rac.med.ufl.edu/preparation/rac_dsr_irb/rac/</a>. If your study DOES require a Billing Compliance Review, the OCR office will provide both the Costs and Subject Injury language for your consent(s) via the Financial Language Assessment (FLA). You will need to ensure that the FLA language is used in your consent(s). For more information regarding the FLA process, see <a href="http://rac.med.ufl.edu/preparation/rac_dsr_irb/fla/">http://rac.med.ufl.edu/preparation/rac_dsr_irb/fla/</a>.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have any additional HIPAA Authorization language template documents?</td>
<td>No</td>
</tr>
</tbody>
</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.

<table>
<thead>
<tr>
<th>Do you have a component site on your FWA?</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the name of this component site?</td>
<td>U of Florida Jacksonville</td>
</tr>
</tbody>
</table>
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)?

Submit through local myIRB system developed specifically for ceding

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)

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
- Unanticipated problems

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 changes including PI, anything that triggers an ancillary review or affects local context

What should be submitted at continuing review?

Reviewing IRB approval and current consent and protocol

What should be submitted for unanticipated problems?

Internal forms detailing event

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

Ivana Simic

Email

isimic@ufl.edu

Phone Number

(352) 273-9600
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?** | 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 DETERMINATIONS AND ACTIONS: REVIEWING IRB ACTIONS** | If UF is the reviewing IRB, it'll serve as the privacy board and will use our Authorization language. |
| **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** | Study PI/Point of Contact |
| **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** | Another party will review congruence |
| **NAME OF PARTY THAT WILL BE RESPONSIBLE FOR** | Institution |
## REVIEW

### 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 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

Indemnification agreements not required: Indemnification agreements or other contractual arrangements for allocation of liability are not required with respect to the identified study(ies).