Institutional Profile

Site Name: Children's Healthcare of Atlanta, Inc.

Last modified date: 12/12/2018

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 It may not be accurate and may be subject to change, withdrawn or revised at any time without notice.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>Children’s Healthcare of Atlanta, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federalwide Assurance (FWA) #</td>
<td>00000644</td>
</tr>
<tr>
<td>FWA Expiration Date</td>
<td>2021-09-16</td>
</tr>
<tr>
<td>Does your institution have an internal IRB?</td>
<td>Yes</td>
</tr>
<tr>
<td>IRB Registry Number(s)</td>
<td>IRB00001436</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>No</td>
</tr>
<tr>
<td>Describe any board specialties of your IRB.</td>
<td>Pediatrics</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provided in the IP will be superseded by information provided by the relying site HRPP on any study-specific HRP surveys (including consent form language and format).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?

- GA

<table>
<thead>
<tr>
<th>Age of majority in your state?</th>
<th>18</th>
</tr>
</thead>
</table>
| What circumstances affect age of consent in your state? | Georgia law authorizes minors to consent for certain types of treatment:  
- Minor females for treatment in connection with pregnancy, pregnancy prevention and childbirth (does not include abortion or sterilization)  
- Minors for treatment for substance/drug abuse  
- Minors for treatment of venereal/STD (law unclear on HIV testing)  
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?

Yes

Please describe how long you are required to keep your records.

Medical Records: Adults: 10 years from last discharge or contact that resulted in a record. Minors: Until the patient's 23rd birthday or 10 years from last discharge or contact that resulted in a record, whichever is longer.

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.

For minimal risk studies, include the following statement: “If you think you have been harmed from this study, please call the Principal Investigator at: (insert PI phone number). For greater than minimal risk studies, include one of the following options that is consistent with your project and any contracts. For
studies where the sponsor does not pay for subject injury costs or where there is no sponsor: We will arrange for emergency care or medical treatment if you are injured by this research. Provision of such medical care does not imply any negligence or other wrongdoing on the part of Children’s or any of the physicians or other personnel involved in individual care or services rendered. No further money has been set aside by Children’s Healthcare of Atlanta, Inc. (or the Sponsor) other than what your insurance carrier may provide. You or your insurance company would be billed for the treatment. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of a Children’s (or Sponsor) employee. For more information about risks or if you believe you have been injured by this research, you should contact [insert Principal Investigator] at [insert phone number - ensure it directly connects to the PI, or else provide directions for reaching the PI, especially if it connects to a phone tree, administrative assistant, or message service and if this changes after regular office hours and include a 24 hour emergency contact for interventional studies where subjects may experience adverse events].

For studies where sponsor may choose to pay for subject injury costs: We will arrange for emergency care or medical treatment if you are injured by this research. Provision of such medical care does not imply any negligence or other wrongdoing on the part of Children’s or any of the physicians or other personnel involved in individual care or services rendered. If you get ill or injured as a direct result of being in this study, the sponsor will pay the costs for your medical treatment if it: • Is not a medical condition you had before you started the study; is not the result of the natural progress of your disease or condition; is not caused by your failure to follow the study plan; AND is not proven to be directly caused by the negligence of a Children’s or sponsor employee. You or your insurance company will be billed for any costs of medical treatment for your injury or illness that the sponsor does not pay. No further money has been set aside by Children’s Healthcare of Atlanta, Inc., other than what your insurance carrier may provide. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of a Children’s or sponsor employee. For more information about risks or if you believe you have been injured by this research, you should contact [insert Principal Investigator] at [insert phone number - ensure it directly connects to the PI, or else provide locations or directions for reaching the PI, especially if it connects to a phone tree, administrative assistant, or message service and if this changes after regular office hours and include a 24 hour emergency contact for interventional studies where subjects may experience adverse events].
directions for reaching the PI, especially if it connects to a phone tree, administrative assistant, or message service and if this changes after regular office hours]. For studies where the sponsor may choose to pay for subject injury costs for uninsured subjects or subjects with Medicare/Medicaid and to pay any part of costs for privately insured subjects that are not covered and/or paid by their private insurance: We will arrange for emergency care or medical treatment if you are injured by this research. Provision of such medical care does not imply any negligence or other wrongdoing on the part of Children’s, sponsor employee or any of the physicians or other personnel involved in individual care or services rendered. If you get ill or injured as a direct result of being in this study and you have Medicare, Medicaid or are uninsured, the sponsor will pay the costs for your medical treatment if it: • Is not a medical condition you had before you started the study; is not the result of the natural progress of your disease or condition; is not caused by your failure to follow the study plan; AND is not proven to be directly caused by the negligence of a Children’s or sponsor employee. If your case meets the above criteria and you have private insurance, Children’s will review the claims for these costs to see if they can be sent to your insurer for payment. You will have to pay for any costs that the sponsor or your insurer does not pay. The sponsor will pay for any costs that are not paid by your insurance provider. The sponsor will not pay for costs like co-payments that your insurer says you have to pay. No further money has been set aside by Children’s Healthcare of Atlanta, Inc. other than what your insurance carrier may provide. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of a Children’s or sponsor employee. For more information about risks or if you believe you have been injured by this research, you should contact [insert Principal Investigator] at [insert phone number - ensure it directly connects to the PI, or else provide directions for reaching the PI, especially if it connects to a phone tree, administrative assistant, or message service and if this changes after regular office hours].

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

Guidelines: • If the subject is likely to incur any costs, this must be stated. • Explain who the costs will be paid by or if there is no cost to the subject for participating. Describe services that the insurance provider may be charged for. Include the following statement, if applicable: Services related to your usual
medical care are part of your routine care. You or your insurance company would be charged for these services. If you join the study, costs to you would include your usual insurance deductibles and co-payments for standard care. • State whether the subject will be compensated for their time and travel to participate in the study. Indicate the payment amount, how payment will be issued (i.e., cash, gift cards, etc.), how payment will be prorated and what information you will need to collect for payment (i.e., social security number, address, etc.). If subjects are to be compensated using ClinCard the following language should be included: You will be compensated using "ClinCard", which works like a debit card and is provided by Greenphire. When visits are completed, funds will be loaded onto your card. You will be able to use the funds in approximately 1 business day. You will have up to XX visits over the period of the study (total that you can receive is $XX). To issue your card, we need to give Greenphire some of your personal information (or your child’s). If you do not wish to provide this information, you can still take part in the study, but you will not be paid. Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Children's is required by law to report any payments we make to the IRS. To do this, the Finance department needs to keep you social security number on file. We are asking you to allow us to give your name, address, date of birth, research study name and social security number to Greenphire. If you want to receive email or text alerts when payments are made to you, we will ask you to provide your email or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card or use of your personal information. If payments will exceed $500 in one year, include the following statement: Since this compensation will be greater than the minimum reporting requirements as set by the Internal Revenue Service (IRS), Children's must report this income to the IRS and will issue you a 1099 form as your compensation will be considered taxable income. We will ask that you provide your social security number for this purpose. You will be responsible for reporting this compensation when you file your tax return. • If this is a clinical trial, include the following statement: This is a Clinical Trial that
involves services related to your usual medical care and services related to research. Services related to the research are done only for the purpose of the study; these include: (insert research services here). Clearly indicate whether the research services are provided at no cost to subject or insurance company OR if subject or insurance may be charged for services.

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)?

Contact irb@choa.org

Do you have a reliance request packet or reliance application that needs to be completed before deciding to rely? No

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
- Final report

What should be submitted for serious or continuing non-compliance? Provide the description of the event (preferably the submission document to the IRB of record) and a copy
What should be submitted for unanticipated problems?

Provide the description of the event (preferably the submission document to the IRB of record) and a copy of the determination letter to irb@choa.org.

What should be submitted for serious adverse events?

Provide the description of the event (preferably the submission document to the IRB of record) and a copy of the determination letter to irb@choa.org.

What should be submitted for final reports?

Provide a copy of the close out letter to irb@choa.org.

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
Meredith Capasse

Email
meredith.capasse@choa.org

Phone Number
(404) 785-7555

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