Reliance Information

1 * What Institution will rely on the Boston Children’s IRB (the IRB ceding review to BCH)?
   ABC University
   FWA00001234
   If Other:
   1.1 Please enter the name of institution.
   1.2 FWA Number

2 * Who is the Principal Investigator at the relying site?
   Mickey Mouse

   If the person you need to add to your protocol cannot be found using the "Add" button above, please send an email to
   CHERP Support (cherp.support@childrens.harvard.edu) requesting that the NON BCH person be added to the
   Research Staff. CHeRP Support will need the following information:
   • First Name
   • Last Name
   • Email Address

3 Who is the IRB Contact at the relying institution?
   3.1 Name
      Abe Lincoln
   3.2 Title
      IRB Analyst
   3.3 Email
      honestabe@abc.edu
   3.4 Phone Number
      555-555-5555

4 What type of reliance agreement is being requested? Please select one:
   4.1 [ ] Single: Standard reliance agreement between BCH and another Non-Harvard institution
   4.2 [ ] Harvard Catalyst: Reliance agreement between BCH and another Harvard Catalyst affiliated
      institution
      See link for more information: http://catalyst.harvard.edu/services/irbcede/
   4.2.1 What is the Harvard Catalyst ‘IRB Cede Review Request’ ID?
   4.3 [ ] Master: Reliance agreement among a consortium/network of institutions (other than Harvard Catalyst
      institutions) for one or more protocols
   4.3.1 Please select a consortium/network of institutions from the list:
      • Pediatric/PEDSnet Consortium
      • Other
      
      If Other:
   4.3.1.1 Please specify:
5 Please list all researchers/staff engaged in the protocol at the relying site. BCH IRB considered ‘engaged’ to be interacting with subjects and/or obtaining individually identifiable data.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Role</th>
<th>Email</th>
<th>Required Training Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>View</td>
<td>Smith</td>
<td>Jane</td>
<td><a href="mailto:janesmith@abc.edu">janesmith@abc.edu</a></td>
<td>yes</td>
</tr>
<tr>
<td></td>
<td>Ward</td>
<td>Bill</td>
<td><a href="mailto:billward@abc.edu">billward@abc.edu</a></td>
<td>yes</td>
</tr>
</tbody>
</table>

If the person you need to add to your protocol cannot be found using the “Add” button above, please send an email to CHERP Support (cherp.support@childrens.harvard.edu) requesting that the NON BCH person be added to the Research Staff. CHeRP Support will need the following information:
- First Name
- Last Name
- Email Address

6 * Financial Disclosure: Do any of the NON-BCH researchers, or staff affiliated with the protocol have or expect to have any financial interest, financial relationship, or position or advisory role with any other entity that may be affected by the research to be conducted under the protocol relationship with any entity that is providing funds or other support in connection with the protocol?

- Yes
- No

If YES:
6.1 Please describe the conflict of interest and any pertinent management plan.
6.2 Please submit any pertinent documentation.

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<thead>
<tr>
<th>Name</th>
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<th>Version</th>
<th>Owner</th>
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</thead>
<tbody>
<tr>
<td>There are no items to display</td>
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</table>

7 Please upload the reliance request information that the relying site completed, (if applicable). If this request is part of the Harvard Catalyst System, please upload a copy of the Catalyst cede review request form.

<table>
<thead>
<tr>
<th>Name</th>
<th>Date Last Modified</th>
<th>Version</th>
<th>Owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliance Agreement BCH for ABC_12345.pdf</td>
<td>3/2/2015 3:44 PM</td>
<td>0.01</td>
<td>Jane Smith</td>
</tr>
<tr>
<td>ABC University Application for Relying on BCH.pdf</td>
<td>3/2/2015 3:45 PM</td>
<td>0.01</td>
<td>Jane Smith</td>
</tr>
</tbody>
</table>

8 * Will consent/assent form(s) need to be individualized for the relying sites (include site specific information such as additional HIPAA language, conflict of interest disclosures, injury language, contact information, addition of site header/logo, etc. boiler plate signature section).

- Yes
- No

9 * Will recruitment documents need to be individualized for the relying sites?

- Yes
- No

Consents and Recruitment Materials

1 Please upload the site specific consent here. Please be sure that the title includes the name of the institution.

<table>
<thead>
<tr>
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<th>Owner</th>
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</thead>
<tbody>
<tr>
<td>ABC U Healthy Volunteers Consent.doc</td>
<td>3/2/2015 3:45 PM</td>
<td>0.01</td>
<td>Jane Smith</td>
</tr>
<tr>
<td>ABC U Parent Consent.doc</td>
<td>3/2/2015 3:45 PM</td>
<td>0.01</td>
<td>Jane Smith</td>
</tr>
<tr>
<td>ABC U Child Assent.doc</td>
<td>3/2/2015 3:45 PM</td>
<td>0.01</td>
<td>Jane Smith</td>
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</table>

2 Please upload the recruitment documents here

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PI's Statement

1 Upload any additional documents you think may be pertinent to this reliance request.

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<th>Owner</th>
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There are no items to display

2 * I am aware of and support the reliance request that is being made for Boston Children’s Hospital IRB to serve as the IRB for record for the above mentioned site. As the PI, I take full responsibility for submitting initial and ongoing information that requires IRB review from the other relying sites. I will also keep the relying site PIs informed about any associated IRB review activities and will make available to all sites the approved protocol, recruitment materials, consents, reports of actions, and any other documents and communications pertinent to IRB review. I assure that I have the appropriate resources to fulfill these additional responsibilities in order to assure all required human subject protection policies.

☐ Yes ☐ No