## **Application for Relying on Boston Children’s Hospital IRB**

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| **purpose of this form**  The purpose of this form is to facilitate centralized review of research. The form will provide the Boston Children’s Hospital Institutional Review Board (IRB) with additional information to consider assuming responsibility for serving as the IRB for your site. | | |
| **Site Requesting Reliance on Boston Children’s Hospital** | | |
| **Institution:** | **FWA #:** | |
| **IRB Contact:** | **Phone:** | **Email:** |
| **Institution Official:** | **Phone:** | **Email:** |
| **URL for the IRB (if available):** | | |
| **Organizational Questions (Site-Specific)**  **1.** Is the site AAHRPP (Association for the Accreditation of Human Research Protection Programs) accredited?  Yes  No  If yes, latest accreditation date:  If no, list any other type of accreditation:  2. Has the site’s federal wide assurance (FWA) been extended to non-federally funded research?  Yes No  (Please note Boston Children’s Hospital has not extended its FWA to non-federally funded research and may choose not to report to Office for Human Research Protections (OHRP) serious or continuing or noncompliance, terminations and suspension of research that are not federally funded.)  3. State any other names by which the organization is known or does business and any corporate affiliations it has with other organizations, such as a university or hospital network.      If the organization is part of a network or system, describe which entities or sites within the system will conduct the research and how regulatory oversight is provided or structured within the system with respect to those entities/sites.    Do those other entities/sites operate under their own independent FWAs?  Yes  No  If yes, each of those entities/sites will need to complete this form.  If yes, please inform Boston Children’s IRB as a network/system reliance agreement may be needed.  4. Are there any governmental inquiries or investigations over the past three years that may be material to the activities that would be conducted under the proposed IRB Authorization Agreement, including research compliance problems (e.g., OHRP or FDA inquiries or investigations and corrective actions)?  Yes  No  If yes, provide the status of such matters, including how they were resolved if resolved:  5. Are there any state or local laws that need to be considered that would impact this research protocol or informed consent document (wards of state, emancipated minors, results of pregnancy testing)?      6. Are there any local, community or cultural issues that may be different for your population of subjects that require consideration?    7. Do you expect a large percentage of the potential research population to speak languages other than English? If so what languages:    8. Does your site approve of the use of short forms for non-English speaking individuals?  Yes  No  If yes, are there any limitations on the use of short forms (i.e. only minimal risk research)  Yes  No    9. Please describe any institutional policies and procedures or generally-accepted ways you operationalize obtaining assent of children for participation in research.      10. Please describe any institutional policies and procedures or generally-accepted ways you operationalize obtaining surrogate consent for adult individuals with impaired decision-making capacity.    11. Are there any special characteristics of your institution or community of which Boston Children’s IRB should be made aware?  Yes  No  If Yes, please describe:   1. For research which is approved with written consent (signature required), will the site utilize an electronic informed consent platform to meet the regulatory requirements for written consent and HIPAA authorization?  Yes  No     If Yes, specify the electronic consent platform that will be used.  If Yes, has the eConsent platform been approved by your Institution?  Yes  No  13. Is there anything described in the protocol(s) that would not fall within the policies and practices of your institution that Boston Children’s IRB needs to be aware of? | | |
| **Research Investigators Education/Training (Protocol-Specific)**  **Research Protocol:**   1. Describe the organization’s human subject protection training and education requirements for researchers and study staff. Please include initial as well as continuing education requirements.     Each Relying Site is responsible for ensuring their Principal Investigators and Research Personnel have appropriate training requirements.    Please check here that investigators and staff involved in the protocol have satisfied local training requirements.  Notes:  **Conflicts of Interest (Protocol-Specific)**  **Research Protocol:**   1. Each Relying Site is responsible for reviewing the protocol and determining whether a conflict of interest exists in accordance with their institutional policies. It is the Relying Site’s responsibility to manage or eliminate any conflict. The conflict and the management plan must be disclosed to the Reviewing IRB, who will have the final determination whether it is appropriate for the Reviewing IRB to assume IRB review responsibilities given any disclosure and management plan.   Does the protocol present any potential conflicts of interest as defined in the relying Site’s institutional policies?  Yes  No  If yes, list investigators with a conflict of interest and attach a full description of the conflict of interest and associated management plan:  Notes:  **Local Ancillary Reviews (Protocol-Specific)**  **Research Protocol:**   1. Each Relying Site is responsible for obtaining any required local institutional ancillary reviews (radiation safety/MRI review, nursing review, pharmacy review, Clinical Trials/Sponsor Agreements, Biomechanical Engineering review, etc.) that apply to the conduct of this research protocol.   Please check here that all required ancillary reviews have been conducted (or that reliance can be executed while ancillary reviews are pending, per local policies/procedures, with protocol not being initiated until all required reviews are completed).  Notes: | | |
| **Mechanisms for Oversight**   1. Does the organization have a quality assurance/audit group responsible for overseeing ongoing research?   Yes  No    Other oversight mechanisms?  Yes  No  If Yes, please describe:  17. Who would we contact about any quality improvement or other oversight mechanism?  Name:  Email:  Phone Number: | | |
| **Approval**  The information provided represents current institutional information in which Boston Children’s IRB can consider in order to serve as IRB of Record for the relying site.              Signature of Designated IRB Contact at Relying Site Date | | |