Boston Children's Hospital | Clinical Research Operations

SPONSORED STUDIES: SITE QUALIFICATION INFORMATION

This document contains information about the structure of the clinical research organization at Boston Children's Hospital (BCH), regulatory binders, IRB policies, timelines, contract and budget information, and other topics related to study startup. Most site qualification questions required by sponsors are contained in this document. Clinical Research Associates (CRAs) and study sponsors will be asked to refer to this document before asking the site to complete any site qualification questionnaires/documentation.

BCH is committed to starting up multi-site industry sponsored protocols using an Independent IRB in 100 days or less. Please refer to this document for detailed workflows.

BCH Clinical Research Operations
Email: BCH.CRO.Help@childrens.harvard.edu
Internal Site: http://crowiki/
External Site: https://tinyurl.com/BCHCRO

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01 IRB Information

1.1	Federal Wide Assurance (FWA)	FWA00002071, Expiration Date: May 10, 2028
1.2	BCH IRB	BCH IRB maintains an updated Compliance Statement which provides information on the composition of the IRB committees, the BCH FWA and the regulations which govern the BCH IRB. The BCH Compliance Statement should be provided to study sponsors when the IRB Roster is requested as documentation that BCH maintains a roster in compliance with all regulatory requirements. BCH IRB Statement of Compliance
1.3	IRB Meetings	Our IRB meets twice per month; the schedule can be accessed on the BCH IRB website.
1.4	BCH Relying on External IRB	When a request is made for BCH to rely on (cede review to) an external IRB, the BCH PI must create a 'New Research Activity' with submission type "Reliance on Another IRB" application in CHeRP (Children's Hospital eResearch Portal). The application smartform will generate applicable questions (based on categories selected for BCH's involvement) and allow for study documents to be uploaded. The activity is not an IRB review process (since the IRB review will be ceded to another institution) but rather a mechanism to conduct a local context review and to accept (approve) the request to rely on another IRB. Submission of the "Reliance on Another IRB" will also trigger applicable ancillary institutional reviews, and track research activities conducted at BCH or elsewhere by BCH investigators. Resources and submission instructions for the Reliance on Another IRB may be found on the BCH IRB Reliance website.

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1.5	BCH Serving as a sIRB	To initiate a request for BCH IRB to serve as the sIRB, the Single IRB Request Form must be completed. When the BCH IRB agrees to serve, the protocol must first be submitted and approved by the BCH IRB as the sIRB. Once approval is obtained, the research team will be directed to create an "Add Reliance on BCH" within the approved protocol in CHeRP for each site that will rely on BCH. This activity will collect information (such as principal investigators from the relying sites, consent forms applicable to the participating institutions, site-specific recruitment documents) to be added to the main protocol, thereby allowing the BCH IRB review to extend to other sites. This request can be submitted as long as a BCH protocol has been submitted (and approved). The sIRB Request Form may be found on the BCH IRB Reliance website.
1.6	Reliance Agreement	SMART IRB: Boston Children's Hospital is a signatory to the SMART IRB master reliance agreement. It is the preference of BCH to use the SMART IRB agreement as the basis of reliance for all studies where we rely on an external IRB or serve as the sIRB. Master Agreement with Independent IRBs: BCH has master agreement with WCG and Advarra. Currently BCH relies on Independent IRB for federally funded cooperative research and industry funded and initiated multisite human research studies. Detailed Instructions for Reliance on Independent IRB are available on the BCH IRB Reliance website. Reliance Agreement with Dana-Farber/Harvard Cancer Center: Boston Children's Hospital is one of the institutions participating with the Dana- Farber/Harvard Cancer Center (DF/HCC). As such, all cancer-relevant research will be reviewed through the DF/HCC IRB.
1.7	Unanticipated Problem, and Noncompliance Reporting	Our IRB requires reporting of unanticipated events and noncompliance in compliance with all regulatory requirements, the IRB approved protocol, and institutional policies. Reporting can be done through our online protocol and reporting system, CHeRP. More information about reporting requirements can be found here: https://www.childrenshospital.org/research/irb/guidelines-policies in Section 5: Reporting, Unanticipated Problems, Noncompliance.

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1.8	Additional IRB Information	More information about specific policies and procedures can be found here: http://www.childrenshospital.org/research/institutional-review- board/guidelines-and-policies

02 Informed Consent

2.1	Informed Consenting Process	Please refer to BCH IRB for guidance on Informed Consent (Section 6 Informed Consent/Assent) and department specific SOPs for the consent process, if applicable. The PI is responsible for delegating and training individuals to obtain informed consent. Who is delegated this responsibility will depend on the nature of the specific study and risk level.
2.2	ICF Templates and Assenting	Protocols reviewed by the BCH IRB must use the BCH ICF template available on the IRB website. The IRB has also developed an assent template which is available on the website: https://www.childrenshospital.org/research/irb/information-researchers/informed-consent.

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03 Study Startup and Timeline (IRB)

3.1	Study Startup Process	1. Once the BCH site has been selected and received the full regulatory packet, the team will begin ICF creation based on the templates and will begin internal IRB submission form via CHeRP (see ICF section on page 2). 2. The modified ICF will be returned for sponsor approval. 3. Once the CHeRP submission and ICF are finalized, it will be submitted through CHeRP for scientific review, if applicable, for protocols going through the BCH IRB. For reliance agreements only specialty scientific review will be conducted if the protocol is related to gene therapy or fetal medicine. The protocol will also be routed for Department/Division Sign off and will then be submitted to the IRB. The IRB office will pre-review the submission and provide initial comments back to the research team. Our IRB meets twice per month, and the following pre-review will be assigned to the IRB for review. **There are no specific deadlines, and this is a rolling submission**. **Note: Budget/Contract negotiations, IRB review, IRB reliance, IBC, EPIC orders, and CTRU implementation are all done in parallel.**
3.2	Ancillary Reviews	Ancillary reviews are automatically triggered after the IRB submission is assigned for review. All ancillary reviews need to be completed per BCH policy before final IRB approval is released.

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04 Startup Package Requirements (IRB)

4.1	Required Documents	Please note that the timeline above applies ONLY once we have received all of the relevant startup documents, as applicable. Drafts will not be accepted: 1. Protocol 2. Template ICF (and assents, if applicable) 3. Investigators' Brochure 4. Recruitment Materials 5. Family/Participant-facing questionnaires 6. Medication diaries, logs, etc. 7. DSMB/DSM Charter 8. FDA Approval Correspondence (IND number, IND approval letter, IDE Number, etc.) 9. Data Transmission & Security considerations (study team will provide list of specific questions in a separate document for review) 10. Lab Manual/SOP (including blood volume totals, as described above) 11. Pharmacy Manual 12. Safety Data Sheet (SDS) for drug trials 13. Sponsor's budget template 14. Clinical Trial Agreement template 15. Studies using a central IRB: sIRB consent template, sIRB approval letters IMPORTANT NOTE: DO NOT SEND THESE DOCUMENTS AS .ZIP FILES Emails with attached .zip files are automatically blocked by the BCH firewall. Documents sent as this type of attachment are not received by us. Neither the sender nor the study team is notified when this occurs. If startup or other documents cannot be shared as regular attachments due to file size, please contact the study team, who can facilitate sharing using BCH's secure file sharing system.

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05 Budget and Contract Information

5.1	Budget/Contract Timing considerations	The budget and contract process is done in parallel with IRB submission, The Clinical Research Finance and Agreement groups- will shift priority of a study depending on the study's IRB review status.
5.2	Budget/Contract/Protocol Submission Requests	Sponsors/CROs will send Budget, Contract, Protocol, and any other necessary documents to the Investigator/Study Team. The Investigator/Study team will submit the necessary documents to Clinical Research Finance and Agreements groups via CHeRP. Once it is submitted, it will be assigned to a budget and contract analyst who will be the point of contact for budget and contract negotiations.

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06 Research Facilities

6.1	IDS Research Pharmacy	The research pharmacy at BCH is only used for investigational products. It is a secure area, monitored 24/7 via video cameras. Only pharmacy staff have badge access to IDS (Investigational Drug Service) Pharmacy. IDS Pharmacy is in the dedicated research unit (CTRU). The pharmacy is temperature controlled. PDFs of temperature logs are available to CRAs upon request. Combination safe and cold (i.e., refrigerators and freezers) storage available if needed. We have backup generators for the hospital if necessary.
6.2	Schedule I Medications	For studies involving a Schedule I medication, there is a C-I compliant safe with study-specific storage in IDS Pharmacy. Further details on C-I handling and procedures are available upon request.
6.3	Pharmacists	Head Research Pharmacist: Joel Jerome, PharmD Research Pharmacy Techs: Liudmila Kochyieva Contact: IDSPharmacy-DL@childrens.harvard.edu
6.4	Research Medication Delivery	Ship medication ONLY to: Boston Children's Hospital IDS Pharmacy c/o Central Pharmacy SK B1-410 300 Longwood Ave Boston, MA 02115 Investigational product (IP) deliveries can be made 7 days per week (but ideally limited to weekdays). Medication will only be logged into the IVRS system Monday through Friday.
6.5	Mediation Accountability, Handling, and Destruction	All IP accountability records are kept electronically using Vestigo. CRA access to Vestigo can be provided upon request, or PDFs of IP logs can be provided. IP Destruction SOP is available to view on site upon request. Returns: IDS does not accept returns for storage; returns will be processed and destroyed immediately upon receipt, and the research team will be provided with a certificate of destruction upon request.

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6.6	Clinical & Translational Research Unit (CTRU)	Study activities can be performed in a 6-bed designated outpatient research unit. Certain studies may require study activities to take place on the clinical wards; however, whenever possible, utilization of CTRU is preferred. Each exam room is equipped with a bedside cardiorespiratory monitor to obtain vital signs (automated BP, HR, RR, 02 sat). Other bedside supplies include a body thermometer, ophthalmoscope, and an otoscope. The unit has a standing scale and stadiometer and recumbent infant scale/length board (calibrated daily) and a 12-lead ECG machine. It also has a fully stocked Code Cart for emergencies. The department also provides inpatient services for overnight research admissions. The CTRU also provides nutrition services by licensed dieticians (Indirect calorimetry, food challenge or meal preparation, diet recall, teaching, etc.). The CTRU also houses the IDS Pharmacy and a sample processing lab inside the unit.
6.7	Biorepository Core for Research Sample Processing and Storage	Biorepository Core provides sample processing including labeling, aliquoting, serum separation, plasma separation, DNA automated extraction, quantification and normalization, tissue weighing and cutting. The core also offers long-term storage and sample shipment and tracking. All samples are logged in to a laboratory information management system (BioStor) and can show a real-time sample inventory to study coordinators. Lab equipment includes ambient centrifuge, refrigerated centrifuge, -20C freezer, -80C freezer, 4C refrigerator, autogen starflex DNA extraction, nanodrop, quantits machine. All lab equipment is on a routine service maintenance schedule; freezers are on a 24/7 temperature probe monitor for any temperature excursion. 24/7 temperature probe logs are maintained and may be produced upon request.

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6.8	Department of Radiology	The Department of Radiology provides a full range of imaging services for newborns, infants, children, teenagers, young adults and pregnant women at Boston Children's Hospital and our satellite clinics in Brookline, Lexington, North Dartmouth, Peabody, Waltham, and Weymouth. Our experienced radiology team carries out more than 200,000 imaging studies each year, using the latest equipment and techniques specially designed or adapted for use with children. Radiology capabilities include Computed Tomography (CT); EOS Imaging System; Fetal Imaging; Fluoroscopy; Magnetic Resonance Imaging (MRI); Nuclear Medicine and Molecular Imaging; PET; Ultrasound; Advanced Image Analysis; Diagnostic Imaging; Interventional Radiology For additional information please visit the following sites: https://www.childrenshospital.org/departments/radiology https://www.childrenshospital.org/departments/radiology/programs- services

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07 General Study Team/Site Information

7.1	Electronic Medical Record	Our site uses EPIC for our clinical EMR. Monitors can work with their study teams to request access to site visits via EPIC CareLink. Certified copies of records can be requested as needed. Please see the attached EMRQ for information regarding our EMR system.
7.2	Monitoring Visits	Monitoring visits are scheduled at the discretion of the study team and may be conducted on site or remotely, based on study needs.
7.3	Regulatory Binders	Study teams utilize electronic regulatory binders at BCH. Our regulatory binders are through eReg (Advarra), a Part 11 compliant platform. Documents will be signed using electronic signatures, and the DoA will be maintained electronically using a task list set at the institutional level. Monitors can be given access to the binders to review the regulatory documents remotely. Please contact the coordinator to set up access. Note: Our eReg platform has the ability to integrate with Longboat. If you utilize Longboat, please let the coordinator know and they can discuss with the platform manager how to initiate set up.
7.4	Research Staff Trainings	Good Clinical Practice (GCP) and Human Subjects Protection (HSP) training is completed through CITI. GCP and HSP re-training is completed every 3 years.
7.5	Institutional Certification	Joint Commission and CLIA certification will be provided for our clinical laboratory. The Biobank is CAP certified. Our clinical site does not receive accreditation through the American Society of Clinical Pathology (ASCP BOC). Our IRB is AAHRPP accredited.
7.6	Off-Site Record Storage	When studies have been closed teams may send all documents to ACCESS long-term storage facility (storage fees will be added to budget) per the departmental policies and study specific requirements: 500 Unicorn Park Drive, Suite 503 Woburn, MA 01801
7.7	SIV Scheduling	A SIV can be scheduled prior to IRB approval.

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08 Overview of Institutional IT Applications

Boston Children's Hospital leverages a diverse suite of IT applications to support clinical research, patient care, operations, and compliance. These systems include both homegrown solutions tailored to BCH-specific workflows, and third-party applications that meet industry standards for security, interoperability, and performance.

	Application Name	Function & Purpose	Ownership	Security & Compliance	Integration	User Base
8.1	EPIC	Electronic Medical Record (EMR)	Third-party	HIPAA-compliant, access-controlled	Integrated with CareLink and other systems	Clinicians, Research Teams
8.2	eReg	Electronic regulator binders and document management	Third-party	21 CRF Part 11 compliant, electronic signatures	Can integrate with Longboat	Study Coordinators, Monitors
8.3	CHeRP	eResearch portal for IRB submissions and reviews	Boston Children's Hospital	Role-based access, tracks IRB and ancillary reviews	Interfaces with Institutional databases	Investigators, IRB Staff
8.4	BioStor	Sample tracking and biorepository inventory	Third-party	Secure, traceable, temperature-monitored	Links to lab processing equipment	Lab Technicians, Study Teams
8.5	Vestigo	Investigational Product (IP) accountability	Third-party	Secure audit trials, CRA-accessible	Data exported for CRA and sponsor review	IDS Pharmacy, Study Coordinators
8.6	CareLink	Remote monitor access to EMR	Third-party	HIPPA-compliant, limited access	Direct access to EPIC	Monitors, Sponsors

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09 Additional Information

9.1	Documents to be available in the eReg Platform:	• Signed CVs for PI and Co-investigators • Local lab ranges • Medical Licenses • CLIA certification • Joint Commission • FDFs
9.2	Biosafety (IBC)	• The hospital Biosafety committee reviews all gene and cellular therapy protocols • The application is separate from the IRB submission and can be submitted in parallel with the initial IRB application. • The Biosafety committee meets the 3rd Thursday of every month

10 General BCH Research Contact Information

10.1	Study 1572	Boston Children's Hospital 300 Longwood Avenue Boston, MA 02115
10.2	IP Shipping ONLY	Boston Children's Hospital IDS Pharmacy c/o Central Pharmacy SK B1-410 300 Longwood Ave Boston, MA 02115
10.3	IRB mailing address	Institutional Review Board (IRB) Boston Children's Hospital 300 Longwood Avenue Boston, MA 02115

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