Customization, Submission, and Review of Relying Site-Specific Informed Consent Forms (ICFs)

This document describes the manner in which Relying Institution-specific consent documents are managed when Boston Children's Hospital (BCH) serves as the Single IRB (sIRB).

Consistent with the SMART IRB SOP manual, BCH IRB is responsible for ensuring the consent documentation remains as consistent as possible across all relying sites. When informed consent forms are required for an sIRB protocol for which reliance is executed under the SMART IRB Agreement, BCH ICF templates will be used for all relying Institutions for that research.

As the reviewing/sIRB, BCH will determine the content of the ICFs and identify sections in which relying sites must provide their institution-specific language (as applicable). Site-specific ICF language to be included by relying Institutions under the associated **BCH ICF template headers** is generally limited to the following:

- **Within ICF page headers**
  Local header details
- **Who is conducting this research study, and where is it being conducted?**
  COI disclosures
- **Are there costs associated with this research? Will I receive any payments?**
  Payment or reimbursement of research costs incurred by participants
- **Are there costs associated with this research? Will I receive any payments?**
  Research related injury: availability of treatment for injury, compensation for injury
- **What should you know about HIPAA and confidentiality?**
  HIPAA waiver and authorization language (when the relying site does not require a separate HIPAA authorization document)
- **Contact Information (or site-specific header, if added)**
  Local study team contact information
- **What do I have to do if I am in this research study?**
  Relying site-specific research activities that differ from those described in the BCH ICF template
- **Where appropriate**
  Content changes mandated per local laws, regulations, other federal/state requirements and/or institutional policy for which adequate justification and pertinent documentation is provided for BCH review/records.

BCH does not permit changes beyond the aforementioned during the reliance process. However, relying site and BCH investigators may discuss offline whether subsequent modifications are appropriate for the overall study/across all sites. If such is the case, an amendment is required for BCH IRB review/approval of proposed revision(s) to the ICF(s).

Relying Institution customization and BCH IRB approval/finalization of site-specific ICF(s)

The Relying Institution's Principal Investigator (PI) and/or Point of Contact (POC) is expected to take responsibility for working with their local HRPP/IRB/Reliance personnel to incorporate the above information into the ICF template(s). Once completed per local HRPP/IRB/reliance requirements, the relying institution POC forwards the ICF(s) to the BCH (Lead) Study Team. The BCH Study Team will then submit the edited, site-specific ICF(s) via an "Add Reliance on BCH" activity in CHeRP for BCH IRB review/final approval.

Per BCH IRB's established processes, an electronic stamp is used to indicate final approval of all relying site-specific ICFs. Once a relying site has been added to the protocol ("Add Reliance on BCH" completed), the BCH Study Team distributes the IRB-approved, site-specific ICF(s) to the Relying Institution's PI and/or POC.

Site-Specific ICF Changes Post Relying Institution Approval

If a Relying Site Study Team or Relying Institution requires changes to its language after BCH has finalized the site's ICF(s), an amendment is required for BCH IRB review and approval before the revised ICFs can be used locally. Content changes to site-specific consent forms that are requested after the relying institution approval, must be limited solely to those mandatory per local laws, regulations, other federal/state requirements and/or institutional policy. In those instances, BCH IRB will require documentation of the relevant, local regulations and/or institutional policy in order to review and approve the modification. Documentation may be provided in the form of a copy/link to the regulation(s) and/or policy(ies), or email confirmation of the same from the Relying Site Designee in the local IRB/HRPP office.