Boston Children's Hospital

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HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Boston Children's Hospital Institutional Review Board

Updated Informed Consent Template - July 2026

Introduction

We are pleased to announce that Boston Children's Hospital IRB has revised the BCH informed consent template. The IRB provides an informed consent template to assist PIs and research teams in developing research consent documents. We have worked with various individuals and departments across BCH to perform a comprehensive update. The new template is intended to be participant centered and includes simple lay language. It also sets expectations for the language inserted or created by investigators. The template provides universal formatting and identifies language that is either required by the IRB or is provided as a sample for researchers to use if they so choose.

The new ICF template is available on the IRB website. Use of the new ICF template will be required for NEW protocols submitted to the BCH IRB on or after October 1, 2026. There is no requirement for currently approved protocols to revise their consent forms. Detailed information on implementation of the new ICF templates may be found in the FAQ.

This ICF template update:

1. **Made consent forms easier to read:** IRB-required and sample language were revised to a 6th–8th grade reading level when possible, and investigators are expected to use a similar reading level in any new language they write or insert.

2. **Updated and expanded template language:** The template was revised to address common IRB findings and changes in the research environment, with input from BCH stakeholders to ensure alignment with IRB, regulatory, and institutional requirements.

3. **Improved usability of the template:** The format and structure were updated to make the template easier to navigate, and new instructional text was added to help research teams prepare consent forms**.**

4. **Identifies required and suggested language**: The template clearly differentiates between language that is either required by the IRB for all protocols, required as applicable, or is provided as a sample for researchers to use if they so choose.

To facilitate implementation of the NEW ICF templates, researchers may use the:

- Summary of Key Changes
- Frequently Asked Questions

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Summary of Key Changes

Section/Topic	Change to Updated ICF Template
GENERAL	Revised language to a 6-8 grade reading level when possible.
	Expanded instructions throughout the template to address common IRB review questions/requests.
Intro	Moved Contact Information section to beginning of document
Summary of Key Information	Transition from narrative to tabular format
Why is this research being done?	Added sample language for First-in-Human studies
What do I have to do if I am in this research study?	Expanded instructions to advise researchers on how to describe when procedures performed as part of clinical care will be modified for research or describing situations in which risks from clinical care will exist regardless of participation in research.
	Added sample language Long Term Follow-up for Investigational Gene Therapy Studies
What are the risks of this research study? What could go wrong?	Expanded instructions based on common IRB review requests to present the most significant and potentially related risks first.
	New instructions added to advise research teams when to include language on *Greater than usual chance of uncovering child abuse risk* and *Greater than usual chance of uncovering suicidal risk or risk of harming others*
	Potential risks to a fetus –restructured section; added instructions including advising researchers that the language should generally be used for participants aged 12 years and older. Pregnancy language directed only to minors pulled out and placed in separate assent template.
	Use of Audio and/or Video Recordings – added instructions and added new template language when recordings are made in participant's home
	Added new language to address risks of Investigational Gene Therapy
	Added new language to address Risk of *Required Anesthesia/Sedation for Research Purposes* and *Risk of Extending Anesthesia/ Sedation for Research Purposes*
	Removed section on *Research Imaging Study Results in Medical Records* as topic is covered in section *Participation may be noted in the participant's medical record*, which is required for all studies
	Added new language for Risk of Early Termination & Risks associated with QST

Section/Topic	Change to Updated ICF Template
What are the benefits of this study?	Expanded section to include new sample language for when there is no benefit or potential benefit from use of an investigational product, randomized to intervention, and no randomization/one benefit group.
Will I receive my study results?	Restructured section to provide additional instructions and clearer language options for return of non-genetic research results. Added section for return of genetic research results; clarified use of CLIA-certified labs language; added language for incidental/secondary genetic research findings.
	Added new language to disclose review of behavioral questionnaires in *Mental Health Safety Plans in Research*
Are there costs associated with this research? Will I receive any payments?	Added new language in the *Injury Language for greater than minimal risk research section* for studies funded by the Department of Defense.
Will my samples/information be used for research in the future?	Restructured section and added clarifying instructions Added sample language for when Information will be entered into the National Institutes of Mental Health Data Archive
Who may see, use or share your health information?	Added section with required language for FDA-regulated studies that discloses the possibility of FDA inspection of records
	Added section for Mandated Infectious Disease Reporting
What should you know about HIPAA and confidentiality?	Added new language, "This authorization to use or disclose your data will not automatically expire (i.e., is not time-limited)."
Documentation of Informed Consent	Added "Print Name" to signature sections

Frequently Asked Questions

1. Why was the ICF template updated?

The ICF template is considered a "living document" and is revised as needed, for example, when regulatory or institutional requirements change, or when the research environment evolves. In addition, the IRB continually assesses the needs of research participants and the BCH research community. The new template is intended to be participant centered and includes simple lay language. It also sets expectations for the language inserted or created by investigators.

2. When must the new ICF template be used?

- New protocols submitted to the IRB on or after October 1, 2026 must use the new ICF template format and language.
- Because IRB submission happens after scientific review and departmental review, teams should plan accordingly.
- Protocols already under IRB review as of October 1, 2026, do not need to be updated, although certain new required language may still be requested during review if applicable.
- We are encouraging research teams to use the new template as soon as possible, therefore we have removed the previous template from the IRB website.

3. Besides the requirement to use template language, are there other expectations for consent forms submitted on or after October 1, 2026?

Yes. The goal of the template is to set expectations for simplifying the entire informed consent form. Any language inserted or developed by investigators should generally meet a 6th- to 8th-grade reading level. We recognize that medical terminology may make it difficult to achieve that level in every instance, but it should be possible in most sections. During the review process, the IRB will take reading level into consideration and may request revisions as needed.

4. My protocol is in scientific review or department review, am I required to update to the new ICF template?

Possibly. If your protocol is still in scientific or departmental review **close to October 1, 2026**, it may not be submitted to the IRB until on or after that date. If so, the new ICF template will be required.

5. My protocol is currently under review with the IRB, do I need to update the consent form?

- No. If your consent form is already under IRB review, you do not need to update it to the new ICF template.
- If you want to make the update anyway, you may ask the IRB Analyst to return the submission to you. Depending on where the study is in the review process, you may then revise the consent form using the new template language.

6. My protocol is approved. Do I need to update the informed consent?

No. Approved consent forms do not need to be updated to the new ICF template. If you would like to update an approved consent form, you must submit an amendment.

7. Am I required to use the new consent template for Amendments that add new consent forms to an approved study?

No. The IRB does not require the new template is used for Amendments submitting a new ICF for an already-approved protocol that has existing approved consent forms.

Study teams are welcome to unify ALL consent forms to the new template in an Amendment, but the IRB does NOT recommend using different consent templates for the same study.

8. If I submit an amendment to revise the consent for newly enrolled participants, am I required to reconsent previously enrolled participants?

Generally, no. Changes to template language alone usually do not qualify as significant new information, so the BCH IRB would not typically require previously enrolled participants to be re-consented. However, external sponsors may have different requirements.

9. My protocol is reviewed by an external IRB, what should I do?

- Use of the full BCH ICF template is not required for protocols reviewed by an external IRB.
- However, certain BCH-specific consent language is still required, and the sIRB team will continue to add those edits during the initial Reliance on Another IRB submission.
- There is no requirement to update consent forms already approved by an external IRB.

Questions on this process should be directed to reliance@childrens.harvard.edu

10. Am I required to use the language provided in the template?

The ICF template is structured such that there are three categories of language provided in the ICF template:

1. Language that is ***required for all protocols.***
   Language marked as "Required for all protocols" is required to be included in ALL consent forms. No modifications to the language is permitted.

2. Language that is ***required when applicable.***
   Language marked as "required when applicable" is required to be included in consent forms when the topic is applicable to the research. No modifications to the language is permitted.

3. Language that is "Sample language when applicable".
   Language that is marked "sample language when applicable" means the language provided is an option for researchers to use, and alternate language can be used. Please note that while the sample language in provided in this category is optional, the *topic* must be addressed when applicable to the research.

It is important to note that the updated consent template generally includes language written at or below a 6th-8th grade reading level. The IRB expects that any language added to the consent form is at a similar reading level.

11. When I develop new language for the consent form, how can I be sure it's at an appropriate reading level?

The IRB encourages Investigators and Research teams to utilize a variety of resources to confirm that language included in an informed consent document is generally at or below a 6th- 8th grade reading level. The template instructions provide samples of resources, but this list is not exhaustive, and you are encouraged to use any other tools that may be useful.

- Reading level can be measured by various methods; a common scale is the Flesch-Kincaid Grade Level test.
- Consider using a readability tool to ensure your proposed language meets the goal of a 6th- 8th grade reading level. The following readability tools are examples that are publicly available:
  - https://hemingwayapp.com/articles/readability/flesch-kincaid-readability-test
  - https://humantone.io/tool/readability/
  - https://storytoolz.com/readability
  - https://www.webfx.com/tools/read-able/

- Use active voice to simplify text and keep the tone conversational. For example, instead of saying, "A sample will be collected" say, "A study team nurse will collect your sample."
- Avoid the use of complex medical and/or research terminology. Consult the links below for alternative language and see the tables below for some suggestions:
    - Harvard Catalyst Plain Language Checklist
    - MRCT Clinical Research Glossary
    - University of Michigan plain language medical dictionary
    - CDC Everyday Words for Public Health Communication

12. May I use AI tools like ChatGPT to help simplify informed consent language?

Yes. Tools such as the BCH internal ChatGPT may be helpful in simplifying informed consent documents. Please keep the following in mind:

- The internal version of ChatGPT should be used. If you need access, please visit the BCH AI Resource Hub for instructions.
- Institutional policies regarding the use of AI must be followed.
- Investigators are responsible for complying with any sponsor requirements or restrictions related to the use of AI.
- AI should be viewed as a helpful tool, but all output must be carefully reviewed and verified by the research team. Suggested changes may not always reflect the concepts you intend to convey accurately.

13. How can I provide feedback on the new ICF template?

The IRB would like to hear your feedback on the new ICF template. You can provide feedback by emailing irb@childrens.harvard.edu.