Boston Children's Hospital

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HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Institutional Review Board

Guidance on Informed Consent & Research Documentation in EPIC

March 2025

Introduction

EPIC is an integrated Electronic Health Record which facilitates clinical and research workflows at Boston Children's Hospital. With the roll-out of EPIC, research study records are created from the CHeRP IRB submission, and the study record is pushed to EPIC through OnCore.

The use of many research tools in EPIC requires that research participants be associated with the research study record in EPIC. The patient study association allows study teams to use many downstream tools in the EPIC Research Module such as order and encounter linking for charge routing, notifications when the participant is admitted, cancels or reschedules an appointment, release to monitors for review sessions, and more.

To ensure transparency with participants and families, the IRB has revised the informed consent template language to communicate how involvement in research is documented in EPIC.

This guidance was developed to:

1. Inform the research community of the new required consent template language.
2. Identify the approved protocols which are required to submit an amendment to update language in the consent form and/or inform participants of this change.
3. Provide instructions to research teams working on protocols reviewed by an external IRB.

The document is structured to answer anticipated questions from the research community and may be updated as new questions or issues are raised.

A webinar is scheduled on Wednesday March 26 at 12PM to review this guidance and answer any questions you may have. Please register for the webinar here.

Boston Children's Hospital Institutional Review Board
Guidance on Informed Consent & Research Documentation in EPIC
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Guidance Q&A

1. What is the new template language?

The informed consent template on the IRB website has been revised to:

> *Your participation in this research study may be noted in your electronic medical record. If you do not have an existing medical record, one may be created. Information placed in your medical record may include the informed consent or the results of tests or assessments we collect during the research. This could be viewed by staff from Boston Children's Hospital, study monitors and others who provide oversight of the study. Everyone who sees this information is required to keep it confidential in accordance with hospital policies and laws. Information about your research participation may not be given to anyone unaffiliated with Boston Children's Hospital in a way you can be identified unless we obtain your permission, or it is permitted or required by law.*

2. What protocols are required to use the new template language?

- New protocols submitted to the IRB on or after April 1, 2025, are required to use the new template language.
- New protocols under review with the IRB as of April 1, 2025, will be required to update their consent forms to the new language before the protocol can be approved.
- Approved protocols should follow instructions provided in Question 8.

3. My protocol is currently in scientific review, how can I update the consent form?

- Once Scientific review is complete the submission will be returned to the study team in CHeRP. When this happens, the team can navigate to the Written Informed Consent and use "upload revision" to upload the consent form with the new template language.
- Once the consent form is updated, please submit the application to the IRB.

4. My protocol is currently in department review, can I update the consent form?

No. Once department review is complete, the protocol is automatically submitted to the IRB. Your IRB analyst will return the submission to you and request the consent form be edited to included new template language. This will likely be part of the analyst review process.

5. My protocol is currently with the IRB, how can I update the consent form?

Your IRB analyst will return the submission to you and request the consent form be edited to included new template language before the protocol is approved.

6. My research does not recruit patients from BCH. Do I still need to include this template language in the consent form?

We request that all consent forms include the new language which contemplates that research participation may be documented in the medical record. However, we recognize some investigators do not recruit from the Boston Children's patient population and do not intend to associate research participants with the research study record in EPIC.

In these situations, investigators may consider removing template language and explain why it is not required in the Written Consent of the Smartform. It is also important to note that EPIC records can be created for participants who are not BCH patients, and the template language may be important to include. Investigators should carefully consider this and review information on the EPIC Research Tools. Please reach out CRO with any questions.

7. The previous Boston Children's informed consent template contained language on whether the informed consent and study results would be put in the medical record. Is that language being removed from the template?

Yes. The following statements have been removed from the informed consent template and will no longer be used for NEW protocols approved by the BCH IRB as of April 1, 2025.

a) *If you are not currently a patient at Boston Children's Hospital and do not have a medical record at Boston Children's Hospital, one may be created for you for your participation in this research. You may also be required to register as a patient of Boston Children's Hospital in order to participate in this research.*
b) *A copy of this consent form will be placed in your medical record. If you do not have a medical record at Boston Children's Hospital, one will be created for you.*
c) *Information collected during this research will become part of your medical record, if the information is related to the care you receive at Boston Children's Hospital. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Boston Children's Hospital and may be reviewed by Hospital staff when carrying out their responsibilities; however, they are required to maintain confidentiality in accordance with applicable laws and Hospital policies. Information contained in your medical record may not be given to*

anyone unaffiliated with Boston Children's Hospital in a way that could identify you without written consent, except as required or permitted by law.

d) *A copy of this consent form will not be placed in your medical record.*

e) *The results of the tests performed for research purposes will not be placed in your medical record. Because of this, it is unlikely that others within the hospital, an insurance company, or employer would ever learn of such results.*

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

Investigators and research team members need to review the current approved consent form to determine if there is a statement in the consent form which conveys that no research documentation will be placed in the medical record, e.g., statements d) and e).

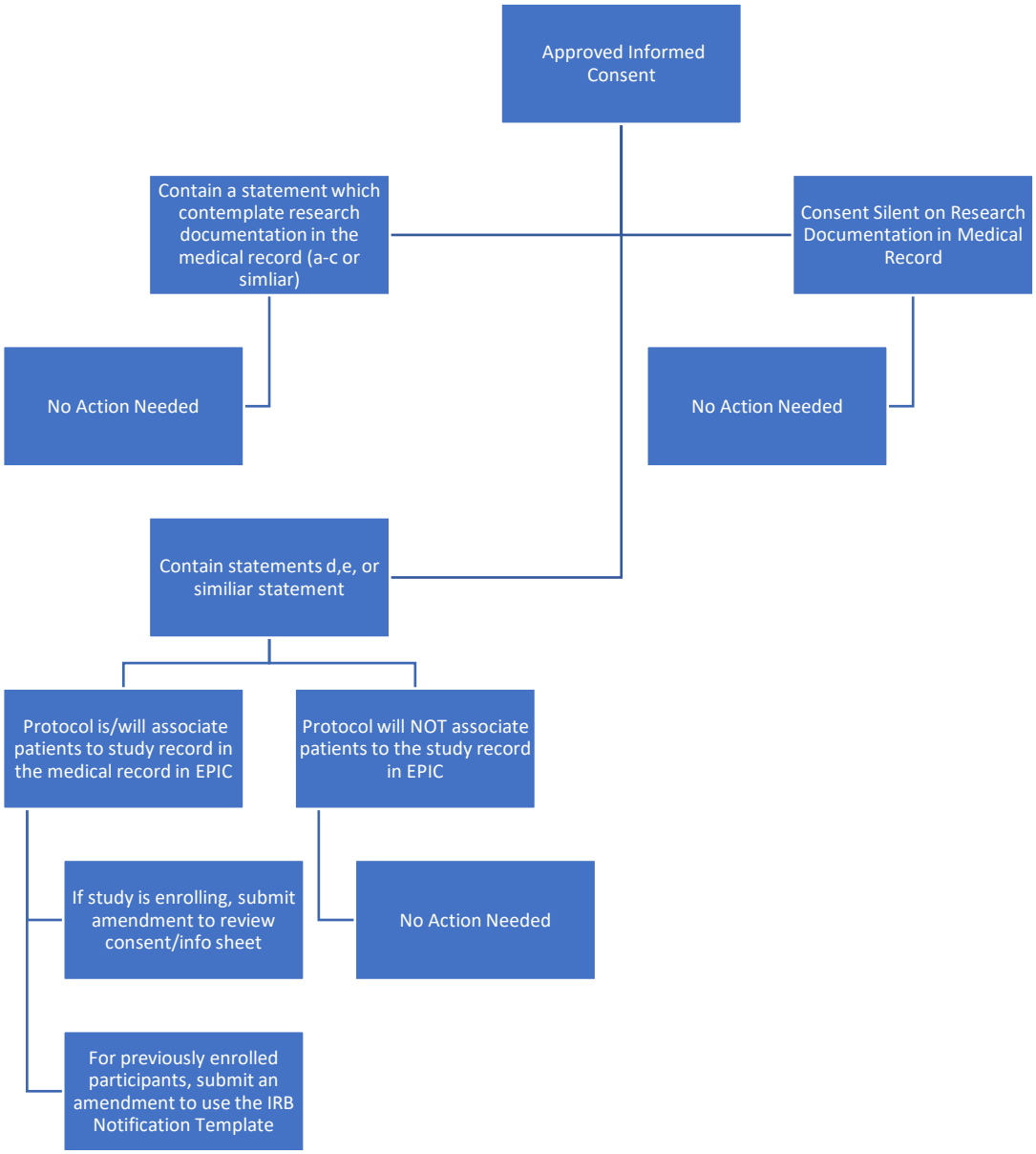
If the approved consent contained these statements, or similar statements:

- Protocols actively enrolling participants AND have or plan to associate patients to a study record in EPIC, must submit an amendment to update the consent to the revised language.

Protocols which have enrolled participants AND have or plan to associate patients to a study record in EPIC, must inform participants of this change. A Notification Letter (Appendix 1) has been developed by the IRB to inform participants/families that due to the hospital's transition to EPIC, research documentation may be included in their medical record. You will need to submit an amendment to inform the IRB that you will be distributing the Notification letter.

The IRB has also prepared an Action Determination Flowchart to assist researchers in determining whether any action is needed.

Figure 1. Action Determination Flowchart



9. My protocol requires that we submit an amendment, what should we do?

1) Confirm your protocol approved consent form contains statements d), e), or similar. statement. If you are unsure reach out to irb@childrens.harvard.edu.
2) Confirm your protocol has already, or plans to, associate patients to the study record in EPIC. If you have questions on the process for associating patients to the study record, reach out to CRO.
3) Once you have confirmed 1 & 2, submit an amendment to include:
    - For protocols that are currently enrolling, revise informed consent with NEW template language.
    - For protocols where existing participants have or will have a patient association to the study record in EPIC, submit an amendment to include the Notification Letter (Appendix 1).
    - Be sure to include a description of how you will provide the Notification Letter to participants in the Amendment form. The IRB will rely on the investigator to determine the best way to do this. We would find all the following acceptable: provide at time of next study visit, through the mail, secure email, or unsecured email if participants/families provided consent to use unsecure email. Other ways of providing the Notification may also be acceptable.
    - The Notification Letter should be uploaded to Additional Document Smartform. As the Notification Letter is not an informed consent document, the IRB will not stamp these documents and there is no requirement to obtain signatures from participants or families.
    - All amendments will be reviewed and approved through Expedited Review.
    - No changes are required to CHeRP Smartforms.

10. If applicable, do I need to notify all research participants even if they already completed the research?

The IRB requirement is to notify only those participants who will be impacted by this change. This means you will need notify research participants who signed an informed consent which indicated there would be no research documentation in the medical record and for whom there is a patient association to the study record in EPIC. Keep in mind the IRB is only requesting:

- If the consent signed contained statements about any research documentation in the medical record, the IRB would not require any notification.
- If the approved consent is silent on research documentation in the medical record no action is needed as there is no information to be corrected.

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

No. The IRB developed the Notification Letter to inform research participants who signed an informed consent which indicated there would be no research documentation in the medical record and for whom there is a patient association to the study record in EPIC. However, you always have the option to reconsent participants instead of providing the Notification Letter. If you choose to reconsent participants, please provide details of this plan in the Amendment Smartform.

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

- For "Reliance on Another IRB" applications that are currently in process, the IRB office will update all consent/information sheets with the new template language and return it to the research team for submission to the external IRB.
- For approved "Reliance on Another IRB" protocols, study teams should use the flowchart above to determine if any revision is needed to the approved consent form or whether Notification Letter is required to inform enrolled participants.
- If revision to the approved consent form is required and/or Notification of enrolled participants is required, an amendment should be submitted to the external IRB updating the Boston Children consent form and/or providing the Notification Letter. The reliance team has prepared a letter for external IRBs (Appendix 2) which should also be submitted to the external IRB.
- Once the external IRB has approved the revised consent/info sheet and/or Notification Letter, the research team should submit an amendment in CHeRP including the approved consent form/info sheet and/or Notification Letter.
- Questions on this process should be directed to reliance@childrens.harvard.edu.

Appendix 1. NOTIFICATION LETTER TEMPLATE

Protocol: IRB-[identifier]

IRB Protocol Title: [title]

Date: [date]

Dear [Research Participant]:

You are receiving this communication because you are a participant in the research study listed above. The purpose of this letter is to notify you of a change to the information in the consent form that you read and signed.

Boston Children's Hospital has recently implemented a new electronic medical record (EMR) system. The new electronic system includes information about individuals that participate in research. This change was made to facilitate clinical research operations such as scheduling, billing, ordering tests and communicating with participants. Your medical record now includes reference to participating in the research noted above. All other information contained in the original consent form remains unchanged. Your medical record is protected in accordance with the with hospital policies and laws. Information about your research participation may not be given to anyone unaffiliated with Boston Children's Hospital in a way you can be identified unless we obtain your permission, or it is permitted or required by law.

You can talk to a research team member about any questions.

Please contact [****].

If you have questions about your rights as a research participant, please email irb@childrens.harvard.edu.

Thank you.

[PI name]

[PI contact information]

Appendix 2. NOTIFICATION LETTER FOR EXTERNAL IRB

To: External IRBs reviewing Boston Children's human research studies

RE: Update to Informed Consent Template due to EPIC

EPIC is an integrated Electronic Health Record which facilitates clinical and research workflows at Boston Children's Hospital. With the roll-out of EPIC at Boston Children's Hospital, utilization of the EPIC research tools (for example, tools which facilitate research ordering and billing) requires that research participants be associated with the research study record in EPIC. To ensure participant and families are informed that participation in research may be documented in the patient electronic medical the Boston Children's IRB had updated the informed consent template to include the following:

> *Your participation in this research study may be noted in your electronic medical record. If you do not have an existing medical record, one may be created. Information placed in your medical record may include the informed consent or the results of tests or assessments we collect during the research. This could be viewed by staff from Boston Children's Hospital, study monitors and others who provide oversight of the study. Everyone who sees this information is required to keep it confidential in accordance with hospital policies and laws. Information about your research participation may not be given to anyone unaffiliated with Boston Children's Hospital in a way you can be identified unless we obtain your permission, or it is permitted or required by law.*

Effective April 1, 2025, the above language is required in the consent form for all new human research studies. This includes studies seeking reliance on an external IRB. Boston Children research teams are instructed to submit a Reliance on Another IRB in the CHeRP IRB submission system to formally request reliance and prompt local context and ancillary review. The Boston Children's sIRB team will review all Reliance on Another IRB submissions and ensure the consent form submitted to the external IRB contains the required institutional language.

For studies previously approved by an external IRB, Boston Children's researchers are required to review their current approved consent form to determine if the consent form contains either of the two previous consent template statements.

a) *A copy of this consent form will not be placed in your medical record.*
b) *The results of the tests performed for research purposes will not be placed in your medical record. Because of this, it is unlikely that others within the hospital, an insurance company, or employer would ever learn of such results.*

If researcher confirms that the approved consent contains a and b above, an amendment must be submitted to the external IRB:

- For protocols that are currently enrolling, research teams must revise the informed consent to remove statements a and b above and include the NEW template language.
- For protocols where existing participants have or will have a patient association to the study record in EPIC, Boston Children's require participant and families be informed. The IRB developed a Notification Letter to inform research participants who signed an informed consent which indicated there would be no research documentation in the medical record and for whom there is a patient association to the study record in EPIC. Boston Children's researcher are asked to submit the Notification Letter to the external IRB via an amendment. Once approved by the external IRB, research teams are responsible for providing the Notification Letter to participants/families.
- For studies approved by the Boston Children's IRB, "reconsent" is not required and study teams will be encouraged to use the Notification Letter to inform participants and families of this change. However, we recognize that external IRBs may require Boston Children's research teams reconsent participants instead of providing the Notification Letter.

Questions related to this change in Boston Children's local consent language may be directed to reliance@childrens.harvard.edu.