Pitt Research
Office of Research Protections

University of Pittsburgh
Human Research Protection
Guidance on Informed Consent & Research Documentation in Epic

September 2026

Introduction

Epic is an integrated Electronic Health Record that facilitates clinical and research workflows at UPMC. Many of the research tools in Epic require 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 a modification 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.

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Guidance Q&A

1. What is the new template language?

The Building Your Consent guidance on the HRP website has been revised to include the following paragraph:

> **What is an Electronic Medical Record (EMR) and what research information may be included in the EMR?**
>
> *<<This language is required for all studies that have Medicare Coverage Analysis (MCA) and any study where inclusion of information in the EMR is possible. >>*
>
> An Electronic Medical Record (EMR) is the electronic system UPMC uses to store your medical chart. If you have never been seen at UPMC before, a new medical record will be created for you in this system as part of this study.
>
> Some information from this study will be put in your patient medical record. Examples include your consent form, test results, and scheduled procedures as well as any communications with the study team or assessments completed through MyChart, a portal used by patients to access their patient medical record. This information will be visible to any of your providers who view your patient medical record.
>
> The information in your patient medical record may also be used and shared consistent with other medical information about you as described in the UPMC Notice of Privacy Practices.
>
> Information within your patient medical record can be accessible to others (e.g., health insurance company, life insurance company, disability provider, third-parties specified in this consent). It is possible this information could be used to make decisions about coverage.
>
> If you have any questions about what information may be added to your patient medical record from participating in this research, please ask the study team. If you do not want information from this research study included in your medical record you should not participate in this study.

<<Add this sentence if it is not included in the costs section because there is no MCA:>>

We are required to collect information about your health insurance to register you in our medical record system as a participant and for billing, if applicable. If you do not have health insurance, this does not preclude you from participating in a research study.

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

- New protocols submitted to the IRB on or after October 15, 2026, are required to use the new language template.
- New protocols under review with the IRB as of October 15, 2026, 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 5.

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

Once Scientific Review is complete a pre-review will be conducted and a comment included to update the consent document with the new language.

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

While recruitment might not take place within a UPMC facility, if your study uses any UPMC or CTRC resources, the new language must be included in the consent document. It is recognized that some investigators do not use UPMC or CTRC resources and do not intend to associate research participants with the research study record in Epic. In these situations, investigators may revise the language for review by the IRB.

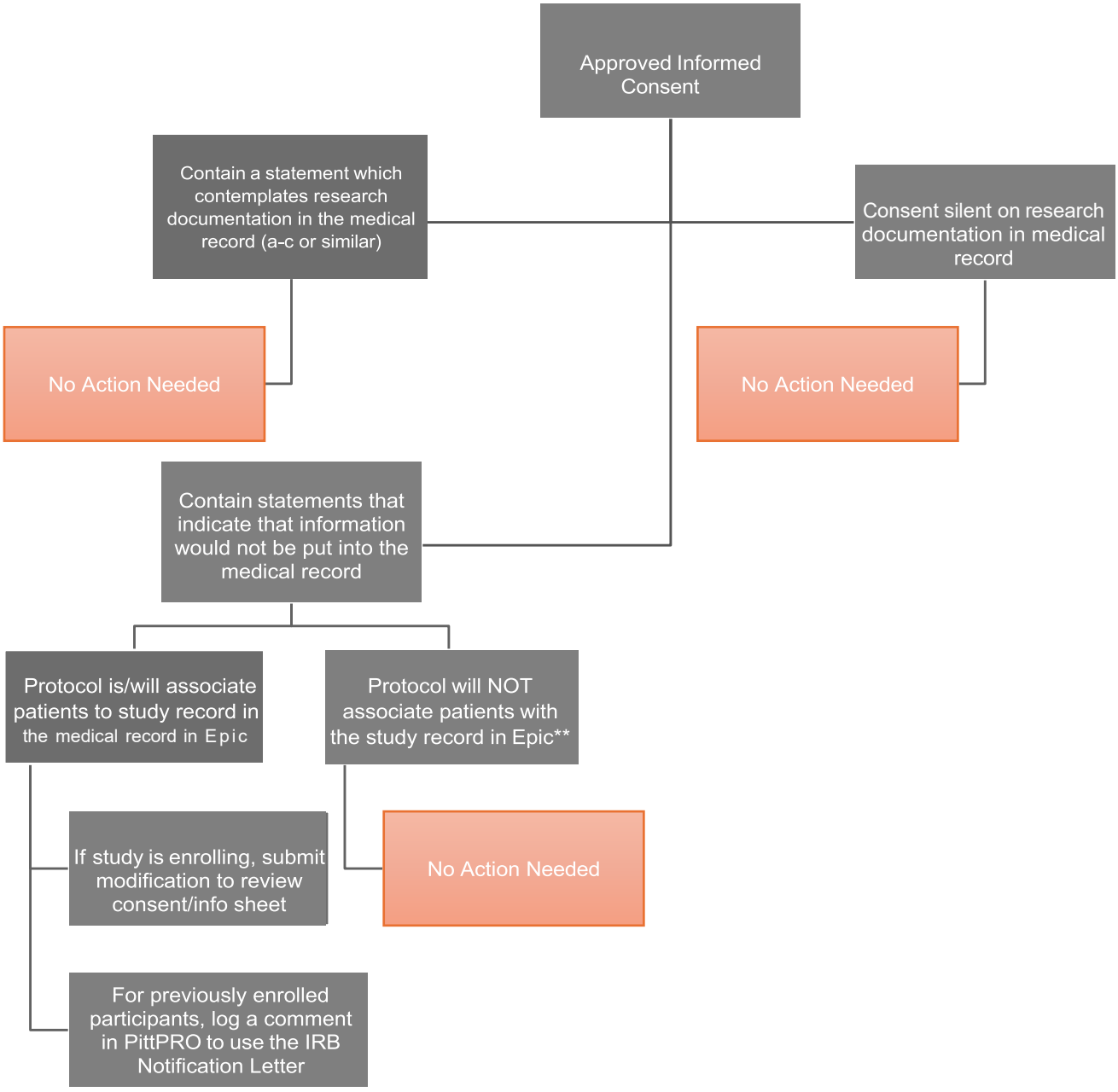
5. My protocol is approved. Do I need to update the informed consent?

Investigators and research team members need to review the currently approved consent form to determine if there is a statement in the consent form that states or implies that research documentation will not be placed in the medical record.

If the approved consent form states or implies that research documentation **will not** be placed in the medical record, take the following action:

- Protocols that are actively enrolling participants AND are required to associate patients with a study record in Epic must submit a modification through PittPRO to update the consent form to the revised language.
- Protocols that have enrolled participants AND have already, or plan to associate patients with a study record in Epic, must also 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 log a comment in the study history in PittPRO to inform the IRB that you will be distributing the Notification Letter.** If you are using another method than the Notification Letter or making additional changes, you will need to submit a modification.

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



** This would include observational studies without a physical intervention (e.g., surveys, interviews), studies with no clinical services provided, and data (not including specimens) collection for a research repository or registry

6. My protocol requires that we submit a modification, what should we do?

a) Confirm that your protocol/approved consent form does not adequately state that the study record will be in the medical record. If you are unsure reach out to askirb@pitt.edu

b) Confirm your protocol has already, or plans to associate patients with the study record in Epic. If you have questions on the process for associating patients to the study record, please submit a ticket to the Bridges Epic Research team. *This may be accomplished through the Epic application using the EMR Help functionality or by calling the UPMC Help Desk at 412-647-4357*.

c) Once you have confirmed a & b, submit either a modification in PittPRO or a comment in PittPRO in the study history:

- For protocols that are currently enrolling, revise informed consent with NEW template language (see #1 Q&A above).
- For protocols where existing participants have or will have a patient association to the study record in Epic, log a comment in PittPRO to include the Notification Letter (Appendix 1).
- Be sure to include a description within the comment of how you will provide the Notification Letter to participants in the PittPRO comment. 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
- Please review the PittPRO application and make changes to the following sections as applicable:
  - **Consent Process:**
    - New Studies: no additional information is needed
    - Modifications: if a reconsent process will take place, update this section.

- **Medical Records:** Include what information will be reflected in the medical record from services completed at a UPMC facility. It is not required that the Informed Consent be put into the medical record, but if it is, that should be included.
- **Return of Results:** If services will be completed at a UPMC facility, and the Epic record is not marked to withhold results from the participant, study teams should choose "routinely" under question #1 and then provide responses to the remaining questions

7. 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 to notify research participants who signed an informed consent that 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:

- If the consent signed contained accurate statements about research documentation in the medical record, participant notification is not required.
- 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.

8. If I submit a modification 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 that 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, you will need to submit a modification.

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

- For ceded applications (reliance on another IRB) that are currently in process, the IRB office will update all information sheets with the new template language and return it to the research team for submission to the external IRB.
- For approved ceded applications, 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, a modification should be submitted to the external IRB for approval of the revised consent form and/or Notification Letter prior to providing new information to participants. 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 Notification Letter, the research team should submit a modification to the PittPRO Reliance application including the approved consent form/info sheet and/or Notification Letter.

Questions on this process should be directed to irb.reliance@pitt.edu

Appendix 1. NOTIFICATION LETTER TEMPLATE

Protocol: STUDY[identifier]

IRB Protocol Title: [title]

Date: [date]

Dear [Research Participant]:

You are receiving this letter 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.

Our healthcare partner, UPMC, recently put a new electronic medical record (EMR) system in place. The new electronic system includes information about people who participate in research. This change streamlines 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 under hospital policies and laws. Information about your research participation will not be given to anyone unaffiliated with UPMC in a way you can be identified unless we obtain your permission, or it is permitted or required by law. If you don't have a medical record at UPMC, one will be created for you.

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 askirb@pitt.edu.

Thank you.

[Pl name]

[Pl contact information]

Appendix 2. NOTIFICATION LETTER FOR EXTERNAL IRB

To: External IRBs reviewing University of Pittsburgh human research

RE: Update to Informed Consent Template due to Epic

Epic is an integrated Electronic Health Record which facilitates clinical and research workflows at our healthcare partner, UPMC. With the roll-out of Epic at UPMC, 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 University of Pittsburgh IRB had updated the informed consent template to include the following:

> **What is an Electronic Medical Record (EMR) and what research information may be included in the EMR?**
>
> *<<This language is required for all studies that have Medicare Coverage Analysis (MCA) and any study where inclusion of information in the EMR is possible. >>*
>
> An Electronic Medical Record (EMR) is an electronic version of your medical chart. If you do not already have an EMR at UPMC, one may be created for this study. Some information from this study will be put in your EMR. Examples include your consent form, test results, and scheduled procedures as well as any communications with the study team or assessments completed through MyChart, a portal used by patients to access their EMR. This information will be visible to any of your providers who view your EMR.
>
> The information in your EMR may also be used and shared consistent with other medical information about you as described in the UPMC Notice of Privacy Practices.
>
> Information within your EMR can be accessible to others (e.g., health insurance company, life insurance company, disability provider, third-parties specified in this consent). It is possible this information could be used to make decisions about coverage.

If you have any questions about what information may be added to your EMR from participating in this research, please ask the study team. If you do not want information from this research study included in your medical record you should not participate in this study.

<<Add this sentence if it is not included in the costs section because there is no MCA:>>

We are required to collect information about your health insurance to register you in our medical record system as a participant and for billing, if applicable.

Effective October 15, 2026, the above language is required in the consent form for all new human research studies where UPMC resources are being utilized. This includes studies seeking reliance on an external IRB. The University of Pittsburgh Reliance team will review all ceded applications and ensure the consent form submitted to the external IRB contains the required institutional language.

For studies previously approved by an external IRB, University of Pittsburgh researchers are required to review their current approved consent form to determine if the consent form included statements that no information would be included in consent forms. If that type of language appeared:

- **For protocols that are currently enrolling**, research teams must revise the informed consent to remove those statements and include the NEW template language.
- **For protocols where existing participants have or will have a patient association to the study record in Epic**, University of Pittsburgh 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. University of Pittsburgh researchers are asked to submit the Notification Letter to the external IRB via a modification. Once approved by the external IRB, research teams are responsible for providing the Notification Letter to participants/families.
- **For studies approved by the University of Pittsburgh 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 University of Pittsburgh research teams to reconsent participants instead of providing the Notification Letter.

Questions related to this change in University of Pittsburgh's local consent language may be directed to irb.reliance@pitt.edu.