

1/16/2020

Consent Form Requirements for Studies Linked in Epic

Certain studies that involve patients of or procedures at Columbia University Irving Medical Center (CUIMC) and/or NewYork-Presbyterian Hospital will be linked in the new electronic health record, Epic, that will launch at CUIMC on February 1, 2020. The medical record of participants in those studies will include documentation of their participation.

What studies will be linked in Epic?

- Clinical trials involving drugs and devices
- Clinical research with research billable events

Research participants whose study involvement will be documented in Epic must receive the following new information: *“- Your participation in this research study will be documented in your electronic medical record and can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and NYP affiliate institutions who are involved in your health care.”*

For IRB-approved Studies with Active Participants at Epic launch

- Options to inform previously enrolled participants
 - Provide participants with a consent form addendum that includes the new information but does not require a signature; documentation in the research record is required.
 - Modify the IRB-approved consent form to include the new information, in the Confidentiality section, and re-consent participants.
- IRB review:
 - A modification to the protocol is not required prior to providing the addendum to the participants; however, the IRB must be informed, at the time of the next IRB submission for this study, of the option that was used. If the next submission will be more than six months after the Epic launch, a modification solely to address this notification is required within six months post-launch.
 - A modification to the protocol and IRB approval is required if the consent form will be revised. This is necessary so the version of the consent form that is used will be documented in Rascal.
- Participants should be notified as soon as possible but not later than three months after Epic launch.

For IRB-approved Studies Open to Enrollment at Epic Launch

- Options for new enrollment
 - At the time of enrollment, provide participants with a consent form addendum that includes the new information.
 - At the time of enrollment, provide participants with a consent form that has been revised to include the new information.
- IRB review:
 - A modification to the protocol is not required prior to providing the addendum to the participants; however, the IRB must be informed, at the time of the next IRB submission for this study, of the option that was used. If the next submission will be

1/16/2020

more than six months after the Epic launch, a modification solely to address this notification is required within six months post-launch.

- A modification to the protocol and IRB approval is required if the consent form will be revised. This is necessary so the version of the consent form that is used will be documented in Rascal.
- Participants must be notified at the time of enrollment.

For Not-Yet-IRB-approved Studies

- The consent form must include the new information