MONTHLY IRB-INVESTIGATOR MEETING

Columbia University
Human Research Protection Office

February 6, 2020

COLUMBIA | COLUMBIA UNIVERSITY IRVING MEDICAL CENTER

Agenda

Impact of Epic functionality for certain research studies

- Studies that have to be in Epic
- Confidentiality language in CFs
- Identifying study participants
- HIPAA requirements

Studies that have to be in Epic

- Clinical trials involving a drug or device
  - CUIMC/NYP
- Clinical research studies with a research billable event
  - “Research billable” is any visit, clinical test, procedure, or service at NYP or CUIMC billed to the research funding

Keep in mind….

- In the legacy system iNYP, a subject's participation in a clinical trial was identified for safety purposes via IBM CTMS.
- Present and historical study participation was transferred to Epic for active studies in IBM CTMS.
  - For these participants, the new information is that WCMC and affiliate personnel will have access to the study information in Epic
- New Studies now needed in CTMS/Epic to link patients to studies.
  - For other participants, new information may also be that they have a medical record and/or that their study participation is reflected there.

Informing participants

- The Epic medical record of research participants enrolled in these studies will reflect their participation These participants must be informed of this:
  - *"- Your participation in this research study will be documented in your electronic medical record. This record 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, because these institutions share an electronic medical record system. Study monitors may also need to access this record."* (v2)

**This version is not yet IRB approved*

Participants to be informed

- Current participants
  - Addendum to consent form for current participants (v2)
  - Revised consent form and re-consent
- Past participants if linked in Epic
  - Addendum to consent form for past participants (new)
- Future participants
  - Addendum (v2; limited – prior to CF revision only)
  - Revised consent form

Timing/processes vary for:

- Already enrolled participants and past participants
  - Participants should be notified asap, and not later than 3 mo.
  - Submit modification for each protocol w/in 6 mo.
- Participants enrolled soon after Epic launch
  - Submit modification for each protocol w/in 6 mo.
- Studies not yet approved
  - Incorporate language into consent form

Special considerations

- Sponsors may not allow use of an addendum and/or may require signature
- If the reviewing IRB is not Columbia, approval from the reviewing IRB is required
- Revised boilerplate language is being submitted to NCI CIRB
- Spanish translation of the addendum for current participants (v1) is available.
  - Spanish translations of the other documents will be available

Rascal CF Builder sample language

- [***ADD, IF THIS STUDY WILL BE LINKED IN EPIC AT CUIMC/NYPH:***] Your participation in this research study will be documented in your electronic medical record. This record 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, because these institutions share an electronic medical record system. Study monitors may also need to access this record.

This version is not yet IRB-approved.

Sponsored, FDA-regulated, NYP example

The following individuals and/or agencies will be able to look at, copy, use, and share your research information:

- The investigator, Columbia University Irving Medical Center and NewYork-Presbyterian Hospital study staff and other medical professionals who may be evaluating the study or providing services for the study;

- Authorities from Columbia University and NewYork-Presbyterian Hospital, including the Institutional Review Board ('IRB');

- The Office for Human Research Protections ('OHRP') and the United States Food and Drug Administration ('FDA');

- The sponsor of this study, New Drug Company, including persons or organizations working with or owned by the sponsor;

- Other government regulatory agencies (including agencies in other countries) if the sponsor is seeking marketing approval for new products resulting from this research.

Your participation in this research study will be documented in your electronic medical record. This record 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, because these institutions share the electronic medical record system. Study monitors may also need to access this record.

Process

- Document how and when current and past participants were notified.
- Reminder: Epic is an electronic medical record, not a research chart.
  - Study specific documents must be maintained in a separate research chart outside of Epic.
- Refer any questions about informing participants – or concerns expressed by participants - to the HRPO/IRB: irboffice@columbia.edu.

Pre-consent Status

- "Pre-Consent for Epic Encounter Linking" - Active enrollment status in CTMS and Epic to enable linking of a visit and/or test to research prior to signing consent.
- Potential research subjects may need to be registered in Epic with a medical record number (MRN) and identified in CTMS and Epic as a potential subject prior to signing consent.
- Person has been recruited (perhaps by phone or through discussion with a health care provider), and is eligible.
- Scheduling of the visit and ordering of procedures/tests under a research protocol prior to signing consent in anticipation of the study visit is necessary.

“Pre-consent” procedures

- When scheduling visit/tests with prospective participants, inform them of the medical record creation and linkage to the study.
- Once the participant provides consent, the status should be changed to “Consented-In screening”
- If the person does not come to the visit, or declines to participate, the status should be changed to “Declined”
- Linkage to the study remains in their medical record in Epic, whether person provides consent or declines.

IRB/Privacy Board requirements

- Describe procedures in Recruitment and Consent section of Rascal
  - Indicate that the pre-consent status will be used
    - Constitutes alteration of authorization
  - Include that notification of linkage in Epic will be provided to prospective participant and participant verbally agrees
    - Document in research record
- Attach necessary HIPAA forms

HIPAA requirements for “Pre-consent” status

Requirements depend on manner of recruitment

Scenario	Study team will initiate contact; Prospective subject is a patient (has MRN in our system) and EHR info will be accessed to identify eligible patients.	Study team will initiate contact; Prospective subject is not a patient or it is unknown if he/she is a patient (i.e., not using EHR to identify eligible individuals).	Prospective subject initiates contact; may or may not be a patient but initiates contact with the study team about the study (e.g., after seeing a flyer etc.).

Scenario	Study team will initiate contact; Prospective subject is a patient (has MRN in our system) and EHR info will be accessed to identify eligible patients.	Study team will initiate contact; Prospective subject is not a patient or it is unknown if he/she is a patient (i.e., not using EHR to identify eligible individuals).	Prospective subject initiates contact; may or may not be a patient but initiates contact with the study team about the study (e.g., after seeing a flyer etc.).
HIPAA	Form D (prep to research) to identify potentially eligible patients Form B (request for waiver of authorization) to use the information to contact if cold calling (note that IRB rarely approves this). Alteration of authorization if obtaining verbal authorization on the phone (IRB would likely require) – patient should be told that there will be information about their potential research participation in Epic Form A (authorization, whether standalone or in CF) at time of study visit.	Alteration of authorization if obtaining verbal authorization on the phone (IRB would likely require) or otherwise before consent is obtained – person should be told that there will be information about their potential research participation in Epic. This would include telling non-patients that a medical record will be created for them in Epic (as it seems necessary for them to have one if tests/labs will be ordered for them through Epic). Form A (authorization, whether standalone or in CF) at time of study visit.	Alteration of authorization if obtaining verbal authorization on the phone (IRB would likely require) or otherwise before informed consent is obtained – person should be told that there will be information about their potential research participation in Epic. This would include telling non-patients that a medical record will be created for them in Epic (as it seems necessary for them to have one if tests/labs will be ordered for them through Epic). Form A (authorization, whether standalone or in CF) at time of study visit.

Contact us (CUIMC)

HRPO staff identified in correspondence (for returned Events)

irboffice@columbia.edu

212.305.3553

No appointment needed consultations:

- Mondays 3-4pm, PH10
- Tuesdays 10-11am, 154 Haven Avenue, First Floor
- Wednesdays 10-11am, PH10
- Thursdays 10-11am, PH10

HRPO website: https://research.columbia.edu/irb

Questions?