Version 2; 2/10/2020

Informed Consent Requirements for Epic-linked Studies

Requirements:

Certain studies that involve procedures at Columbia University Irving Medical Center (CUIMC) and/or NewYork-Presbyterian Hospital (NYPH) will be linked in Epic, the new medical record system that will be shared by CUIMC, Weill Cornell Medical Center (WCMC), NYPH and certain NYPH affiliated institutions. The medical record of participants in those studies will include documentation of their participation.

Studies that meet the following criteria and involve CUIMC/NYPH clinical facilities will be linked in Epic:

- Interventional clinical trials involving drugs and devices
- Clinical research with research billable events
    - A "research billable event" is any clinical test, procedure, or service at NYPH or CUIMC billed to the research funding

Research participants whose study involvement will be documented in Epic must be informed of this. These include:

- Participants who completed the study, who were withdrawn by the PI, or who decided to stop participating prior to the Epci roll-out. Because these participants were not designated as "inactive" in CTMS before the roll-out, they are now linked in Epic to the study. For participants who did not previously have a medical record at CUIMC/NYPH, a medical record was created for them in Epic so the linkage could occur.
    - The "Informational Letter for Past Participants" should be provided to these participants. This Letter is on page 3 of this document.
- Current participants, who were designated as "active" in CTMS at the time of the Epic roll-out.
    - The "Consent Form Addendum for Current Participants" should be provided to these participants. This Addendum is on page 2 of this document. This is a revised version incorporating comments we received after issuance of version 1.
- Future participants, i.e., those not yet enrolled.
    - The "Consent Form Addendum for Current Participants" can be used for enrollees for a limited time, until the study team has a chance to revise the relevant consent form.
    - A new paragraph will need to be included in the Confidentiality section of new and revised consent forms. This language is provided below. This is a revised version incorporating comments we received after issuance of version 1.

All final versions will be translated into Spanish.

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Language to be added to consent forms (version 2):

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 NewYork-Presbyterian Hospital and its affiliated institutions. because these institutions share the electronic medical record system. Study monitors and others who provide oversight of the study may also need to access this record.

Consent Form Addendum for Current Participants

ADDENDUM TO THE INFORMED CONSENT DOCUMENT

Protocol: IRB-AAA[#]

IRB Protocol Title: [title]

Date: [date]

Dear Study 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.

The following is new information to be added to your consent form:

Columbia University Irving Medical Center (CUIMC) has recently implemented a new electronic medical record (EMR) system, which will be shared with Weill Cornell Medical Center and New-York Presbyterian Hospital and its affiliated institutions.

Your participation in this research study will be documented in our new EMR system. Medical records in this system can be viewed by authorized personnel from these institutions. Study monitors and others who provide oversight of the study may also need to access this record.

All other information contained in the original consent form remains unchanged.

Your participation in this study continues to be voluntary. You may withdraw your consent to participate at any time, and for any reason, without affecting your future care at any of the above institutions or your relationship with your study doctor.

You can talk to the Principal Investigator, [PI name], about any questions or concerns you have about this study. Contact information: [contact information].

If you have questions about your rights as a research subject while taking part in this study, you should contact:

Institutional Review Board
Columbia University Irving Medical Center
154 Haven Avenue, first floor
New York, NY 10032
Telephone: (212) 305-5883
Email: irboffice@columbia.edu

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects in research.

Thank you.

[PI name]

This form has been approved by the Columbia University Human Research Protection Office. 2/10/2020

Information for Past Study Participants

INFORMATION FOR PAST STUDY PARTICIPANTS

Protocol: IRB-AAA[#]

IRB Protocol Title: [title]

Date: [date]

Dear (past research participant):

You are receiving this communication because you were 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.

The following is new information:

Columbia University Irving Medical Center (CUIMC) has recently implemented a new electronic medical record (EMR) system, which will be shared with Weill Cornell Medical Center and NewYork-Presbyterian Hospital and its affiliated institutions.

Although you are no longer in this research study, your past participation will be documented in the new shared EMR system. Medical records in this system can be viewed by authorized personnel from these institutions. Study monitors and others who provide oversight of the study may also need to access this record.

If you have any questions or concerns about this new information, or about your rights as a research subject, please contact:

Institutional Review Board
Columbia University Irving Medical Center
154 Haven Avenue, first floor
New York, NY 10032
Telephone: (212) 305-5883
Email: irboffice@columbia.edu

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects in research.

Thank you.

[PI name]

[PI contact information]

This form has been approved by the Columbia University Human Research Protection Office. 2/10/2020