MONTHLY IRB-INVESTIGATOR MEETING

Columbia University
Human Research Protection Office

January 16, 2020

COLUMBIA | Columbia University Irving Medical Center

Agenda

- GDPR guidelines and applicability questionnaire – update

- Annual/Progress Report status

- CoC update w/r/t agencies other than NIH

- Posting of consent documents as required by revised Common Rule

- Confidentiality language in CFs for studies that will be linked in Epic

- Reliance procedures

- Tips for contacting the HRPO

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GDPR tools posted: research.columbia.edu/irb

🔗 [Federally Funded Research](#) ❯

15 FDA Policies ❯

16 [General Data Protection Regulation (GDPR)](#) ⌄

- GDPR Guidelines for Clinical Research
- Sample GDPR Privacy Notice and Consent (research)
- GDPR applicability questionnaire 11 27 19 version

17 Genetic Testing ❯

When is an Annual Report Required?

- As per the revised 2018 Requires, Annual reports are needed for eligible studies that:
  - Were reviewed by an expedited review process, unless the reviewer justifies why CR would enhance protection of subjects
  - Have progressed to the point that they involve only data analysis or "accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care".

- Brief report to account for:
  - Active research
  - Track recruitment

What can be submitted?

- Update to subjects section only

- Modifications are not accepted with Annual Reports

- May attach Cancer Center Renewal form or approval from non-CU reviewing IRB

Changes to the research and/or submission of violations must be made via the modification module in Rascal

Annual Progress Report is now Live!!

Certificates of Confidentiality

- Definitions

- 21st Century Cures Act

- Processes for Obtaining a CoC

- Amending or Extending a CoC

- Subcontract sites

- Links for further reading

What is a Certificate of Confidentiality?

- The Certificate of Confidentiality (CoC):
    - Protects the privacy of research subjects.
    - Allows researchers to refuse disclosure of a subject's identifiable sensitive information
    - Researchers cannot be forced/compelled to provide information that may identify subjects, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

21st Century Cures Act

- "(d)(1)(A) If a person is engaged in <u>biomedical, behavioral, clinical, or other research</u>, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary:
    - (i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and '
    - (ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded"

Definition

- "Identifiable, sensitive information" means information about an individual that is gathered or used during biomedical, behavioral, clinical, or other research, where the following may occur:
    - An individual is identified; or
    - For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

Obtaining a CoC

- NIH Policy effective date: October 1, 2017
  - *….All NIH funded research studies involving identifiable data that commenced or are ongoing on or after December 13, 2016, are deemed to be issued a Certificate of Confidentiality.*
  - Policy: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html
- For NIH-funded research, the CoC is automatically included as a term and condition of the NIH award. The NIH also issues CoCs for other federally funded research (where a CoC is not included as a term and condition of award) or for non-federally funded research that falls within the mission of the NIH.

Obtaining a CoC (continued)

- Several non-NIH HHS agencies, including CDC, FDA, HRSA, and SAMHSA, issue Certificates of Confidentiality (CoCs) similar to NIH.
    - A CoC is included as a term and condition of the award. Non-funded researchers may not apply for and obtain a CoC from these agencies.

- For other HHS agencies (that do not provide a CoC as a term and condition of the award) or for research without federal funding, researchers may apply for an NIH CoC if a primary focus of the research is within the NIH mission (i.e., health/mental health-related).

HHS Agencies that Issue CoCs as a Term & Condition of Award

- NIH

- FDA

- CDC

- HRSA*

- SAMHSA*

*Although a term and condition of the award, PI must apply for the CoC. Amendments and Extensions also required

What About Other Agencies?

- For other HHS agencies not named in the prior slide, you may **apply to the NIH** for a CoC

- Submit the following to NIH:
    - A copy of the online CoC Application
    - Letter of Assurances (LOA)
    - A copy of the IRB Determination letter
    - IRB-reviewed and approved informed consent/assent documentation
    - Upload the signed LOA to your online CoC application

Once you have obtained your CoC, you must upload the documentation in Rascal

What About Other Agencies?

Funding Agency	Process/Steps
The National Institutes of Health (NIH)	**No need to obtain a CoC**
• Centers for Disease Control and Prevention (CDC), • Substance Abuse and Mental Health Services Administration (SAMHSA), • Health Resources and Services Administration (HRSA), or • Indian Health Service (IHS)	**Contact the Agency CoC Coordinator**

Funding Agency	Process/Steps
Agency for Healthcare Research & Quality (AHRQ)	**Contact AHRQ**
Department of Justice (DOJ)	**Contact the DOJ Project Officer**
None of the above but is under the authority of the Food and Drug Administration (FDA) operating under IND or IDE	**Contact the FDA CoC Coordinators**
None of the Above	**Submit your request online to the NIH Office of the Director**

How do I extend or amend an existing Certificate of Confidentiality?

- For Extensions: If your *non-NIH funded* research project will extend beyond the current expiration date on your Certificate, you should request an Extension.
  - NOTE: If your study has completed all enrollment and data collection, there is no need to extend the Certificate. Sensitive, identifiable research information maintained by investigators during any time a Certificate is in effect, is protected permanently.

- For Amendments: If there is a SIGNIFICANT change in your *non-NIH funded* project after the Certificate has been issued, you should request an Amendment. This includes major changes like a change in the primary institution where research will be conducted, and changes in the Principal Investigator/s.

Does the CoC apply to Subcontract Sites?

"Institutions and their investigators are responsible for determining whether research they conduct is subject to this Policy and therefore issued a Certificate." – see NIHGPS 4.1.4.1 on making the determination

Any subrecipient that receives funds to carry out part of the NIH award involving a copy of identifiable, sensitive information protected by a CoC issued by this Policy are also subject to the Policy

- See NOT-OD-17-109: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

- See NIH's CoC Website: https://grants.nih.gov/policy/humansubjects/coc.htm

Links

- https://grants.nih.gov/policy/humansubjects/coc.htm

- CoC Request Form

- Certificate Coordinators

- Sample CoC Consent form Language

- CoC Kiosk

- How to Apply for a CoC

- NIH-CoC-Coordinator@mail.nih.gov

- See NOT-OD-17-109: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

Posting of Clinical Trial Consent Forms

- Requirement of revised Common Rule (45 CFR 46, Subpart A)
  - 45 CFR 46.116(h)
- Federally funded clinical trials
- *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. [45 CFR 46.102(b)]
- HRPO working with CTO on process

Posting of clinical trial consent form

(1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

CF Confidentiality – studies linked in Epic

- What studies need to be in the CTMS?
  - 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 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.*"
- Guidance document will be distributed via listserv and posted

Considerations/processes vary for:

- Already enrolled participants
  - Addendum to consent form has been approved
  - Participants should be notified asap, and not later than 3 mo.
  - Submit modification per protocol w/in 6 mo.
- Participants enrolled soon after Epic launch
  - Addendum or IRB-approved CF revised to include this language can be used
  - Submit modification per protocol w/in 6 mo.
- Studies not yet approved
  - Incorporate language into consent form

Reliance procedures

- HRPO review and enhancement underway

- Future session will provide details and flow charts

- Tips for today:

  - Reliance must be approved by HRPO

  - Fully executed reliance agreement must be in place *before* any reliance occurs

    - Includes SMART IRB acknowledgement forms

- HRPO requires completion of Reliance Request form

- Setting up new reliance takes time

Tips for contacting the HRPO

- General questions: irboffice@columbia.edu; 305-5883

- Questions about a submission or approved study:
  - Contact staff who work with the IRB to which the study is assigned
  - IRB assignment: Protocol History page
  - https://research.columbia.edu/content/hrpoirbs-directory

- Questions about a protocol that has been submitted for a new study and is not yet assigned to an IRB:
  - irboffice@columbia.edu; 305-5883

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?