2014 CTN Web Seminar Series

Certificates of Confidentiality

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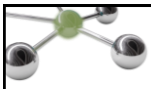
Objectives:

- Understand the requirements for Certificates of Confidentiality.
- Explain the provisions of CoCs.
- Determine how to incorporate the CoC application and approval process into the project timeline.



WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

Statutory Authority

- Under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) the Secretary of Health and Human Services may authorize persons engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subjects of that research.
- This authority has been delegated to the National Institutes of Health (NIH).

Provisions

- Protect against compelled disclosure
- Enable the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Protections

- Personally identifiable information about subjects in the research project that is stored in the U.S.A.
- The protections are for the study subject
- Protections do not extend to the data in general

Protections in Action

Subject

- Subject is protected from forced disclosure of identifying information
- Subject is made aware during consent of limits to protections (exclusions)
- Subject (or family) may voluntarily disclose his/her own information

Researcher

- Institution is bound to uphold the protections
- Researcher may voluntarily disclose in special circumstances, if declared in consent form, E.g. harm to self or others, child or elder abuse.
- Researcher must comply with mandatory state reporting of communicable diseases
- Researcher must comply with federal project/program auditing

DOES MY STUDY NEED A CERTIFICATE?

From the Institution's Perspective

- Your IRB requires that you get a CoC
  - Study subjects face harmful consequences if identity is disclosed
  - The PI is an employee or faculty member at the institution
    - Faculty applies on behalf of fellows, students, postdocs
  - The institution (via an official) will sign to the assurances that obligate upholding CoC protections

From the Researcher's Perspective

Could disclosure be harmful to subjects?

- Social, economic, psychological consequences
  - Criminal or illegal activity
  - Substance use and abuse
  - Alcohol abuse
  - Sensitive health information
  - Risky sexual behaviors
  - Vulnerable group

Is there a strong likelihood that another authority will want access to the information, E.g. law enforcement, court system, or licensing body?

From the Subject's Perspective

Can anyone find out my answers?

- Name, SSN, contact information
- Genetic material/bio-samples
- Easy to identify based on location or situation
- Small sample
- Known street moniker

Study subject or family members can disclose involvement in the covered study and CoC does not protect against such disclosure.

The very best protection…

…is not to collect any identifying information.

Any questions so far?

Let's take a minute before moving on to talk about the application process.

HOW DO I APPLY FOR A CERTIFICATE?

NIDA's CoC Team

Ms. Natisha Rowe, NIDA's Lead CoC Administrator, receives, processes, and tracks applications; works with PIs on submissions; interfaces with NIDA Front Office to finalize CoCs. She is assisted by the newest member of our team Christina (Chris) Page.

What You Need to Obtain a CoC

- A study that is within the scope of NIH mission, even if not NIH-funded
- Current IRB approval, or official notice that the approval is waiting on issuance of a CoC
- IRB-approved consent (assent) form that clearly describes the protections and limitations of the CoC (consider the target audience)
- Application letter, including the assurances, signed by PI and institutional official

Submitting the Application

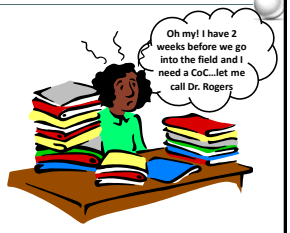
- Manual process
  - Submit an application letter:
    - Answer all of the 14 questions even if your answer is "Not applicable"
    - The study description must be clear and succinct; convey the scientific purpose of the study; exactly what is being done, to whom, in what way, and why?
    - The assurances must be signed by an authorized institutional official (state name, title below signature)
    - If controlled drugs are part of the study, then a copy of current DEA/State licenses must be included
    - If the study is of an IND, the application goes to Sherry George at FDA (NIH has no authority to issue CoCs on IND)

Application instructions:
http://grants.nih.gov/grants/policy/coc/appl_extramural.htm

NIH CoC Kiosk: http://grants.nih.gov/grants/policy/coc/

Figuring Out the Project Timeline

- IRB approval (or conditional approval) received
- You need 12 weeks for the CoC application
- Missing documents, unsigned letters, consent forms that do not address the CoC, out of date IRB approval… all add time to the process



Dr. Smith's dilemma now is whether the IRB will allow her to start the study with a CoC application in process.

Recap / Highlights

- The intent of the CoC is to protect study subjects from unwanted disclosure.
- Subjects must be informed of CoC coverages and limitations during consent process.
- The best protection is to not collect identifying data at all.
- IRB approval is needed for a CoC to be issued.
- It can take up to 12 weeks to get an application processed.
- To minimize additional delays, be sure that the application is complete before submitting to NIDA.

Q&A – Questions / Comments

Alternatively, questions can be directed to the presenter by sending an email to CTNtraining@emmes.com.

THANK YOU FOR YOUR PARTICIPATION

Survey Reminder

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Upcoming Webinar

HUMAN RESEARCH PROTECTIONS – PRISONERS

WEDNESDAY, OCTOBER 1, 2014
1:00 PM ET

A copy of this presentation will be available electronically after this session.

http://ctndisseminationlibrary.org