

2011 Web Seminar Series

Certificate of Confidentiality
August 10, 2011

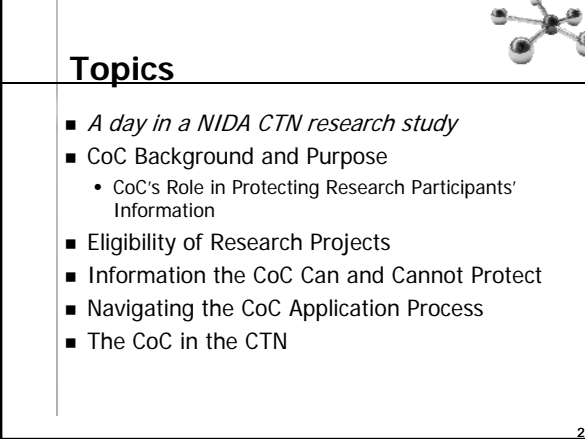
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Topics

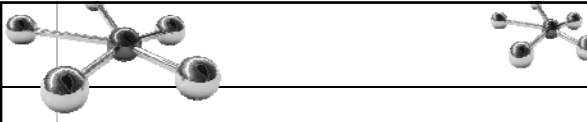
- *A day in a NIDA CTN research study*
- CoC Background and Purpose
 - CoC's Role in Protecting Research Participants' Information
- Eligibility of Research Projects
- Information the CoC Can and Cannot Protect
- Navigating the CoC Application Process
- The CoC in the CTN

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CoC Role Play




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CoC Background & Purpose




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CoC Background

- History
 - 1970
 - Comprehensive Drug Abuse Prevention and Control Act – research legal protections
 - 1974
 - Mental health amendment
 - Alcohol use and psychoactive drugs
 - 1988
 - Amended for health research generally
- Challenges
 - 1973 New York Court of Appeals

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CoC Background

- Public Health Service Act (*Section 301(d)*)
 - Secretary DHHS may authorize persons engaged in
 - Biomedical, behavioral, clinical, other research
- Protects the privacy of individuals who are the subjects of that research
- Authority has been delegated to the appropriate NIH Institute (NIDA)

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CoC
Purpose: *To Protect*

- To protect investigators and institutions from being compelled to release information that could be used to identify research study participants
- Allow investigator and others who have access to research records to refuse to disclose identifying information in any
 - civil
 - criminal
 - administrative
 - legislative, or other proceeding, whether at the federal, state, or local level

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Identifying Information Examples

- Broadly defined
- Not just name, address, social security number, etc.
- Includes any item or combination of items that could lead directly or indirectly to the identification of a research participant.

Pol / ing Question !


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Eligibility of Research Projects



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Eligible Research Projects 	
<ul style="list-style-type: none">■ Single, well-defined research projects■ Multisite projects<ul style="list-style-type: none">• Must have a coordinating center or "lead" institution• Lead institution can apply on behalf of <u>all</u> institutions associated with the multisite project• Lead institution must ensure that all participating institutions conform to the application assurances	
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Eligible Research Projects 	
<ul style="list-style-type: none">■ IRB-approved research collecting identifying information■ Certificates granted to institutions based on PI's application - if disclosure could have adverse consequences for participants or damage:<ul style="list-style-type: none">• financial standing• employability• insurability or• reputation	
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Sensitive Information Examples 	
<ul style="list-style-type: none">■ Collecting data on substance abuse or other illegal risk behaviors■ Collecting genetic information■ Collecting information on psychological well-being of participants■ Collecting information on sexual attitudes, preferences, or practices	
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Ineligible Research Projects

- Not research
- Not collecting personally identifiable information
- Not reviewed and approved by an IRB
- Collecting information, that if disclosed, would not significantly harm or damage the participant

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What Information the CoC Can and Cannot Protect



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Boundaries of Protection

<p>Can Protect</p> <ul style="list-style-type: none">■ Identifying data maintained during any time the certificate is in effect<ul style="list-style-type: none">• Retroactive to when the study started and continues forever	<p>Cannot Protect</p> <ul style="list-style-type: none">■ Voluntary disclosure:<ul style="list-style-type: none">• Child abuse• Threat of harm to self or others• Reportable communicable diseases• Participant's own disclosure or written authorization to disclose
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A Word About Voluntary Disclosure

- All persons with data access must understand that:
 - Inquiries or even subpoenas do not automatically require a disclosure
 - Automatic reporting to state/local health officials may or may not be waived by requiring agency
 - CoC acknowledges that certain disclosures are necessary
 - Institutional policy may identify "voluntary"
- ⇒ ■ The CTP/Site PI is responsible for providing guidance for handling inquiries

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Other Disclosures


- Must disclose information about participants for DHHS audit or program evaluation or if required by the Federal Food, Drug, and Cosmetic Act

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An Important Reminder

- Certificates of Confidentiality do not replace the need for data security!
- Research participants' privacy
 - HIPAA and other regulatory protections still apply
- Know your institution/IRB's guidance on CoC or voluntary disclosures

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Navigating the CoC Application Process



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Certificates of Confidentiality



- Issued by the applicable institute within the National Institutes of Health (NIH)
 - CTN CoC is issued by the National Institute on Drug Abuse (NIDA)
- NIH or Public Health Service (PHS) funding is not required
 - Research should match the institute's mission

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Requirements



- Certificate applications should be submitted 3 months prior to enrollment
 - 14 sections on institution's letterhead
 - Assurances
- Must have and document:
 - IRB approval
 - IRB qualifications
 - IRB-approved consent forms
- PI and Institutional Official must sign application

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The PI and the Institution Assure

- Agree to protect against compelled disclosure and to support and defend the authority of the Certificate against legal challenges
- Agree to comply with Federal regulations that protect human participants
- Agree to not represent Certificate as endorsement of project by DHHS or NIH or use to coerce participation
- Agree to inform participants about Certificate, its protections and limitations

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Reminders


- Must notify participants that Certificate is in effect in consent form
- Must provide fair and clear explanation of Certificate's protection, including
 - limitations
 - exceptions (may be state level)

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The CoC in the CTN


- Who needs to be aware of the CoC?
- How do you handle requests for information?
- Where can you get support?

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Who Needs to Understand CoC? 


- Medical Clinicians
- Counselors
- CCC Monitors
- Administrators
- Pharmacists
- Pharmacy Administrators
- Laboratory Personnel
- Node Personnel
- CTP Study Personnel
- CTP and Node Investigators
- Study Participants
- You!

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Requests for Participant Information 

- Record their name and number and arrange to call them back
- Notify the following:
 - Your Principal Investigator
 - The CCC
 - > The NIDA Certificate Coordinator
 - Local Node
 - Lead Node
 - Your Supervisor
 - Local Institution Legal Authorities


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Take-Home Messages! 

- Protects against most requirements to release information about research participants
- Participants must be informed of CoC, including limitations
- Issued for a single, well-defined, IRB-approved project
- Cannot prevent voluntary disclosure
- All personnel who have access to participant information need to understand and utilize CoC protections

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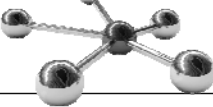
Certificates of Confidentiality Kiosk



<http://grants1.nih.gov/grants/policy/coc/index.htm>


- Kiosk includes:
 - background information and instructions
 - application information
 - FAQs
 - contact list
 - reportable communicable diseases policy

Polling Question 1 28



Questions or Comments?

Have any of your participants had questions or concerns regarding the Certificate of Confidentiality?



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National Drug Abuse Treatment

A copy of this presentation will be available electronically after the meeting from:

CTN Dissemination Library
<http://ctndisseminationlibrary.org>

and

NIDA Livelink
<https://livelink.nida.nih.gov>

Mark Your Calendar



- **September 14**
 - Integrated Treatment of Co-Occurring Disorders
- **October 12**
 - Informed Consent
- **December 7**
 - A New Look at Manual of Procedure (MOP) Development

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