An Overview of Certificates of Confidentiality

Ann M. Hardy DrPH

Office of Extramural Programs (OEP), Office of Extramural Research (OER)

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• Legislative Background
• What CoC can do and cannot do
• Eligibility
• Process for obtaining a CoC
• Results of recent legal analysis
• Future Plans
• Included in PHS Act:
  Secretary may authorize persons engaged in research to withhold names and other identifying characteristics; may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative or other proceedings to identify.

• Scope has changed over time
  – 1970: use and effect of drugs
  – 1974: mental health, alcohol, and other drugs
  – 1988: biomedical, behavioral, clinical, other research

• Intended to help with subject recruitment
• Regulations: 45 CFR Part 2a (1979)
  – For research; DHHS funding not required
  – Application details
    • Describe research project including location, facilities, key personnel, drugs to be administered
    • Assurance
      – Comply w/ 45 CFR 46
      – Use the authority to refuse to identify subjects
      – Inform subject about Certificate
  – HHS evaluates the application; can deny request
  – Separate request for an extension or amendment
What Does a CoC Do?

• Authorizes researchers to withhold “names or identifying characteristics”
  – Name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data that could reasonably lead directly or indirectly to identification

• Protects identifiable info for subjects participating during any time CoC is in effect

• Protection is permanent
What are the limitations of CoC?

• CoC can’t be used to refuse to provide info:
  – At subject’s written request
  – As requested by DHHS for audit/program evaluation or as required by FDA regulations

• Voluntary disclosure is allowed
  – Harm to self or others
  – Reportable communicable diseases

• Protects info kept in US from US legal demand

• Protects identifying info not data

• Won’t protect original non-research records
• Until 1997
  – NIDA, NIAAA, NIMH issued CoC for studies related to their areas.
  – Dept. issued CoCs for other topics
• 1997: authority to issue delegated to HHS agencies
• NIH further delegated to NIH Institutes/Centers
How CoCs are Issued by Agencies

- Agencies that issue for research they fund:
  - Centers for Disease Control (CDC)
  - Health Resources and Services Administration (HRSA)
  - Indian Health Service (IHS)
  - Substance Abuse and Mental Health Services Administration (SAMHSA)

- FDA, for studies with IND or IDE

- NIH, for NIH funded studies and for mission relevant studies without federal funding
How NIH Issues CoCs

• Issued by the NIH Institutes/Centers (ICs)
  – 10 ICs use on-line application system developed by NICHD (list on NIH Kiosk website)
  – Other ICs take materials by email or regular mail
  – Requirements are on website (“Extramural Projects – Application Instructions”)

• Which IC?
  – Funding IC or IC that supports similar research

• Contact info: http://grants.nih.gov/grants/policy/coc/contacts.htm
  – Contact for each NIH IC and other Agencies
  – Link to IC homepage and to on-line application
Eligibility for a Certificate

- Research
- Collecting identifiable, sensitive info
- IRB Approval
- For research not funded by HHS, must be mission-relevant and allowed by PHS policy (legal counsel interpretation)
- Not covered by other regulations (AHRQ, DOJ)
CoC Application

• Include
  – Institution and research sites/facilities
  – Funding source
  – Project Title and description
  – Reason for requesting CoC
  – How privacy will be protected
  – Documentation of IRB approval
  – IRB-approved consent forms
  – Assurance
Informed Consent Language

• Must appropriately describes protections afforded by CoC

• Must state if researcher will voluntarily disclose info (child abuse or harm to self/others)

• NIH has suggested language: http://grants.nih.gov/grants/policy/coc/appl_extramural.htm
• Consent Form that promises to obtain CoC in future

• Voluntary disclosures, not “as required by law”

• Our current sample language
  – Researchers can use CoC to legally refuse to disclose identifying information in any federal, state, local civil, criminal…
• Assurance signed by PI and Institutional Official:
  – Institution will use the CoC to protect against compelled disclosure
  – Comply with 45 CFR 46
  – Subjects will be informed about CoC
  – Won’t use CoC as endorsement or to coerce participation
• Institution agrees to use the CoC to protect against the compelled disclosure of PII and to support and defend the authority of CoC against legal challenge
CoCs for Multi-Site Studies

• A lead site can apply for and receive a CoC on behalf of all member institutions

• Lead would submit their IRB approval, consent language, and assurance

• Lead is responsible for:
  – Obtaining signed assurances and copies of IRB approvals from each site
  – Ensuring appropriate consent language at each site
  – Providing copies of CoC to all sites

• Sites should work out arrangement to implement the assurances
Issuing a CoC

• Application is reviewed at IC level
• CoC is signed by IC Director or appropriate designee
• CoC is issued to the institution (not PI) for certain time period
• CoC may be extended if study goes beyond time and/or amended if significant changes (separate request)
• Recent study by Lauren Beskow and colleagues

“Assessing the Use and Understanding of Certificates of Confidentiality”

– Examined understanding and use of CoCs by research institutions (IRB Chairs and Legal Counsel)
– Conducted thorough legal analysis of CoCs

• Publications:

– Minn J L Sci & Tech (2013) 14(1) (Legal analysis)
• Few cases
  – 3 “reported” cases
  – < 10 unreported cases
• Generally upheld CoC protections
  – Protects identifiable info not data
  – Waiver of protection
• Institutional legal counsel often resolve requests w/o going to Court; CoC is one of several options to resolve
• Increasing awareness and understanding
  – Updates to website
    • Added 1-page Key Info for IRB member, Institutional Officials, Investigators
    • Flow chart – to determine eligibility and contacts
  – Presentations at PRIM&R and OHRP conference

• More consistency within NIH
  – Regular meetings; now include all agencies
  – Instructional materials for CoC contacts (FAQs)
  – Standardized approach to review of requests for research not funded by NIH and for multi-site studies
  – NIH-wide training December 2012
Future Plans

• One on-line application for all NIH ICs
  – Seeking OMB approval; recent FRN

• Future version will handle amendments and extensions

• System will allow for production of program metrics
CoCs Are An Important Tool

• Helpful in protecting privacy of research participants and in recruitment
• Have generally been upheld in court cases
  – Distinction between subject identifiers and other data
  – Waiver of protections
• Do NOT replace good data security practices
• Is it necessary to collect/retain identifiers?
• Studies in which legal demands/litigation likely should involve institutional legal counsel at the planning stage
Where to get Information

- NIH Certificates of Confidentiality Kiosk
  Website:
  http://grants.nih.gov/grants/policy/coc/

- List of IC Coordinators:
Questions or Comments?