An Overview of Certificates of Confidentiality

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Presentation Overview

- **Legislative Background**
- **What CoC can do and cannot do**
- **Eligibility**
- **Process for obtaining a CoC**
- **Results of recent legal analysis**
- **Future Plans**

Statutory Authority for CoCs

- 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

DHHS Implementation

- 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

Issuing a Certificate

- 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

Problems w/ Informed Consent Language

- 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…

CoC Assurance

- 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

Assurance Language Issues

- 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

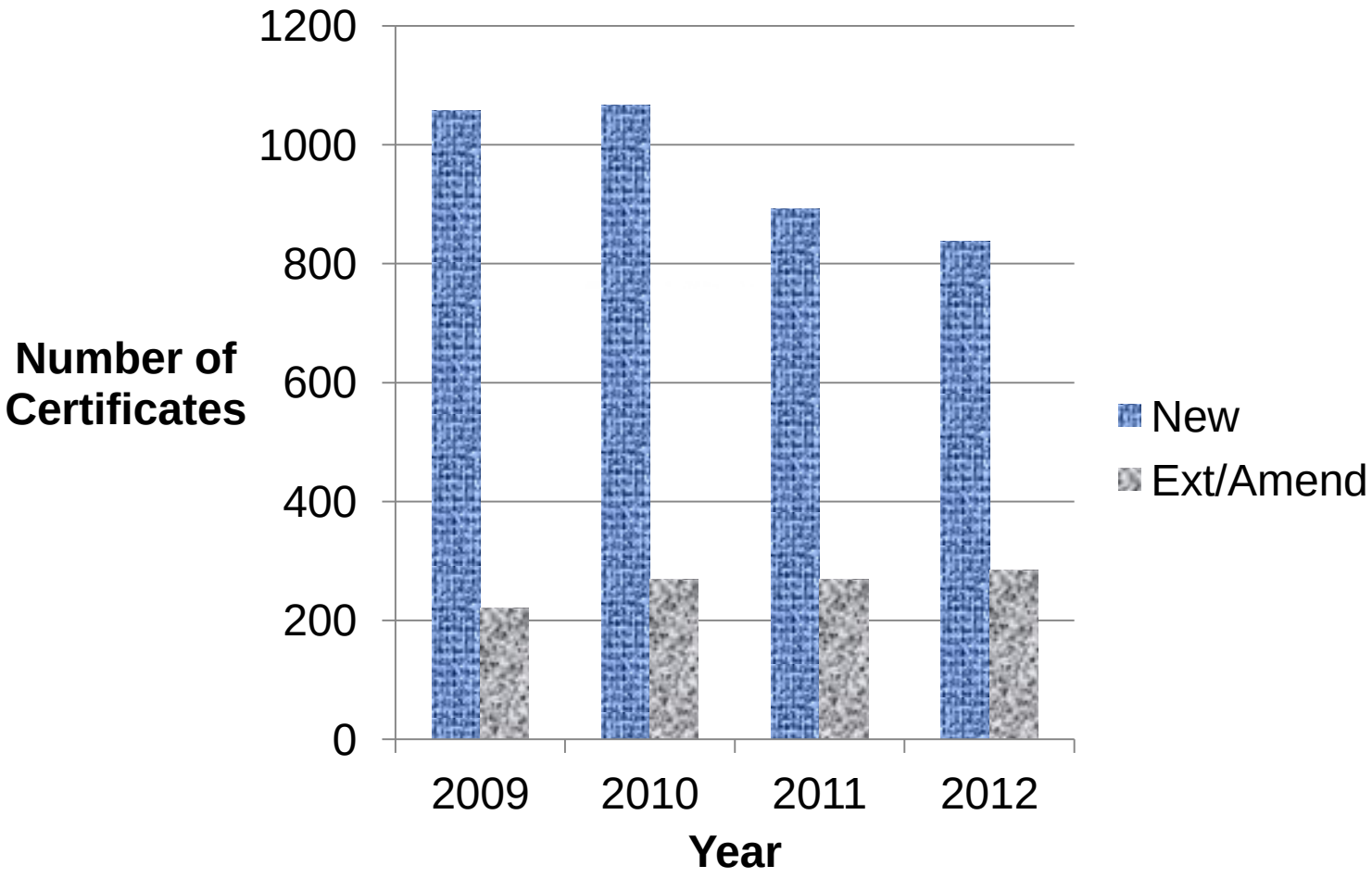
CoCs for Multi-Site Studies

- 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)

NIH Certificates Issued, 2009-11



Research on CoCs

- 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:
  - PLoS One (2012), 7(9) (IRB Chairs)
  - J Empirical Res Hum Res Ethics, (2012), 7(4):1-9 (Legal counsel understanding)
  - Minn J L Sci & Tech (2013) 14(1) (Legal analysis)

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

Improving the CoC Process

- 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:

  http://grants.nih.gov/grants/policy/coc/contacts.htm

Questions or Comments?