Protections Provided by Certificates of Confidentiality

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Presentation Overview

- Scope of protections
- Considerations in obtaining a Certificate of Confidentiality (CoC)
- Are CoCs effective?
- Other federal privacy protections
- Future plans
Statutory Authority for CoCs

- Public Health Service Act (Section 301(d), 42 USC 241(d))

Secretary (DHHS) may authorize persons engaged in research to protect the privacy of subjects by withholding names and other identifying characteristics; may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative or other proceedings to identify.

- Type of research 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 w/ subject recruitment
DHHS Implementation

- Regulations: 42 CFR Part 2a (1979)
  - For RESEARCH; DHHS funding not required

- Certificate Application
  - Describe 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 subjects about Certificate

- DISCRETIONARY
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 required for federal auditing
- Voluntary disclosure is allowed
  - Harm to self or others (incl. child abuse)
  - Reportable communicable diseases
- Protects info kept in US from US legal demand
- Protects identifying info not data
- Won’t protect original non-research records
Should I Request a CoC for My Study?

- Is it for a research study that is
  - Collecting identifiable information?
  - On a sensitive topic?
    - Sexually transmitted diseases
    - Drug or alcohol use
    - Mental health
    - Genetic studies
  - IRB approved?
  - Funded by DHHS or relevant to NIH/DHHS research mission and allowed by DHHS policy?
  - Not covered by other federal privacy regs?
- Would it be helpful for subject recruitment?
Examples: NOT ELIGIBLE for CoC

- To protect an organization’s administrative files that they believe will be subpoenaed because of a lawsuit
- Study of economic factors influencing the migration of adult immigrants who crossed into US as unaccompanied minors
- Study of landlord practices in areas with housing voucher systems
How are CoCs Issued in DHHS?

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

- **FDA**: for studies with IND/IDE
- **IHS**: for funded studies and studies done on tribal lands or in Indian health care facilities
- **NIH**: NIH funded studies and for health related studies without federal funding
How to Get a CoC from NIH

• Issued by the NIH Institutes/Centers (ICs)
  ▫ Funding IC or IC that supports similar research
  ▫ Some IC’s use e-application

• Application requirements, including suggested informed consent language, are on website ("Extramural Projects –Application Instructions")
  ▫ Consent Form must appropriately describes the CoC protections
  ▫ Must state if researcher will voluntarily disclose info (child abuse or harm to self/others); NOT b/c of state or local reporting laws
Do CoCs Work?
Research on CoCs

- Study by Lauren Beskow and colleagues at Duke and GA State
  - Examined understanding and use of CoCs by IRB Chairs and Institutional Legal Counsel
  - Conducted legal analysis of CoCs

- Publications:
  - PLoS One (2012), 7(9) (IRB Chairs)
  - Minn J L Sci & Tech (2013) 14(1) (Legal analysis)
Legal Analysis

• Institutional legal counsel often resolve requests w/o going to Court; CoC is one option

• Few court cases (< 10)
  ▫ Can offer strong protection (Newman (1973))
  ▫ Limited disclosure may be ordered
    • Bradley v North Carolina (2006)
      • Trial Court ordered production to appellate lawyers w/ restrictions
      • Appellate Court found research records not relevant and Trial Court erred in requiring production
Legal Analysis (2)

- When identities are made known outside research
  - Court ordered production of records (w/ limitations) to child welfare agency for subjects voluntarily reported b/c of child abuse concerns

- Protects identifiable info not data
  - Court ordered production of de-identified data w/ other restrictions in product liability cases
Other Federal Privacy Protections

• AHRQ
  ▫ Broad protections for research data obtained by agency, its contractors, or grantees
  ▫ No disclosure w/o consent

• DOJ Privacy Certificate
  ▫ Only for DOJ awardees
  ▫ No disclosure w/o consent
SACHRP Recommendations on CoCs

- **Administrative**
  - Improve timeliness and consistency
    - Concurrent with IRB review
  - Provide guidance to IRBs

- **Substantive**
  - Refine definition of “sensitive”, ex: for genetic research
  - Remove the mission-relevant criteria
  - Broaden protection to all data

- [http://www.hhs.gov/ohrp/sachrp/mtgings/mtg03-14/cocrecommendations.html](http://www.hhs.gov/ohrp/sachrp/mtgings/mtg03-14/cocrecommendations.html)
Recent and Future Improvements

- Added brief documents on our website: Key Information for IRB members, Institutional Officials, Investigators
- Developing on-line application for all NIH
CoCs Are A Useful Tool

- Additional protection for research participants and can help in recruitment

- Have generally been upheld in court cases
  - Distinction between subject identifiers and other data
  - Waiver of protections if ID is revealed

- 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/

Questions or Comments?