UNDERSTANDING CERTIFICATES OF CONFIDENTIALITY

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BACKGROUND ON CERTIFICATES OF CONFIDENTIALITY

• Secretary of Health and Human Services (HHS) authorized by federal law to allow researchers to refuse disclosure of names or other identifying characteristics of research participants in response to legal demands

• CoCs arose out of 1970s “drug wars” and the need to collect information on illegal drug use

• Subsequent amendments expanded CoC scope to include research on mental health (including use of alcohol) and then health research generally
CERTIFICATES OF CONFIDENTIALITY ARE ONLY ISSUED FOR RESEARCH PROJECTS THAT ARE:

• Collecting participant names or other identifying characteristics, on a sensitive research topic
• Approved by an IRB operating under a Federalwide assurance (FWA) or with the approval of the FDA
• On a topic within the HHS health related research mission
• Storing research data in the United States
• Allowable under federal regulations
ALTHOUGH CERTIFICATES OF CONFIDENTIALITY ARE ISSUED BY HHS AGENCIES (e.g., NIH), FEDERAL FUNDING IS NOT REQUIRED TO OBTAIN A CERTIFICATE, BUT ISSUANCE IS AT THE DISCRETION OF EACH AGENCY
OBTAINING A CERTIFICATE

- Listing of CoC coordinators for NIH and other HHS agencies, including FDA, CDC, Health Resources and Services Administration (HRSA) and Substance Abuse and Mental Health Services Administration (SAMHSA): [http://grants.nih.gov/grants/policy/coc/contacts.htm](http://grants.nih.gov/grants/policy/coc/contacts.htm)

- Note: The Department of Justice requires and issues Privacy Certificates to prohibit the use of identifiable research or statistical information for any purpose other than that for which it was obtained, and to protect such information from legal process; see [http://www.nij.gov/funding/humansubjects/documents/NIJ_pccr_fillable.pdf](http://www.nij.gov/funding/humansubjects/documents/NIJ_pccr_fillable.pdf)
AN IMPORTANT CAVEAT!

While CoCs protect research participants from compelled disclosure of identifying information, they DO NOT prevent the voluntary disclosure of identifying characteristics of research subjects.

Hence, researchers MAY voluntarily disclose certain information about research subjects, such as evidence of child abuse or a subject's threatened violence to self or others.

**OHRP guidance:** *If a researcher intends to make such voluntary disclosures, the consent form should clearly indicate this* [(http://www.hhs.gov/ohrp/policy/certconf.html)](http://www.hhs.gov/ohrp/policy/certconf.html)
NORTHWESTERN POLICY REQUIRES THAT “ALL UNIVERSITY EMPLOYEES (INCLUDING ALL FACULTY, STAFF, AND STUDENT EMPLOYEES) REGARDLESS OF THEIR POSITION OR ASSIGNMENT, ARE REQUIRED BY LAW (UNDER THE ABUSED AND NEGLECTED CHILD REPORTING ACT (ANCRA), 325 ILCS 5/1 ET SEQ.) AND BY UNIVERSITY POLICY TO REPORT SUSPECTED CASES OF CHILD ABUSE AND/OR NEGLECT”  

http://policies.northwestern.edu/docs/Reporting_Child_Abuse_and_Neglect.pdf
LEGAL CASES INVOLVING CERTIFICATES OF CONFIDENTIALITY
PEOPLE v NEWMAN, 298 N.E.2D 651 (N.Y. 1973)

- Director of Methadone clinic received a Grand Jury subpoena for photographs for use in identifying a murder suspect.
- Director moved to quash the subpoena claiming production was prohibited under federal law (which authorized the COC) and NY state law (doctor/patient privilege).
- Trial Court denied motion but Director refused to turn over photographs. Held in contempt and sentenced to 30 days in jail.
- Appellate Division focused on doctor/patient privilege and affirmed the contempt finding but modified the subpoena order (who could see, etc.)
- NY Court of Appeals focused on the 1970 Act and Attorney General’s letter stating that Methadone clinic records are absolutely confidential. NY AG argued that the 1970 Act was repealed by 1972 Act (can be compelled by court order). Court of Appeals found that 1972 Act did not affect confidentiality provisions of 1970 Act and held that Director did not have to turn over photographs.
- Court’s decision really turned on the conflict between two statutes rather than the scope of the COC protection.
PEOPLE v STILL, 369 N.Y. S. 2D 759 (APP.DIV. 1975)

• Methadone clinic received a subpoena for records of a patient charged with criminal possession of Methadone.

• Clinic moved to quash the subpoena and trial court granted the motion as to defendant’s records but allowed witnesses to testify about clinic’s operations. Trial court relied on Newman’s interpretation of 1970 Act’s confidentiality.

• Court of Appeals reversed and ordered the defendant’s records produced for limited inspection (guilt/innocence) reasoning that is what fairness requires, without jeopardizing the clinic’s programs.
Other cases involving subpoenas for research records but Court did not rely on Certificate of Confidentiality to deny production of records:

• **North Carolina v Bradley** (Duke received a subpoena for study records of witness in criminal case. Court quashed the subpoena saying that the records were not material so not admissible)

• **Murphy v Phillip Morris, Inc.** (Subpoena for raw data in USC’s cancer research database quashed under 42 U.S.C. 241(d) because data could be re-identified even though there was no COC. Court seems to have misinterpreted Secretary’s authority to grant researchers the ability to resist subpoenas for participant’s identifying information, but does not extend that authority to all research projects.)
WHAT SHOULD YOU DO IF YOU GET A REQUEST FOR STUDY DOCUMENTS?

Call
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