

Rehabilitation Amendments of 1974 (Reference b) to include "mental health, including research on the use and effect of alcohol and other psychoactive drugs." Later, the Public Health Service Act Health Omnibus Programs Extension of 1988 (Reference c), expanded these protections to include compelled disclosure of identifying information about subjects of "biomedical, behavioral, clinical, and other research."

The Public Health Service Act states:

"The Secretary [of Health and Human Services] may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This power was institutionalized with the development of the Certificate of Confidentiality (CoC), which is granted by the National Institutes of Health and other Health and Human Services agencies to individual research studies and protects the privacy of research subjects for that particular study. Several Federal Common Rule agencies have developed CoCs, with the National Institutes of Health (NIH) being the most well-known and most frequently used (Reference d). The following characteristics preclude a study from obtaining an NIH CoC:

1. The project is not research based,
2. The study is not approved by an Institutional Review Board (IRB) operating under either an approved Federal-Wide Assurance issued by the Office for Human Research Protections or the approval of the Food and Drug Administration,
3. The study is not collecting sensitive information or information that, if released publicly, might harm the research participants,
4. The study is not collecting personally identifiable information, or
5. The study is not involving a subject matter that is within a mission area of the National Institutes of Health.

The CoC does not protect against disclosure in all cases. The following instances are considered reportable:

1. Possible threats to self or others,
2. Child abuse or neglect, and
3. Communicable or infectious diseases requiring reporting to the Center for Disease Control and Prevention or other entities.

Per the National Institutes of Health Office of Extramural Research. Frequently Asked Questions: Certificates of Confidentiality (Reference e), other disclosures not listed above need to be included in the consent form the research subject receives.

To date, there have not been many reported legal challenges of the CoC. In 1973, the New York Court of Appeals ruled against a challenge to the CoC in the case of *People v. Newman* (32 N.Y.2d 379, 298 N.E.2d 651, 345 N.Y.S.2d 502) on the basis that “law was implicitly repealed by later drug abuse patient confidentiality statute.” The U.S. Supreme Court declined to hear the case

3. **POLICY**. CoCs allow researchers to refuse to disclose names or other identifying characteristics of research subjects in response to legal demands. On August 27, 2015, the Office of the Assistant Secretary of Defense for Research and Engineering (OASD(R&E)), issued a memo (Reference (f)) stating that DoD conducted and supported research that have obtained a Department of Health and Human Services (DHHS) issued CoCs are expected to abide by the privacy protections afforded by the certificate. This is regardless of civilian or military status.

4. **GUIDANCE**. All guidance issued prior to the OASD(R&E) policy memo (August 17, 2015), is now considered outdated and non-compliant with DoD policy. Investigators whose OUSD(P&R) conducted or supported research meets the criteria for a CoC may, with institutional concurrence, request a CoC from DHHS. Investigators are expected to protect information collected as a part of a research study that is issued a DHHS CoC from forced disclosures, including those that fall under the UCMJ or the Military Rule of Evidence. If necessary and appropriate, investigators should update the consent forms used for newly recruited subjects and inform current subjects of the change in confidentiality protections.

OUSD(P&R) institutions engaged in research involving human subjects will operationalize the DoD policy promulgated in Reference (f). Institutions should review and update their policies and procedures to ensure that they are in compliance with the OASD(R&E) policy.

For questions regarding this guidance document, please contact the OUSD(P&R) Research Regulatory Oversight Office at DHA.R2O2.PR@mail.mil.

5. **RELEASABILITY**. **Cleared for public release.** This Guidance Document is available on the Internet at the R2O2 website (<http://www.health.mil/Military-Health-Topics/Research-and-Innovation/Research-Oversight>).

ENCLOSURE 1

REFERENCES

- (a) The Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, §3(a)
- (b) The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Amendments of 1974, Pub. L. No. 93-282, §122(b)
- (c) Public Health Service Act §301(d), 42 U.S.C. §241(d), Health Omnibus Programs Extension of 1988, Pub. L. No. 100-607, §163
- (d) Office for Human Research Protections: Guidance on Certificates of Confidentiality
- (e) National Institutes of Health Office of Extramural Research Frequently Asked Questions: Certificates of Confidentiality
- (f) Policy Memo, “DoD Acceptance of Department of Health and Human Services (DHHS) Issued Certificates of Confidentiality (CoC),” August 17, 2015