

Certificates of Confidentiality – What are they, who issues them, and what do they mean for both researchers and individuals enrolled in a research study?

The National Cancer Institute (NCI) issues Certificates sparingly for single, well-defined projects and for cooperative, multi-site studies. Certificates empower PIs to refuse disclosure of sensitive research results for individuals in a study or clinical trial, even when responding to a court-ordered subpoena. Eligible projects must involve the collection of sensitive information that, if disclosed, could be damaging to an individual's financial position, reputation, insurability, or employment status. Protocols must be IRB-approved in order to be eligible.

Some examples of research that would qualify include:

- Projects involving genetic testing for cancer predisposition.
- Studies that collect information on an individual's mental health.
- Research that requires information on sexual attitudes, preferences, or practices.
- Research on HIV/AIDS.
- Studies gathering information about substance abuse.
- Research on occupational or environmental exposures and cancer in which participants may be involved in class action litigation.

Certificates of Confidentiality were first authorized by the Department of Health and Human Services (DHHS) in 1970 to protect participants in drug-abuse related studies. Researchers at that time acknowledged that information disclosure could harm participants' reputations and have adverse legal or financial consequences. Certificates, which now also protect participants in other behavioral and clinical research, take precedence over any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, with few exceptions (DHHS program audit or Food and Drug Administration request).

The NCI brochure "Certificates of Confidentiality: Background Information and Application Procedures" is available through the Cancer Information Service (800-4-CANCER) and at the URL below. For additional information, call the NCI Press Office at (301) 496-6641.

http://cancertrials.nci.nih.gov/NCI_CANCER_TRIALS/zones/TrialInfo/Resources/conf/index.html.