

## Certificates of Confidentiality

**Summary/Purpose:** Criteria for requiring Certificates of Confidentiality (CoC) to add protection for sensitive human research where subjects can be identified. CoC cover investigators funded by Public Health Service agencies automatically under Section 2012 of the “21<sup>st</sup> Century Cures Act.” <https://www.congress.gov/114/bills/hr34/BILLS-114hr34eah.pdf>

### Background and Applicability

(See content from NIH at <http://grants1.nih.gov/grants/policy/coc/faqs.htm> and from CDC at <https://www.cdc.gov/od/science/integrity/confidentiality/applinst.htm>)

A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant.

Any research project that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for a Certificate.

**Sensitive information** includes (but is not limited to) information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information or tissue samples.

### Studies eligible for a Certificate (partial list):

- Research on HIV, AIDS, and other STDs;
- Studies that collect information on sexual attitudes, preferences, or practices;
- Studies on the use of alcohol, drugs, or other addictive products;
- Studies that collect information on illegal conduct;
- Studies that gather information that if released could be damaging to a participant's financial standing, employability, or reputation within the community;
- Research involving information that might lead to social stigmatization or discrimination if it were disclosed;
- Research on participants' psychological well being or mental health;
- Genetic studies, including those that collect and store biological samples for future use;
- Research on behavioral interventions and epidemiologic studies.

### Studies ineligible for a Certificate:

- not research based,
- not approved by an IRB in accordance with these guidelines,
- not collecting sensitive information or information that might harm the research participants, or
- not collecting personally identifiable information.

**Identifying characteristics** include things such as: name, address, social security or other identifying number, fingerprints, voiceprints, photographs, genetic information or tissue samples, or any other item or combination of data about a research participant which could reasonably lead, directly or indirectly by reference to other information, to identification of that research subject.

### **UM Policy**

The IRB generally limits *requiring* researchers to get Certificates to studies where there is a real risk of a subpoena or court order to produce data and where identifying information is retained for a significant period of time.

- The IRB will require a Certificate in studies collecting admissions of criminal activity.

These include studies on rape and illicit drug use, for example.

- Certificates will generally not be required for data that could be socially stigmatizing, because these are less likely to be solicited by the legal system.

Researchers may opt to get Certificates without IRB mandate. Because Certificates require altered consent forms, the IRB must be made aware of Certificates obtained by researchers, and consent forms must comply with NIH / CDC requirements before IRB will approve them. [See <https://www.cdc.gov/od/science/integrity/confidentiality/CoCProtections.htm>]