



## U-MIC TRANSCRIPT

### Certificates of Confidentiality in human subjects research

The National Institutes of Health, or NIH, issue Certificates of Confidentiality to protect sensitive and identifiable information, records, and biospecimens about study subjects against forced disclosure, such as under subpoena. Certificates of Confidentiality allow members of a study team to refuse to disclose such information in any legal proceeding, whether at the federal, state, or local level.

If a study is funded by NIH, a Certification is included as a term and condition of the award, which means the researcher does not have to apply for a Certificate of Confidentiality. Research in which identifiable, sensitive information is collected or used,--including research that

- Meets the definition of human subjects research, including exempt research in which subjects can be identified
- Is collecting or using human biospecimens that are identifiable or that have a risk of being identifiable
- Involves the generation of individual level human genomic data
- or Involves any other information that might identify a person

is automatically protected by a Certificate of Confidentiality from NIH. However, if the funding ends and there is no extension, the researcher may have to apply for a new Certificate if still enrolling new subjects or collecting data after the funding end date.

A study that is not NIH-funded may be eligible for a Certificate if the focus of the research falls within the health, including mental health, mission of the NIH involves collection of sensitive information and identifying characteristics, which includes coded information linked to identifiers, and if disclosure would have adverse consequences for subjects, including damage to

- financial standing
- employability
- insurability
- or reputation

Sensitive information includes things like:

- genetic information
- information about a subject's psychological health
- information about a subject's sexual attitudes, preferences, or practices
- information about a subject's substance abuse or any illegal behavior

Identifying characteristics include a subject's:

- name
- address
- Social Security or other identifying number



## U-MIC TRANSCRIPT

### Certificates of Confidentiality in human subjects research

- fingerprints
- voiceprints
- photographs
- genetic information or tissue samples
- and any other information about a subject that may lead, either directly or by reference to other information, to the identification of that subject

Before NIH will issue a Certificate of Confidentiality, a study must already have IRB approval. Since informed consent documents need to include an explanation of the Certificate, investigators should inform the IRB at the beginning of the application process that they're planning to obtain a Certificate and have included the appropriate language in their consent documents. In some cases, the IRB may require a researcher to obtain a Certificate of Confidentiality.

A Certificate protects the information, research records, or biospecimens investigators maintain while the Certificate is in effect, and that information remains protected in perpetuity. Keep in mind, however, if the Certificate is allowed to expire while research is ongoing, subjects enrolled or data collected after the expiration date will not be covered by a Certificate.

Certificates of Confidentiality do not reduce all research-related risks and *do not* eliminate an investigator's duty to implement data security measures. Likewise, Certificates do not protect sensitive data against all forms of disclosure. For example, even with a Certificate in place, investigators would still be required to disclose sensitive information for audits or program evaluations conducted by the Department of Health and Human Services, or under the Food, Drug, and Cosmetic Act.

Additionally, a Certificate of Confidentiality will not protect sensitive information against disclosure as required by law, as in instances of child abuse, threats of physical harm, and reportable communicable disease; voluntary disclosures by the researcher; and a subject's own disclosure. Investigators must specify in their informed consent documents which voluntary disclosures are not protected by the Certificate.

NIH's Certificates of Confidentiality protect subjects' sensitive, identifiable information from forced disclosure, such as by court order or subpoena.

For more information about Certificates of Confidentiality, visit NIH's web site or contact the IRB.

*Posted August 27, 2021*