



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

NIH Policy for Issuing Certificates of Confidentiality

NIH has recently updated its policy regarding the issuing of Certificates of Confidentiality for NIH-funded and conducted research. Specifically, because of Section 2012 of the 21st Century Cures Act, “HHS shall issue Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical or other research, in which identifiable, sensitive information is collected. The Certificates protect the privacy of subjects by limiting the disclosure of identifiable, sensitive information.”

The updated Policy “applies to all to all biomedical, behavioral, clinical, or other research funded wholly or in part by the NIH, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information.” The policy also notes that “NIH will continue to consider request for Certificates for non-federally funded research in which identifiable, sensitive information is collected or used.”

The policy notes, “...NIH will now provide Certificates automatically to any NIH-funded recipients conducting research applicable to this Policy.” However, the Policy also includes, “Institutions and their investigators are responsible for determining whether research they conduct is subject to this Policy and therefore issued a Certificate. Certificates issued in this manner will not be issued as a separate document.”

What does NIH and this Policy consider to be research in which identifiable, sensitive information is collected or used? Such research includes the following:

1. Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
2. Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
3. Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can

readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or

4. Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

How does an investigator determine if this Policy applies to research conducted or supported by NIH? The investigator will need to ask and answer the following questions:

1. Is the activity biomedical, behavioral, clinical, or other research?

If the answer to this question is “no,” the activity is not issued a Certificate. However, if the answer is “yes,” the following questions will need to be answered:

1. Does the research involve Human Subjects as defined by 45 CFR Part 46?
2. Is the investigator “collecting or using biospecimens that are identifiable to an individual as part of the research?”
3. If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual?”
4. Does the research involve the generation of individual level, human genomic data?

In the answer is “yes” to any these questions, the Policy will apply to the research and the recipient of the Certificate shall not:

1. Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
2. Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

1. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;

2. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
3. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
4. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

In regards to studies where informed consent is sought, the Policy states, “NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.” For more information about suggested consent language, please see the NIH Certification of Confidentiality Kiosk at <https://humansubjects.nih.gov/coc/suggested-consent-language>.

The Kiosk also provides FAQs at <https://humansubjects.nih.gov/coc/faqs>. These FAQs include the following information regarding informing participants of a Certificate and the need to re-consent participants:

1. “For studies that were previously issued a Certificate, and notified participants of the protections provided by that Certificate, NIH does not expect participants to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform participants.” UCSD agrees that participants do not need to be notified unless the investigator provides justification to the IRB/HRPP for such notification.
2. “Neither the NIH Policy on Certificates of Confidentiality nor subsection 301(d) expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented to be re-contacted to be informed of the Certificate, although IRBs may determine whether it is appropriate to inform participants.” UCSD agrees that participants do not need to be re-consented unless the investigator provides justification to the IRB/HRPP for such re-consenting.

For more information regarding this Policy and Certificates of Confidentiality, please see the NIH Certification of Confidentiality Kiosk homepage at <https://humansubjects.nih.gov/coc/index>,