**Information for Investigators Regarding**

**Certificates of Confidentiality**

**Source/Reference:** [NIH Notice NOT-OD-17-109](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html)

**Effective Date:**October 1, 2017

The following information regarding Certificates of Confidentiality is provided to investigators to aid in compliance with NIH requirements for federally funded/supported research, and to clarify issues relating to Certificates of Confidentiality. The full notice from NIH is available via the hyperlink above.

**Applicability:** The NIH policy regarding Certificates of Confidentiality applies 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. NIH will provide Certificates automatically to any NIH-funded recipients conducting research meeting the applicability standard.

**Definition:** The term “identifiable, sensitive information” means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where the following may occur:

* An individual is identified; or
* For which there is at least a very small risk, 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.

**Policy:** Effective October 1, 2017, all research that was commenced or ongoing on or after December 13, 2016 and that meets applicability criteria above is deemed to be issued a Certificate of Confidentiality and is therefore required to protect the privacy of individuals who are subjects of such research.

NIH considers research in which identifiable, sensitive information is collected or used, to include:

* 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;
* 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;
* 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
* 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.

**Responsibilities**: Per the NIH policy the recipient of the Certificate shall not:

* 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
* 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:

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

Recipients of Certificates are required to ensure that any investigator or institution not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate, or any subrecipoent, understand they are also subject to the requirements of the Certificate.

For studies in which informed consent is sought, NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate.

Effective internal controls must be established and maintained (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award.

**Non-Federally Funded Research**: As noted within the “Scope and Applicability” section of this guide notice, for non-federally funded research, the NIH will continue to consider requests for Certificates for specific projects in accordance with the current NIH policy for issuing Certificates.

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Source <https://grants.nih.gov/policy/hs/faqs.htm#5830>

**What NIH funded research is issued a Certificate?**

Effective October 1, 2017, certificates are automatically issued by NIH for all research covered by the policy that was commenced or ongoing on or after December 13, 2016.

To determine if this Policy applies to research conducted or supported by NIH, investigators will need to ask, and answer the following question:

* + - Is the activity biomedical, behavioral, clinical, or other research?

If the answer to this question is no, then the activity is not issued a Certificate. If the answer is yes, then investigators will need to answer the following questions:

* + - Does the research involve Human Subjects as defined by 45 CFR Part 46?
    - Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
    - 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?
    - Does the research involve the generation of individual level, human genomic data?

If the answer to any one of these questions is yes, then this Policy will apply.

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The absence of any reference to a COC in the Notice of Award (NoA) does not mean that the study is NOT covered by a CoC.