



**INVESTIGATOR GUIDANCE: Additional  
Health & Human Services (HHS) Obligations**

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## 1. PURPOSE

- 1.1. This guidance outlines the additional obligations of investigators conducting research supported or conducted by the Department of Health and Human Services (HHS).

## 2. GUIDANCE

- 2.1. Research is automatically covered by a certificate of confidentiality whenever the study is funded in whole or in part by the HHS' National Institutes of Health (NIH) and involves identifiable, sensitive information.
  - 2.1.1. "Identifiable sensitive information" means information about an individual that is gathered or used during biomedical, behavioral, clinical, or other research, where the following may occur:
    - 2.1.1.1. An individual is identified; or
    - 2.1.1.2. 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.
  - 2.1.2. Examples of research automatically covered by a certificate of confidentiality include:
    - 2.1.2.1. Biomedical, behavioral, clinical or other research, including exempt research, except where 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.
    - 2.1.2.2. 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.
    - 2.1.2.3. The generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in a manner that human subjects can be identified, or the identity of the human subjects can readily be ascertained.
    - 2.1.2.4. 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.
  - 2.1.3. Investigators may also apply for a certificate of confidentiality for non-federally funded research.



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- 2.1.4. When research is covered by a certificate of confidentiality, investigators:
- 2.1.4.1. May 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
  - 2.1.4.2. May not 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 the purposes of the research.
  - 2.1.4.3. May disclose information only when:
    - 2.1.4.3.1. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act (FD&C), or state laws requiring the reporting of communicable diseases to the State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
    - 2.1.4.3.2. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual.
    - 2.1.4.3.3. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
    - 2.1.4.3.4. Made for the purpose of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.
- 2.1.5. When research is covered by a certificate of confidentiality, investigators must inform subjects (for example, in the consent document) of the protections and limitations of certificates of confidentiality.
- 2.1.5.1. This requirement also applies to existing studies active on after December 13, 2016. For existing studies, investigators must notify subjects that the research is now covered by a certificate of confidentiality. However, because a certificate of confidentiality reduces risks, the IRB does not need to require the research to obtain consent again based in this information and can simply notify subjects of this change.



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- 2.1.6. Investigators conducting NIH-supported research covered by a certificate of confidentiality must ensure that if identifiable sensitive information is provided to other investigators or organizations, regardless of whether the research is federally funded, the other investigator or organization must comply with applicable requirements when the research is covered by a certificate of confidentiality.

### **3. REFERENCES**

- 3.1. [Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality](#)