



UNIVERSIDAD DE PUERTO RICO, RECINTO DE CIENCIAS MÉDICAS  
UNIVERSITY OF PUERTO RICO, MEDICAL SCIENCES CAMPUS

OFICINA DEL RECTOR  
OFFICE OF THE CHANCELLOR



COMITE DE DERECHOS HUMANOS (IRB)  
INSTITUTIONAL REVIEW BOARD

November 16, 2017

**To:** Investigators and Study Coordinators, UPR MSC

**From:** Human Research Subjects Protection Office (HRSP) & Institutional Review Board (IRB)

**RE: Certificates of Confidentiality (CoC) Changes to NIH Policy**

**Effective October 1, 2017, NIH will automatically issue CoCs to all research funded by NIH that is collecting or using identifiable, sensitive information.**

Effective October 1, 2017, NIH has updated its policy for issuing Certificates of Confidentiality (Certificates) for **NIH-funded and conducted research**, as a result of the need to implement Section 2012 of the 21<sup>st</sup> Century Cures Act, P.L. 114-255, which states that the Secretary, HHS shall issue Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical or other research, in which identifiable, sensitive information is collected.

Effective October 1, 2017, **all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of this Policy** is deemed to be issued a Certificate through this Policy and is therefore required to protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act. **This Policy will be included in the NIH Grants Policy statement as a standard term and condition of award effective October 1, 2017 for new and non-competing awards.**

The NIH Policy 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.

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 issued by this Policy. It is necessary to include language relating to the protections afforded by the Certificate and any exceptions to that protection.

Please, read the CoC policy to learn more (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>) (See Attachment). Also you may refer to NIH Website for further information:

<https://humansubjects.nih.gov/coc/index>; <https://humansubjects.nih.gov/coc/faqs>

<https://humansubjects.nih.gov/coc/suggested-consent-language>



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## SOME FAQs...

### **How do I know if my NIH funded research project is covered by a CoC?**

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.

### **What is meant by identifiable, sensitive information?**

Identifiable, sensitive information is information about an individual, gathered or used during the course of biomedical, behavioral, clinical or other research, through which the individual is identified, or 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 determine the identity of an individual. The policy defines this as "covered information."

Identifiable, sensitive information includes but is not limited to name, address, social security or other identifying number; and fingerprints, voiceprints, photographs, genetic information, tissue samples, or data fields that when used in combination with other information may lead to identification of an individual.

### **Will NIH continue to issue certificates for research involving identifiable, sensitive information funded by another HHS Operating Division?**

Several non-NIH HHS agencies, including CDC, FDA, HRSA, SAMHSA issue Certificates of Confidentiality (CoCs). If your research is funded by one of these agencies or is operating under



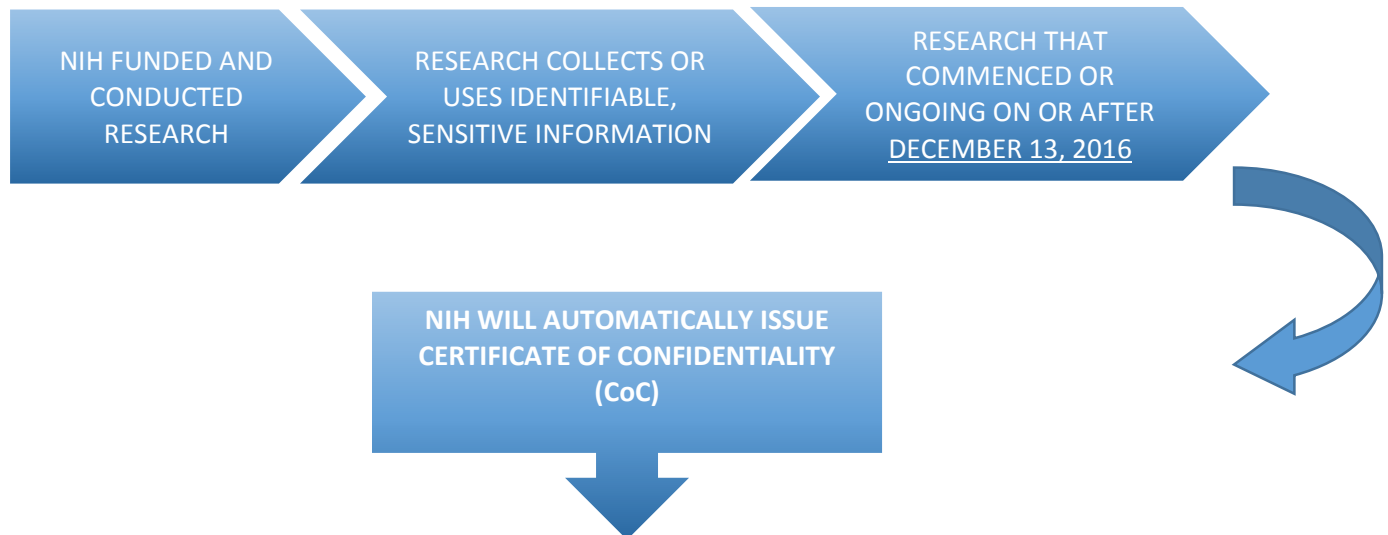
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the authority of the FDA, please contact the Certificate Coordinators at the funding agency to determine how to obtain a CoC.

If your research is funded by an HHS agency other than NIH, CDC, FDA, HRSA or SAMHSA, that does not issue CoCs Health-related research you may request a Certificate of Confidentiality for specific health-related projects using sensitive, identifiable information, using the NIH online application system. NIH issues CoCs on behalf of these agencies.

**Will NIH continue to issue certificates for research involving identifiable, sensitive information that does not have Federal funding?**

Yes. For health-related research that is not federally funded, in which identifiable, sensitive information is collected or used, you may request a Certificate of Confidentiality (CoC) for specific projects using the online application system.



**IMPORTANT** → 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 issued by this Policy.