UNIVERSITY OF SOUTH ALABAMA

IRB SOP 1205
Certificate of Confidentiality

Purpose

This Standard Operating Procedure (SOP) describes procedures to request a federal Certificate of Confidentiality (CoC), or to extend or modify an existing CoC for studies not funded by NIH or for studies whose NIH funding has expired.

Applying for a new CoC is no longer necessary for NIH-funded research. As of October 1, 2017, all NIH-funded human subjects research is automatically issued a CoC as a term of the Notice of Award.

Definitions

Certificate of Confidentiality: COCs provide additional privacy protections to research participant by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. Certificates are issued by NIH and other Department of Health and Human Services (HHS) agencies to institutions or universities where the research is conducted. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Expiration date: The expiration date means that any identifiable information collected after that date is not protected by the CoC. It does not mean that the CoC's protection of already-collected information ends on that date. The identifiable research information collected from subjects under a CoC is permanently protected from forced disclosure, even after the CoC expires and the study ends. The expiration date can be extended, by request.

Institutional Official: This individual is designates as the Vice President for Research and Economic Development.

Policy

The NIH Policy on Certificates of Confidentiality (CoC) 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*" that was commenced or ongoing after December 13, 2016.

If a NIH- funded activity falls within the scope of the NIH policy, CoCs are automatically granted as part of terms and conditions of the award and the requirements of such must be complied with. Investigators and institutions are responsible for determining when a NIH-funded activity falls within the scope of the NIH policy and if the CoC is included as part of the terms and conditions of the award.

NIH policy expands upon 42 U.S.C. 241(d) by explaining that NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in 45 CFR 46, including research determined to be exempt (except for exempt research when 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;** 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.

For all other HHS-funded (non-NIH) research, all other federal agency funded research, and non-federally funded research, researchers may request a CoC for their research or the IRB may request that the researcher obtain a CoC. These will only be issued on request.

Procedure

1.0 **For NIH-funded studies in which a CoC has been issued:**

1.1 Investigators are responsible for clearly representing in the IRB submission that a CoC is in place (e.g. as terms and conditions of an NIH award).

1.2 When reviewing research under a CoC, the IRB will evaluate whether the research protocol is consistent with the obligations to protect information and specimens under a CoC and whether the consent language, if applicable, discloses the CoC and appropriately describes the associated protections and limitations.

1.4 Sample consent language is provided by the IRB or the NIH sample language describing the CoC protections may be used.

2.0 **For all other HHS-funded (non-NIH) research, all other federal agency funded research, and non-federally funded research or when the IRB requests a CoC:**

2.1 Investigators are responsible for clearly representing in the IRB submission that a CoC is in place, if a CoC application is pending, or that an application for a CoC has been submitted. When the CoC application is in process or pending, the IRB may condition final approval upon its receipt.

2.2 When non-NIH research is not under a CoC, the IRB may require an investigator to apply for a CoC if the research includes identifiable, sensitive information and the IRB determines that a CoC is necessary to minimize risks and adequately protect subjects' privacy and the confidentiality of subjects' information or specimens.

2.3 When reviewing research under a CoC, the IRB will evaluate whether the research protocol is consistent with the obligations to protect information and specimens under a CoC and whether the consent language, if applicable, discloses the CoC and appropriately describes the associated protections and limitations.

2.5 Sample consent language is provided by the IRB, or the NIH sample language describing the CoC protections may be used.

2.6 A copy of the Notice of Award or CoC is to be retained in the research record.

Regulated Documentation

NIH Policy on Certificates of Confidentiality
301(d) of the Public Health Service Act (42 U.S.C 241)

University Related Documents

USA IRB Informed Consent Local Context Language

References

NIH Certificates of Confidentiality
NIH Sample Consent Language for Certificate of Confidentiality

HISTORY

Effective Date:
Revisions: October, 2018