IRB Guidance for Certificates of Confidentiality

Purpose

The information in this guidance document is intended to aid researchers in understanding the protections afforded by Certificates of Confidentiality (CoC) and determining whether a CoC is applicable and necessary for their research.

CoCs protect research subjects' privacy and confidentiality by prohibiting disclosure of participants' information to anyone not connected with the research, except under specific circumstances: if the subject voluntarily consents; if required by federal, state, or local law; for the purposes of scientific research that is compliant with human subjects regulations; or if necessary for the medical treatment of the participant and made with the consent of the participant.

Further, CoCs prevent forced disclosure of identifiable, sensitive research information. More specifically, CoCs enable researchers to refuse disclosure in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. A CoC provides an extra layer of privacy protection for participants in research that obtains sensitive information.

In This Document

Applicability

NIH-, HRSA-, or CDC-Supported Research

Research funded by the National Institutes of Health (NIH), the Health Resources and Services Administration (HRSA), or the Centers for Disease Control and Prevention (CDC) that collects or uses sensitive, identifiable information (defined below) and that was on-going on or after December 13, 2016 is automatically covered by a CoC. Such research

- meets the definition of human subjects research, including exempt research in which subjects can be identified;
- collects or uses human biospecimens that are identifiable or that have a risk of being identified;
- involves the generation of individual-level human genomic data, regardless of identifiability; or
- involves any other information that could be used to deduce the identify of an individual.

According to the NIH and HRSA CoC Policies, *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.

Identifiable, sensitive information includes but is not limited to name, address, and social security or other identifying number as well as 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.

Other Research

Research projects funded by other federal agencies and research projects without funding are not automatically covered, but are eligible for a CoC *if* they

- collect or use *identifiable, sensitive information* (defined above), and
- investigate a topic that is within the NIH mission or the U.S. Department of Health and Human Services' (HHS) health-related research mission.

Researchers should consider seeking a CoC for research that gathers *sensitive, identifiable information* about participants that may present risk of criminal or civil liability or be damaging or harmful to the research subject's financial standing, employability, insurability, or reputation if disclosed. Examples of such research include, but are not limited to, the following:

- Studies on sexual attitudes, preferences, or practices;
- Studies on the use of alcohol, drugs, or other addictive products;
- Studies that collect information on illegal conduct;

- Studies that involve information that is potentially damaging to a participant's financial standing, employability, or reputation within the community;
- Research involving information that might lead to social stigmatization or discrimination;
- Research on psychological well-being or mental health;
- Research on HIV, AIDS, or other STIs;
- Genetic studies; and
- Research on behavioral interventions and epidemiologic studies.

How Long Is a CoC Valid?

CoCs for NIH-funded research cover information collected or used while the research is funded by the NIH, including any no-cost extensions. If NIH funding ends, CoC protections do not apply to new data collected from already-enrolled participants or from new participants; however, researchers may apply for a new CoC following procedures for non-NIH-funded research.

CoCs for non-NIH-funded research are issued for a defined period of time. Once a CoC expires, any study information collected after that expiration is not protected. If expiration is approaching but data collection is to continue, researchers should apply for a new CoC using the NIH's online system.

How Long Do CoC Protections Last?

Although CoCs cover research occurring during a defined timeframe, CoC *protections* last in perpetuity. That is, research participants' identifiable information that is collected at any point during the time a CoC is in effect is protected permanently, even after the participant's death. Anyone using information protected by a CoC is required to uphold the protections—this includes secondary researchers who receive data/information gathered during research covered by a CoC.

Obtaining a Certificate of Confidentiality

NIH-, HRSA-, and CDC-funded Research

NIH-funded research: Effective October 2017, *all* biomedical, behavioral, clinical, or other research conducted or funded by the NIH, in whole or in part, whether supported through grants, cooperative agreements, contacts, other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information is automatically issued a CoC. However, investigators will not receive a physical certificate. Researchers may refer to their Notice of Award and the NIH Grants Policy Statement as documentation.

HRSA-funded research: Effective March 31, 2022, *all* biomedical, behavioral, clinical, or other research funded wholly or in part by HRSA, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by HRSA staff, that collects or uses identifiable, sensitive information is automatically issued a CoC. However, researchers will not be issued Certificates as separate documents.

This policy will be included in the HRSA Grants Policy statement as a standard term and condition of award for new and non-competing awards.

CDC-funded research: Per Section 2012 of the 21st Century Cures Act, all ongoing or new research funded by the CDC as of December 13, 2016, that is collecting or using identifiable, sensitive information is automatically covered by a CoC. However, researchers will not receive a physical certificate. Researchers may look to the Terms and Conditions of Award, Guidance on Certificates of Confidentiality, and the Additional Requirement #36 as documentation of the CoC protection.

Other HHS-funded Research

Certain HHS agencies, such as the Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA), and Indian Health Service (IHS), issue CoCs independently. Investigators should consult the Certificate Coordinator at the funding agency to determine how to obtain a CoC. Notably, if the research is being conducted under an Investigational New Drug or is otherwise FDA-regulated, CoC requests should route to the FDA CoC Coordinators.

Other HHS agencies *do not* issue CoCs. In these instances, the NIH issues CoCs on behalf of these agencies. Investigators must submit a request for a CoC via the NIH's online system, as described below.

Other Federal, Non-Federal, and Non-Funded Research

Other funded and non-funded research may still be issued a CoC. Researchers may request a CoC from the NIH for their human subjects research projects that use identifiable, sensitive information.

Note: The Department of Justice (DOJ) and the Agency for Healthcare Research & Quality (AHRQ) have their own privacy requirements. The NIH will not issue CoCs for DOJ-funded research or for research covered by AHRQ regulations.

ISU-Specific Instructions for Requesting and Obtaining a CoC

The following is intended to supplement instructions provided by the NIH for requesting and obtaining a CoC by outlining additional ISU- and IRB-specific steps. To note, CoCs are typically requested *after* IRB approval has been obtained and are issued at the NIH's discretion.

1. Submit an IRB application for review via IRBManager. In the "Certificate of Confidentiality" section of the application, select the appropriate response to the CoC question.

2. Be sure the informed consent document(s) include(s) appropriate language about the protections and limitations of the CoC. See the IRB's Informed Consent Templates for suggested language.

3. After IRB approval is obtained, complete and submit a CoC application using the NIH Online Certificate of Confidentiality System. Applications must be completed in a single session, be submitted at least three months prior to initial participant enrollment, and include the following information:
    - Project details (e.g., research title, start date, projected end date, and description);

- Institution and performance site (if applicable) details, including names and addresses as well as Institutional Official (IO) name, email, and phone number; at Iowa State, the IO is the Vice President for Research;
- Principal Investigator name, phone number, email address, degree, position;
- Key personnel names, degrees, and positions;
- Name(s) of drugs that will be administered, route of administration, and dosage (if applicable); and
- A copy of the DEA certificate/registration (applicable only when a controlled drug is to be administered).

Following submission of the above information, the IO will receive an email, will need to review the request information for accuracy, and will need to affirm the online Institutional Assurance Statement by checking each box and submitting the CoC request.

Researchers should receive notification(s) regarding the CoC application from NIH.

Researcher Responsibilities

Informing Research Participants

Research subjects must be informed, via the informed consent document, of protections afforded by the CoC as well as any exceptions or limitations to those protections. The NIH website includes example informed consent language, as do informed consent templates provided by the ISU IRB. In addition to informing participants of CoC-related protections, researchers should also review study-specific confidentiality, data security, and data sharing/future use language to ensure it is consistent with CoC protections.

If a CoC is obtained after subjects have been enrolled, for example if NIH funding is secured later, subjects should be informed regarding the newly-issued CoC. A formal re-consent process is **not** required for ongoing studies, however. Rather, researchers should inform *already enrolled* participants of the CoC. This could be handled during an upcoming study visit/interaction or provided to participants via stand-alone communication. The ISU IRB's consent addendum may be used as a model for notifying already enrolled participants. If researchers intend to enroll *new* participants, a revised informed consent document containing CoC language should be drafted. Revised consent processes and materials must be approved by the IRB prior to use with participants.

Non-Disclosure Requirements & Exceptions

For research covered by a CoC, investigators may not

- disclose or provide in a 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, biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure of information, physical documents, or biospecimens protected by a CoC 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 a Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for medical treatment of the individual to whom the information, document, or biospecimen pertains and made with consent of such individual;
- Made with consent of the individual to whom the information, document, or biospecimen pertains;
- Made for the purposes of other scientific research that complies with applicable Federal regulations governing the protection of human subjects in research.

Additional Investigator Requirements include

- Establishing and maintaining effective internal controls (e.g., policies and procedures) to ensure compliance;
- Ensuring that any sub-recipient, investigator, or institution not funded by NIH who receives a copy of identifiable, sensitive information protected by a CoC understands they are also subject to the disclosure restrictions and other requirements of subsection 301(d) of the Public Health Service Act; and
- Informing research subjects of the CoC, its protections and limitations, via the informed consent document.

Extending and Amending the CoC

CDC-issued CoCs: If CDC-funding will or has ended but data collection is to continue *without* funding, researchers should consult with the CDC Privacy and Confidentiality Unit (PCU) regarding possible extension.

Any significant change(s) to the research project must be communicated to the Privacy and Confidentiality Unit by submitting a Request for an Amendment of the CoC.

NIH-issued CoCs: If NIH-funding will or has ended but recruitment and/or data collection are to continue *without* funding *or* if a non-NIH-funded research project is to continue beyond the NIH-issued CoC expiration date, investigators must request a *new* CoC using the NIH's online system. The NIH online system does *not* process extensions for existing CoCs. Requests should be made at least three months prior to the existing CoC's expiration date.

If a significant change to a research project occurs *after* the CoC is issued, researchers should use the NIH online system to request a *new* CoC, as the online system does *not* process amendments. Examples of

significant changes include a change in the primary institution where research is conducted, major changes in the scope or aim(s) of the research, and major personnel changes (e.g., PI), and changes in drugs to be administered or those responsible for administering them.

HRSA-issued CoCs: Per the CoC Policy, researchers should direct inquiries to the HRSA Office of Planning, Analysis, and Evaluation (OPAE), Division of Oversight, Reporting, and Regulatory Compliance.

Independently issued CoCs: For research issued a CoC by other HHS agencies (e.g., FDA, SAMHSA, IHS), contact the agency's CoC Coordinator for information regarding CoC extension and amendment requirements.

Practical Tips for Researchers

The expectation that researchers make data publicly available and/or share data beyond the original research project is becoming increasingly common. The following are helpful tips to consider in connection to sharing data protected by a CoCs:

1. Information protected by a CoC can be shared *only if* the disclosure is authorized, such as in cases where participants consent to data sharing. Therefore, be sure the informed consent document clearly describes data sharing plans and all reasonably foreseeable future uses.
2. Protections afforded by a CoC apply to *all* copies of information, even those copies that are shared beyond the current research. Moreover, the NIH Policy on CoCs *expects* that researchers holding the CoC *ensure* anyone receiving a copy of the information understands that they are also subject to the CoC protections and limitations.
3. Be careful when combining data sets, particularly if some data are protected by a CoC while other data are not.

Collaborative research – referred to as Multi-Site (NIH) or Cooperative Research (Revised Common Rule) – has similarly increased in prevalence. Generally, in these scenarios the lead PI should apply for the CoC. For questions or project-specific guidance, contact IRB staff at Iowa State or at the institution providing IRB oversight.

Additional Resources

The above information, along with additional detail, is available from the following websites:

National Institutes of Health

- NIH Certificates of Confidentiality Policy
- CoCs for NIH-funded Research
- CoCs for Research Not Funded by NIH
- NIH CoC FAQs

Centers for Disease Control and Prevention

- Certificate of Confidentiality for CDC Funded Research
- Guidance on CoC for CDC Funded Research

Other Resources

- HRSA Policy on Certificates of Confidentiality
- FDA Guidance on Certificates of Confidentiality
- SAMHSA Guidance on Certificates of Confidentiality

Document History

Created/Approved:	*9/6/2022*