Certificates of Confidentiality

Purpose

This policy outlines and provides guidance concerning the application of Certificates of Confidentiality (CoCs).

Policy

Certificates of Confidentiality (CoC) protect research information by prohibiting certain disclosures and conditioning others upon consent from the subject. The protections and requirements of CoCs are outlined in 42 U.S.C. 241(d) and NIH policy (when applicable), as summarized below.

CoCs are obtained as follows:

- CoCs are issued automatically when research is conducted or supported by NIH and falls within the scope of the NIH policy.

- Research that is not funded by NIH (non-NIH research) may still have the protections afforded by CoCs through successful application to the NIH, FDA, or other authorized Federal Agencies or departments.

Protections and Requirements

When a CoC is issued, whether automatically or under an approved application, the person(s) engaged in the research must not disclose or provide the name of a subject or any information, document, or biospecimen that contains **identifiable, sensitive information** about the subject and that was compiled for the purposes of the research:

1. In any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, unless the disclosure is made with the consent of the individual to whom the information, document, or biospecimen pertains; or

2. To any other person not connected with the research, unless
    a. Required by Federal, State, or local laws (e.g., adverse event reporting to the FDA, transmissible disease reporting required under State law),
    b. Necessary for the medical treatment of the subject to whom the information, document, or biospecimen pertains and made with the consent of the subject;
    c. Made with the consent of the individual to whom the information, document, or biospecimens pertains; or
    d. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research

BCH's Office of Sponsored Programs

At Boston Children's Hospital, the Office of Sponsored Programs (OSP) staff will, in consultation with the Program Director(s)/Principal Investigator(s) (or a member of the PD/PI's research team, if applicable), determine if the NIH policy applies to any NIH-funded activity.
The questions outlined in the NIH policy will be used to guide the analysis.
When it has been determined that the NIH policy doesn't apply, Program Directors/Principal Investigators (or a member of their research teams, if applicable) are responsible for consulting with OSP whenever they are proposing changes to the NIH-funded activity that may impact or change the analysis.

Procedure

NIH Policy

The NIH Policy on CoCs 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 on or after December 13, 2016.

CoCs are automatically granted, and the requirements of such must be complied with, whenever a NIH-funded activity falls within the scope of the policy. Investigators and institutions are responsible for determining when a NIH-funded activity falls within the scope of the policy.

Identifiable, sensitive information: Is defined as, information that is about an individual and that is gathered or used during the course of biomedical, behavioral, clinical, or other research and

1. Through which an individual is identified; or
2. 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.

NIH policy 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.

Application Procedures for non-NIH funded Research

Any investigator that collects or uses identifiable, sensitive information may apply for a CoC. For most research an investigator may apply for a CoC through the NIH Institute or Center funding research in a scientific area similar to the project.

If the investigator is conducting a sensitive research project that is covered by the Agency for Healthcare Research and Quality (AHRQ) confidentiality statute or the Department of Justice (DoJ) confidentiality statute, then a CoC may not be needed.

If there is an Investigational New Drug Application (IND) or an Investigational Device Exemption (IDE), the sponsor can request a CoC from the FDA.

CoCs may also be issued by other Federal agencies and departments, such as Centers for Disease Control and Prevention (CDC), Substance Abuse and Mental Health Services Administration (SAMHSA), or Health Resources and Services Administration (HRSA).

IRB Review

Investigators are responsible for clearly representing in the IRB protocol that a CoC is in place, or that an application for CoC has been submitted. When the CoC application is in process or pending the IRB needs to be notified when it is issued.

For studies that are already underway, investigators must submit an Amendment Request to the IRB, along with updated consent language (if applicable), when a CoC is applied for, or when automatically issued under the NIH policy.

When reviewing research under a CoC, the Boston Children's Hospital IRB will evaluate whether the research plan 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.

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.

Template Consent Language

The following language is recommended for consent forms that are conducted under a CoC:

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Related Content

Regulatory Guidance

NIH: CoC website

FDA: Certificates of Confidentiality: ***Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff***

Document Attributes

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