DMID INFORMATION SHEET - Certificates of Confidentiality

DESCRIPTION

This Information Sheet includes three sections:

1. A brief summary of NIH Policy for Certificate of Confidentiality (CoC) requirements and plan for inclusion in DMID informed consent element checklists,
2. Sample informed consent text to inform subjects of the protections and the limits to protections provided by a CoC, and
3. Additional information for DMID Staff which details the requirements for implementing the NIH Policy for CoC across the spectrum.

EFFECTIVE - October 1, 2017

A CoC will be issued automatically to NIH funded grants, cooperative agreements, contracts and intramural research projects research funded wholly or in part by the NIH that collects or uses identifiable, sensitive information. Compliance with the requirements of the law will become a term and condition of award. All research that was commenced or ongoing on or after December 13, 2016 and is within the scope of this policy is issued a Certificate through this policy.

A Certificate of Confidentiality protects against forced disclosure of identifiable research information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

"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." - Excerpt from NIH Policy for Certificates of Confidentiality (CoC)

In accordance with NIH Policy for CoC, research participants must be told about the protections afforded by the certificate, as well as any exceptions to that protection. Notably, a CoC will not protect information contained in any primary existing records if the applicable research will gather information from an existing record.

To ensure compliance with requirements for disclosure of CoC protections, a description of CoC is added to DMID informed consent template checklists. Informed Consent Templates will be reviewed for the language about confidentiality and data security to be certain that it is consistent with the protections of the CoC. Refer to < Informed Consent Template Checklist >

SAMPLE TEXT

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to give information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, [*except for reporting of communicable diseases to State and local health departments, or as explained* below, see *"Disclosure is permitted only when"*].

[The following or similar language should be included if researcher intends to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others:]
The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities for [*list what will be reported, such as child abuse and neglect, or harm to self or others*].

[*The following or similar language should be included for research that will gather information from existing records:*] The Certificate of Confidentiality cannot be used for information in your medical records.

[*Use the following language as applicable*] A Certificate of Confidentiality does not prevent disclosure of your information to the NIH, Food and Drug Administration (FDA), or federal funding agency.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you give your consent to release information to a medical care provider, an insurer, or other person to receive research information, then the researchers will not withhold that information.

INFORMATION FOR DMID STAFF

Under the new policy, as of October 1, 2017, NIH funded researchers will no longer have to request a CoC, nor will they receive an actual certificate. The CoC will be issued automatically to NIH funded grants, cooperative agreements, contracts and intramural research projects research funded wholly or in part by the NIH that collects or uses identifiable, sensitive information. Compliance with the requirements of the law will become a term and condition of award. All research that was commenced or ongoing on or after December 13, 2016 and is within the scope of this policy is issued a Certificate through this policy.

The CoC protects the privacy of subjects by limiting the disclosure of identifiable, sensitive information. Under the new policy, disclosure is not up to the discretion of the investigator. Disclosure is only permitted in the following circumstances:

- if required by other Federal, State, or local laws, such as for reporting of communicable diseases;
- if the subject consents; or
- for the purposes of scientific research that is compliant with human subjects regulations.

The restrictions on disclosures apply to all researchers or research institutions previously issued a CoC who are engaged in research.

A point that is important to understand is that if research is covered by a CoC, you are required to ensure that any investigator or institution with whom you share a copy of the identifiable sensitive information that is protected by the policy understands that they are they are also subject to the disclosure restrictions, even if they are not funded by NIH.

NIH-Funded Recipient Responsibilities

This Policy applies to biomedical, behavioral, clinical, or other research conducted or supported by NIH if the answer is **yes** to any of 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?

When this Policy applies to the research, the recipient of the Certificate shall 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

- 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 purposes of the research.

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

As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH supported research applicable to this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award.

Recipients of Certificates are required to ensure that any investigator or institution not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate issued by this Policy, understand they are also subject to the requirements of subsection 301(d) of the Public Health Service Act. In accordance with NIHGPS Chapter 15.2.1, recipients are also responsible for ensuring that any subrecipient that receives funds to carry out part of the NIH award involving a copy of identifiable, sensitive information protected by a Certificate issued by this Policy understand they are also subject to subsection 301(d) of the Public Health Service Act.

REFERENCES

- NIH Certificates of Confidentiality (CoC)
- NIH OER/Open Mike: New Policy: NIH's Certificates of Confidentiality Policy Enhances Confidentiality

WHOM TO CONTACT FOR QUESTIONS

- For Questions About NIH Policy for CoC: CoC Contacts at NIH
- For Consent Language, email: NIAIDDMIDHSP NIAIDDMIDHSP@niaid.nih.gov