



## NIH Issues Significant Changes to Certificates of Confidentiality (CoC) Policy

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On September 7<sup>th</sup>, NIH issued a notice of significant updates to its [Certificates of Confidentiality](#) (CoC) related to the implementation of the [21<sup>st</sup> Century Cures Act](#). Under this policy, **CoCs will become a term and condition of NIH grant awards** rather than issued through a separate application process. Institutions and investigators are responsible for determining whether the NIH research they conduct is subject to the policy and therefore automatically under a CoC. Importantly, while the effective date of the policy is October 1, 2017, it will apply retrospectively to all NIH research that was initiated or ongoing on or after December 13, 2016 that falls within the scope of the policy. CoCs will continue to be available through the current application process for research that is not conducted or funded by NIH.

### Key takeaways include:

- CoCs for NIH conducted or funded research will automatically apply when the research falls within the scope of the policy, compliance is a term and condition of grant awards;
- The scope of the new policy is extremely broad and includes research that is not subject to IRB requirements (see [Summary](#) below);
- The policy places responsibility for determining whether research falls within the scope of the policy on institutions and investigators and provides a series of questions to aid in this analysis (see [Appendix](#));
- The policy has an **effective date of 10/1/17 but retrospectively applies to research begun on or after 12/13/16** meaning that a look-back will be needed to identify studies within scope;
- Permitted disclosures are very limited and may require subject consent, including when the disclosure is necessary for medical treatment. It is unclear whether and how this may impact matters such as the administration of research, the use of research alerts and other tools in Electronic Health Record systems, and the common practice of placing copies of research consent forms in medical records. It is also unclear whether consent for such disclosures can be a requirement of participation. Guidance is needed, but given the effective date and the fact that guidance is not yet available, organizations should consult with legal counsel as needed to address such questions;
- Additional responsibilities are placed on institutions for internal controls and to ensure that recipients (e.g., sub-recipients, unfunded investigators) of information or specimens covered by a CoC understand that the [PHS Act](#) also applies to them. This will likely necessitate development of policies and procedures and evaluation of templates or standards used for contracts, Materials Transfer Agreements (MTAs), confidentiality and other agreements;
- NIH expects that information regarding the CoC, and its protections and limitations are provided in studies with informed consent. Existing consent template language will likely need to be modified and provisions put into place for exempt studies when consent will be sought;
- CoCs for research not supported by NIH may still be applied for using the current mechanism.

## CoC Policy Summary

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### Policy Scope:

The scope of the policy is broad, including ***“all biomedical, behavioral, clinical, or other research funded wholly or in part by the NIH...that collects or uses identifiable, sensitive information.”***

Likewise, the definition of identifiable, sensitive information is very broad encompassing more than either the Common Rule or HIPAA concepts of identifiability: ***“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.”*

The policy goes on to specify that the policy includes:

- **Exempt** research **unless** the information obtained is recorded in such a manner that subjects cannot be identified, or identities readily ascertained, directly or through identifiers linked to the subjects;
- 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 identifiability**; 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.

A series of questions that investigators should ask to determine the applicability of the policy is provided and is [appended](#) to this summary.

### Disclosures:

When a CoC applies, organizations and investigators (“recipients of the CoC”) **may not**:

- Disclose or provide in any **Federal, State, or local proceeding**, the name of subjects 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 the subject provides consent for the disclosure; or
- Disclose or provide to **any other person not connected with the research** the names of subjects or any information, document, or biospecimen that contains identifiable, sensitive information about a subject and that was created or compiled for purposes of the research.

Disclosure **is permitted** when:

- **Required by Federal, State, or local laws** (e.g., reporting to FDA, reporting communicable diseases to health departments) excluding proceedings as noted above;
- Necessary for the **medical treatment** of the subject **with consent** of the subject;
- **Made with consent** of the subject; or
- Made for the purposes of **other scientific research** that is in compliance with applicable Federal regulations

**Additional Requirements:**

- Organizations must establish and maintain effective **internal controls** (e.g., policies and procedures) to ensure compliance;
- Organizations must ensure that **sub-recipients and any investigator or institution not funded by NIH** who receives a copy of identifiable, sensitive information protected by a CoC understand they **are also subject to the requirements of [subsection 301\(d\) of the Public Health Service Act](#)**;
- NIH expects investigators to inform subjects of the CoC, and its protections and limitations, in studies in which **informed consent** is sought.

## Questions for Determining Applicability of NIH CoC Policy

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1. Was the research begun or ongoing on or after December 13, 2016? ☐ Yes ☐ No

If the answer is No (i.e., the research was completed prior to 12/13/2016), the policy does not apply. If the answer is Yes, answer the following questions.

1. Is the research conducted or funded by NIH? ☐ Yes ☐ No
2. Is the activity biomedical, behavioral, clinical, or other research? ☐ Yes ☐ No

If the answer to either of these questions is No, then the activity is not issued a CoC and the policy does not apply. If the answer to both is Yes, answer the following questions:

1. Does the research involve human subjects as defined by [45 CFR Part 46](#)? ☐ Yes ☐ No
2. Are you collecting or using biospecimens that are identifiable to an individual as part of the research? ☐ Yes ☐ No
3. 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? ☐ Yes ☐ No
4. Does the research involve the generation of individual level, human genomic data? ☐ Yes ☐ No

If the answer to any one of these questions is Yes, then a CoC is automatically issued and the policy applies.