

**MASS GENERAL BRIGHAM HUMAN
RESEARCH OFFICE
GUIDANCE DOCUMENT
NIH Policy on Certificates of Confidentiality (CoC): What you must do!**

NIH Policy on Certificates of Confidentiality (CoC)

As of October 1, 2017, the NIH has a new policy on Certificates of Confidentiality (CoC) which changes the existing process for obtaining a CoC. The policy applies to all new NIH awards, as well as ongoing NIH research awarded on or after December 13, 2016. These changes were made in response to new requirements included in the 21st Century Cures Act.

Comparison of the old and new CoC Policy:

	Old CoC Policy	New NIH CoC Policy
Process	PI had to apply for a CoC	CoC will be automatically issued for research in scope
Documentation	Hard-copy certificate issued	No document will be issued
Scope	Limited scope: PI determination of sensitive research	Broad scope: See NIH criteria listed below
Specific prohibition	PI could not be forced to disclose identifiable info pursuant to a legal/legislative action such as a subpoena	PI prohibited from disclosure pursuant to legal/legislative action such as a subpoena Consent is now required for some other disclosures

Applicability

All recipients of NIH funding who conduct biomedical, behavioral, clinical, or other research that collects or uses *identifiable, sensitive information* are covered by the new NIH policy and are deemed to be issued a Certificate of Confidentiality as part of the award.

NIH Criteria for Certificates of Confidentiality

NIH considers research in which *identifiable, sensitive information* is collected or used, to include:

- Human subjects research as defined by 45 CFR Part 46 (*virtually anything reviewed by the IRB*);
- Research involving the collection or use of biospecimens that are identifiable to an individual as part of the research or for which there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to identify an individual;
- Generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of identifiability; (*note, this includes activities that may be designated “not human subjects research”*); or
- Any other research that involves information that there is at least a very small risk that alone or in combination with other information could identify an individual.

Responsibilities of NIH Award Recipients

As the recipient of NIH funding, Principal Investigators are responsible for being aware of CoC requirements, communicating CoC requirements to sub-awardees and downstream recipients of data

collected under an NIH award, and complying with the CoC restrictions on disclosure of identifiable, sensitive information.

1. Prohibited disclosures:

- Disclosing or providing, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name or any information, document or biospecimen that contains *identifiable sensitive information* that was compiled or generated for the purposes of the research; *unless*, that individual gives consent for the disclosure.
- Disclosing or providing to any other person not connected with the research the name or any information, document or biospecimen that contains *identifiable sensitive information* that was compiled or generated for the purposes of the research; *unless*, that individual gives consent for the disclosure.

2. Permitted disclosures:

- Required by Federal, State or local laws (e.g., as required by the FDA or state laws regarding reporting of communicable diseases or child/elder abuse), excluding disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of that individual participant and made with the consent of the individual;
- Made with the consent of the individual; 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.

3. Duration of CoC coverage for identifiable data and biospecimens

The CoC protections stay with the data/biospecimens for as long as the data/biospecimens exist. This means that any down-stream recipients of the data/biospecimens must be made aware of the CoC. As a result, the CoC protections extend to **subawards and secondary uses of biospecimens/data collected as part of NIH-funded research**. The institution must notify collaborators working under a NIH subaward of the CoC requirements and investigators requesting to use biospecimens/data for non-NIH funded research.

Mass General Brigham NIH CoC Policy Implementation Plan

The following departments, review committees and research resources will be responsible for ensuring that investigators are provided with information about the NIH CoC Policy and requirements.

Research Management

Research Management will inform investigators of the NIH requirements for Certificates of Confidentiality in the following notifications/communications to investigators:

- New Award Account Set-up
- Subcontracts/Consortium Agreements
- Data Use Agreements (using data collected with NIH funding)

Mass General Brigham Institutional Review Board (IRB)

The Mass General Brigham IRB will inform investigators of the NIH CoC requirements in the Insight/eIRB applicationforms and submission instructions.

- When **written informed consent is required**, investigators will be required to submit the Certificate of Confidentiality Research Consent Form at initial review OR continuing review if the

protocol is open to enrollment and written informed consent is required. Investigators are not required to re-consent participants who have already signed the consent form.

- When **written informed consent is not required**, investigators will be notified of the CoC requirements at initial review, as appropriate.

Mass General Brigham Institutional Biosafety Committee (PIBC)

During the registration process, the Mass General Brigham IBC will inform investigators of the NIH requirements for Certificates of Confidentiality in genomic studies when using purchased cell lines.

Mass General Brigham Biobank

The Mass General Brigham Biobank will inform investigators of the NIH requirements for Certificates of Confidentiality when obtaining de-identified biospecimens from the Biobank.

Requests for Information Pursuant to Subpoena, or Federal, State or Local Civil, Criminal, Administrative, Legislative or Other Proceeding

Whenever you receive requests for information related to the above, contact Beth Watters in the Office of the General Counsel, 857-282-1998 or bwatters@partners.org.

Additional Resources:

NIH FAQs at: <https://humansubjects.nih.gov/coc/faqs>

NIH CoC Website at: <https://humansubjects.nih.gov/coc/index>

NIH CoC Policy at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>

Select Frequently Asked Questions (FAQs):

Q: What is a Certificate of Confidentiality?

A: Certificate of Confidentiality (Certificate) protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive information. The Certificate prohibits disclosure in response to legal demands, such as a subpoena.”

Q: What disclosures are allowed?

A: The CoC allows the following disclosures:

- If required by Federal, State or local laws (e.g., reporting child, elder abuse, communicable diseases) – but excluding civil, criminal, administrative, legislative proceedings
- For medical treatment with the consent of the individual
- With the consent of the individual
- For other research that is in compliance with human subjects protection regulations

Q: CoCs are not new, what has changed?

A: The 21st Century Cures Act introduced two changes:

- (1) CoCs are now *automatically issued* for research involving identifiable sensitive data or biospecimens funded by an HHS Agency (NIH, FDA, CDC, HRSA, SAMHSA). There is no longer a need to proactively apply for a CoC if funded by one of these agencies.
- (2) The old CoC protects an investigator from being forced to disclose research information pursuant to Federal, State or local civil, criminal, or legislative proceedings. The new policy states that investigators are prohibited from making any such disclosures of identifiable sensitive information.

Q: If I am not funded by one of the HHS agencies, can I get a CoC?

A: Yes. You can apply through one of the HHS Federal Agencies which are continuing to use the NIH online application process that can be accessed at: <https://humansubjects.nih.gov/coc/apply>.

Q: Does the NIH CoC Policy apply to all HHS agencies?

A: No. While all HHS agencies must follow the 21st Century Cures Act as noted above, the scope of the NIH policy is informed by the NIH definition of *identifiable sensitive information* as:

- Human subjects research including exempt research if the recorded information is directly or indirectly linked to identifiers.
- Research involving the collection or use of biospecimens or information for which there is at least a very small risk that some combination of the biospecimen/information, a request for the biospecimen/information, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of human genomic data regardless of the identifiability of the biospecimen. (Note this may include research activities which have been designated “not human subjects research” and as such not require IRB review.)

Q: Will other agencies adopt the NIH Policy?

A: Uncertain. Each agency must:

- a. Determine how they will interpret/define ‘identifiable sensitive information.’ The NIH is using a very broad definition that covers anything that is remotely identifiable as well as genomic information (regardless of identifiability of the originating specimen) – but this interpretation is specific only to the NIH. The other agencies must define the scope of research that they will cover under a CoC.
- b. Develop and communicate a process for providing a CoC.

If you have funding from one of these other agencies, contact your Program Officer.

Q: How long does a CoC last?

A: Research data collected under a CoC is covered for as long as the data exists. Therefore, the CoC remains in effect if:

- The covered data is used for secondary research; or
- The covered data is shared with another investigator.

Q: If I have a CoC for my research and I lose NIH funding, does the CoC continue to apply?

A: The CoC protection will continue to apply to data collected while you had NIH funding and a CoC was in place. In contrast, data collected after NIH funding ceased will not automatically be covered by a CoC. Investigators will have to decide whether or not to apply for a new CoC for the remainder of their research.

Q: How will research participants be informed?

A: The only notification will be via the informed consent form (ICF) that includes language describing the protections with a CoC. New CoC language will be required in the ICF at the time of initial review as well as at continuing review for protocols open to enrollment and obtaining written informed consent.

Q: Do I have to re-consent participants who were enrolled in a study after December 16, 2016?

A: No. There is no need to re-consent. If the study is still enrolling at the time of continuing review, the new CoC language will be required in the ICF and used to enroll new participants.

Q: As a PI, what are my responsibilities if I have a CoC?

A: You are expected to:

- Be aware of which disclosures are permitted and which are prohibited.
- Notify sub-awardees and any secondary users of the covered data/specimens that there is a CoC and what protections must be in place
- Contact Beth Watters in the Office of General Counsel, 857-282-1998 or bwatters@partners.org in the event of a request for identifiable sensitive data/biospecimens for the purposes of a legal proceeding. Do not disclose the information.