THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Certificate of Confidentiality

PURPOSE

The purpose of this document is to provide guidance to investigators about Certificates of Confidentiality.

This policy is applicable to NIH funded (automatically applied at the time of funding) and to non-NIH funded research if determined by the IRB or PI.

PROCEDURE

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs work by protecting researchers and institutions from being compelled to disclose information in response to legal demands that would identify their research participants.

Effective October 1, 2017, the NIH updated its policy for issuing CoCs for NIH-funded and conducted research. The update of this Policy comes as a result of the need to implement Section 2012 of the 21st Century Cures Act, P.L. 114-255, which states that the Secretary, HHS shall issue Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical or other research, in which identifiable, sensitive information is collected.

Under the NIH's updated CoC policy, all NIH-funded (wholly or in part) research that is within the scope of that policy and was started or ongoing on or after December 13, 2016, will be automatically issued a CoC. This includes studies that may have since been terminated. If the CoC is obtained and the participants were not made aware of the CoC's protection, the investigator will need to notify the participants. The notification will include the protections afforded by the CoC and any exceptions to those protections.

Funding through DHHS or other federal funding is not a requirement for obtaining a CoC. For non-federally funded research, the NIH will continue to consider requests for Certificates for specific projects in accordance with the current NIH policy for issuing Certificates.

For the purpose of the NIH CoC Policy, the term "identifiable, sensitive information",

consistent with subsection 301(d) of the Public Health Service Act (42 U.S.C 241), means information about an individual that is gathered or used during 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.

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

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if 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 as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); 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, as defined in subsection 301(d) of the Public Health Service Act.

To determine if the NIH Policy for Issuing Certificates of Confidentiality will automatically apply to research conducted or supported by NIH, investigators will need to ask, and answer the following question:

- Is the activity biomedical, behavioral, clinical, or other research?

If the answer to this question is no, then the activity is not issued a Certificate. If the answer is yes, then investigators will need to answer 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?

If the answer to any one of these questions is yes, then the NIH Policy will apply to the research. Investigators of NIH-funded research do not need to apply for a COC. In

accordance with subsection 301(d) of the Public Health Service Act, 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.

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 the NIH Policy for Issuing Certificates of Confidentiality, 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 the NIH Policy for Issuing Certificates of Confidentiality understands they are also subject to subsection 301(d) of the Public Health Service Act.

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 the NIH Policy for Issuing Certificates of Confidentiality.

NIH-funded research conducted internationally and meeting the above criteria will still be considered to have been issued a COC, however the enforceability of the COC is uncertain in foreign jurisdictions.

What information does the CoC protect?

- The recent policy change broadened the meaning of sensitive, identifiable information and focuses more directly on identifiability. Identifiable information is

now considered to be sensitive regardless of the subject matter, in contrast to previous interpretations of what sensitive data might refer to in the research setting (illegal behaviors, sexual history, etc)

- CoCs protect names or any information, documents, or biospecimens containing identifiable, sensitive information related to a research participant. This includes all information collected, not only data included in a dataset.
- Identifiable, sensitive information is information about an individual, gathered or used during the course of biomedical, behavioral, clinical or other research, where the following may occur:
- The individual is identified; or
- For which there is at least a very small risk, that that some combination of the information, a request for the information, and other available data sources could be used to determine the identity of an individual.
- Identifiable, sensitive information includes but is not limited to name, address, dates, social security or other identifying number; and 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.

How long do the protections of a COC last?

The protections provided by the COC lasts in perpetuity. However, data collected after a CoC expires, or NIH funding ends, may not be protected. COCs issued automatically by this policy change apply to information collected during the NIH funding period. If the study continues after NIH funding ends and continued protection of a COC is needed for new information, you should apply for a COC following the process in place prior to the recent policy changes. The COC application process for non-federally funded research remains the same and should be followed to extend a COC beyond the NIH funding period. For information on that process see the NIH Frequently Asked Questions about COC.

Continuing Confidentiality Protections – Data Analysis, Dissemination and Retention

Once the study has been completed, PIs should consider taking additional precautions that may not have been feasible while the protocol was actively enrolling participants to protect the data that was collected during the study, including:

- Removing some or all direct identifiers (e.g., name, medical record number) and coding the information;
- Limiting the individuals who have access to the participant identifiable information
- Employing secure archival methods or Information Security Office-approved long-term storage services.

MD Anderson IRB Applicability of a CoC

MD Anderson has established written policies and procedures to assure compliance with the NIH CoC requirements. The IRB Standard Operating Procedure for CoC determinations and reviews include:

- A matrix to determine applicability of CoC requirements
- Templated informed consent language to inform new participants of the CoC applicability
- Participant notification letters to inform existing participants of the CoC applicability
- IRB reconsent guidance - IRB Guidance on Re-Consenting Participants on a Research Protocol
- Flag in CORe to identify studies where a CoC is applicable
- Researchers consider extension of CoC if NIH funding has ended

Additionally, IRB Meeting Presenter Guidelines includes the following statement: Does the study contain a data confidentiality plan for the protection of study participants' data? If appropriate, is there a Certificate of Confidentiality (*see* NIH Certificate of Confidentiality Kiosk.)

For non-funded NIH research, where a protocol involves the collection of sensitive information (e.g., about illegal conduct), the IRB may determine that special steps are needed to protect participants from the risks of external investigative or judicial processes (legally mandated release of information for use in federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings). In such situations, the IRB may require that the PI obtain a CoC.

When the PI obtains a CoC, the IRB requires that participants be informed about the protections and limitations under the CoC, through the consent document. The consent document must explain if the investigators will release information under any anticipated mandatory reporting or for internal or external audit purposes (e.g., DHHS, or FDA). In order that a participant may weigh the risk of such release of information and not expect more confidentiality protection than is actually provided by the CoC, the IRB requires that the possibility of release for those purposes be stated clearly and explicitly in both the protocol and the consent form. The IRB also requires that any participant enrolled after expiration or termination of a CoC be informed that its protection will not apply to them, and that issuance of a CoC is not an endorsement of the research by the DHHS.

INFORMED CONSENT

The NIH expects that participants enrolled moving forward and active participants who will continue to complete research activities be informed when a project meets the new Certificate of Confidentiality (CoC) criteria. Consent forms and scripts should include CoC language; the IRB approved language is provided below. A Sponsor or reviewing IRB may provide alternative language, in which case the PI may use the alternative language provided, although the MD Anderson IRB retains final approval of any

alternative CoC language to be used in informed consent forms or scripts at MD Anderson.

Language to be included in the informed consent document

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this CoC cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below).

The CoC cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation. You should understand that a CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to.

#2 version of Certificate of Confidentiality *(if the above language does not apply)***:**
{Sponsor} has received a Certificate of Confidentiality from the federal government, which will help them protect the privacy of research participants. The Certificate protects against the involuntary release of information about participants collected during the course of covered studies. The researchers involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the participant or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the participant or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review {Sponsor's} records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act. The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

Participant Notification Letter

The following letter can be sent to existing research participants who are taking part in a study, where a CoC has been added after protocol has been IRB-approved and activated:

(**Please print on MD Anderson letterhead)**

Dear **(Insert Patient Name):**

You are receiving this letter because you are taking part or are being asked to take part in the MD Anderson research study titled **(Insert protocol name and number).**

We would like to make you aware of the following protections on your identifiable, sensitive information.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this CoC cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below).

The CoC cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation. You should understand that a CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to.

If you have any questions about the CoC, please feel free to contact the study coordinator, **(Insert Study Coordinator Name and Number),** the study chair, **(Insert PI Name and Phone number),** or the Institutional Review Board of MD Anderson (the IRB is a committee that reviews research studies) at 713-792-6477. Thank you.

(Insert PI name and signature.)

What should investigators and research teams do to address this policy change?

The MD Anderson IRB has made minor adjustments to the CoC consent language and the IRB procedures to reflect the policy change. All projects considered above minimal risk regardless of funding source are being reviewed by the convened Board (initial, modification and renewal reviews) and are being evaluated for the applicability of the CoC. Exempt research projects are being evaluated at initial review. Expedited research projects are being evaluated at the initial review and renewal reviews.

For NIH-funded research, PIs who have studies meeting the criteria set forth in the "What research is covered automatically by a CoC?" section above should indicate in the protocol and informed consent that a CoC applies to their study. The PI and study team are responsible for updating any active consents or consent scripts to include CoC language. MD Anderson's updated CoC language and a participant notification letter that may be provided to current participants may be found here. The NIH expects that any currently enrolled subjects will be informed of the existence of the CoC at any future research interaction, but does not require formal re-consenting of active subjects, accordingly, study teams should use the prepared participant notification letter. If a consent or consent script already includes CoC language, the PI will not be required to replace that language with the updated CoC language but the PI is expected to provide currently enrolled subjects a copy of the participant notification letter.

NIH-funded investigators who are conducting research affected by the policy update may also submit a modification to update their protocol and consent template in advance of being asked to by the IRB during their next submission.

For non-funded NIH research, the IRB will notify the PI if the IRB determines that a CoC should be submitted for the protocol.

Where can I get more information?
For additional guidance, please feel free to contact the MD Anderson IRB Office by phone at 713-745-OHSP or by email to IRB Help.

The full NIH CoC policy may be accessed here https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html. The NIH website also has a helpful page on Frequently Asked Questions about CoCs here https://humansubjects.nih.gov/CoC/faqs or you may review information in the NIH Certificate of Confidentiality Kiosk.

REVISIONS

Date	Action	Initials	Description
06/07/2019	New	JH	
6/26/2019	Rev	SG	Added example of participant letter
6/26/2019	IRB3	MC	IRB3 Approval