Guidance on Certificates of Confidentiality

This guidance describes Certificate of Confidentiality (CoC) requirements and the process to obtain a CoC at the University of Miami.

I. What is a Certificate of Confidentiality?

A Certificate of Confidentiality (CoC) protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. A CoC primarily protects against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. CoC's are appropriate for research studies that gather information about subjects that might be damaging, and which will only exist in the research study records (that is, the information is not already in other records that are subject to subpoena).

II. Key Terms

Certificates of Confidentiality protect the privacy of research subjects by prohibiting the disclosure of identifiable, sensitive information to anyone not connected to the research, with only a few limited exceptions.

The **Assurance document** is the agreement by which the research institution (e.g., the University of Miami) agrees to protect against the disclosure of information that is protected by the CoC and defend the authority of the certificate.

III. When is a Certificate of Confidentiality required?

a. NIH-funded research automatically issued a CoC

Effective October 1, 2017, all new and ongoing National Institutes of Health (NIH)-funded research meeting certain criteria is deemed to be issued a CoC via a new NIH policy. Previously, researchers had to proactively apply to the NIH for a CoC, and only if the study was collecting sensitive information from participants. For more information about the change in policy, please see this notice.

i. What research is now covered automatically protected by a CoC?

Research that is funded by NIH and was commenced or ongoing on or after December 13, 2016, and:

- Is "human subjects research" as defined by federal regulations, *including* exempt research where data is identifiable;
- Or, is research involving the collection or use of biospecimens that are individually identifiable *or for which there is at least a very small risk* that some there is some way to deduce the identity of an individual;

- Or, is research that generates individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is "identifiable" per the Common Rule;
- Or, is 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 the subject's identity could be deduced.

b. What research is NOT automatically protected by a CoC (non-HHS; non-NIH)?

Before submitting a new application to the Institutional Review Board (IRB), Principal Investigators (PI) should consider whether a CoC would be an added protection for study data. If you will obtain identifying information of a sensitive nature from research participants, and the disclosure of such information could harm the participants, you may wish to apply for CoC. The PI should state in the application to the IRB that a CoC will be sought.

During its review of research for which a PI has not identified the need for a CoC, the University of Miami IRB may require that a CoC is a necessary and appropriate protection for the proposed project and may request that the PI apply for one. For these studies, CoCs are issued only upon the discretion of NIH.

Please note that federal funding is **not** a pre-requisite for an NIH-issued CoC, but the subject matter of the study must fall within a mission area of the NIH, including its Institutes, Centers and the National Library of Medicine.

IV. What are the responsibilities of the PI with CoC's?

For studies that obtain informed consent, the human subjects must be informed that their information is protected by a CoC. The University of Miami Human Subjects Research Office (HSRO) provides language in its Informed Consent Form templates. You may also refer to Appendices below for specific language.

For those studies that fall under the revised policy and have a CoC automatically issued, investigators must update their informed consents with this required language and appropriately consent and/or re-consent their subjects. For new studies that fall under the revised policy, Informed Consent Forms must be submitted to the IRB with the required language.

V. How can you apply for a CoC (when the CoC is NOT automatically issued)?

The PI is responsible for submitting the request for a CoC to NIH or other federal agency following IRB approval.

1. Visit the NIH's CoC Kiosk here and complete the steps to submit your application electronically.
2. Please direct your CoC request to the NIH institute or center that supports similar research.

3. You will need to provide a copy of the following:

    - A copy of your IRB Approval Letter
    - A copy of your IRB approved consent form(s) with appropriate CoC language
    - The University of Miami Federal Wide Assurance (FWA) number is FWA00002247.
    - An Assurance document signed by the University of Miami Institutional Official. The CoC assurance statement template is available on the NIH webpage at (https://humansubjects.nih.gov/coc/assurance-language). Once you have the Assurance document ready to be signed, DO NOT send the form directly to the University of Miami Institutional Official. Instead, email a PDF signed assurance on University of Miami Letterhead to the IRB analyst who is responsible for your study. If you are unsure of the analyst, you may contact the HSRO.

4. If the CoC is issued, for tracking purposes, upload a copy of the approval letter via an IRB7 Modification application in the Supporting Documents Section. **After study review and approval, Enrollment may commence once the CoC has been granted.**

5. If there are modifications to the study protocol, contact the CoC issuing agency.

VI. What language should I include in my informed consent for studies involving UChart or a discretionary CoC?

If UChart is being accessed in your study, the research team should follow the guidance applicable to studies involving an automatic CoC at Appendix 1. For studies that are issued a discretionary CoC upon application, and do not access UChart, the research team should follow the guidance at Appendix 2.

For studies ***solely*** involving a retrospective chart review (with data not being sent to the medical record), you will not need to include the UChart language. Studies that are purely chart reviews will likely not have an Informed Consent Form; thus, no consent language is needed. The guidance at Appendix 2 should be followed in this situation. In the event that there is a registry study or a prospective chart review with an informed consent, there will be a need for a consent. In this situation, please contact the HSRO for further guidance.

VII. What if my study is at Commercial IRBs, External IRBs, Multi-site or enrolling at Jackson Health System only?

Certificates are granted to institutions, based upon a PI's application, for single, well-defined research projects. Certificates are sometimes issued for cooperative multi-site projects which must have a coordinating center or lead institution. The coordinating center/lead institution can apply on behalf of all institutions associated with the multi-site project and must ensure that all participating institutions conform to the application assurances.

The HSRO has contacted commercial IRBs to provide the required and updated CoC and UChart language. For studies where UM investigators rely upon another external IRB, this language will be provided as part of local context review information. Please see Appendix 3 for language to be used for studies enrolling only at Jackson Health System.

VIII. Do I still need a HIPAA Authorization Form if I also have a CoC?

Yes. HIPAA and the federal CoC policy are different. The HIPAA Privacy Rule applies to any protected health information collected or used and, generally speaking, requires that "authorization" (permission) of an individual be obtained before a person's health information may be accessed, used, or disclosed for research, unless the IRB has granted a waiver.

IX. What if I am contacted to provide data protected under a CoC?

Researchers who receive a request for information protected under a CoC should immediately contact the HSRO who will immediately notify the Privacy Office and the Office of General Counsel.

For additional guidance, please feel free to contact the HSRO at 305- 243-3195. The NIH website also has a helpful page on Frequently Asked Questions about CoCs.

Appendices

Appendix 1: Language Required in Studies Automatically Issued a CoC under the Revised NIH Policy

If Certificate of Confidentiality Language is to be added to an ICF, then the UChart language also provided below must be included:

[Certificate of Confidentiality]

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers may not disclose or use information, documents, or biospecimens 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 to this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research, except 1) 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); 2) if you have consented to the disclosure, including for your medical treatment and related administrative activities; or 3) if it is used for other scientific research, as allowed by federal regulations protecting research subjects. This information will be available to University of Miami doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care and other health care operations. It may also be released to your insurance company in order to receive reimbursement for covered services.

The Certificate 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 by *[THE AGENCY]*, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to any other person not connected with the research, you must provide written consent to allow the researchers to release it.

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of *[list what will be reported, such as child abuse and neglect, or harm to self or others.]*

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, including the inclusion of research data in

your medical record at the University of Miami. Any information disclosed pursuant to your authorization may no longer be protected by the Certificate of Confidentiality.

[UChart Language.]

If you are, or have been, a patient at a University of Miami facility, you will have a University of Miami medical record. We use an electronic medical record system known as UChart, which improves access to information important to your medical care. UChart will show that you are in a research study and a copy of this signed consent form will be included. To provide as complete a record as possible, some or all of your study-related research information may also be placed in UChart. This specifically includes investigational drugs, devices, biologics, or anything else that may, separately or together with other substances or activities, interfere with your clinical treatment or place you at greater risk of harm. Other information from the research study may be included as well.

This information will be available to University of Miami doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care, or who are otherwise allowed to access your information. Th-e confidentiality of the results and other documents in UChart will be governed by laws, such as HIPAA, that concern medical records. We suggest that you tell any non-University of Miami doctors that you are in a research study and that more information may be made available to them at your request. The research team may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

Appendix 2: Language Required in Studies issued a Discretionary CoC under the Revised NIH Policy

[Include and fill-in if Certificate of Confidentiality applies to this study. Otherwise delete.]

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers may not disclose or use information, documents, or biospecimens 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 to this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research, except 1) 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); 2) if you have consented to the disclosure, including for your medical treatment and related administrative activities; or 3) if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

[Use the following language as applicable.]

The Certificate 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 by *[THE AGENCY]* which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality 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.

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of *[list what will be reported, such as child abuse and neglect, or harm to self or others.]*

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document *[restate what will be disclosed]*. Any information disclosed pursuant to your authorization may no longer be protected by the Certificate of Confidentiality.

Appendix 3: Language Required in Studies with a CoC for research enrolling at Jackson Health System only under the Revised NIH Policy

[Certificate of Confidentiality]

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers may not disclose or use information, documents, or biospecimens 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 to this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research, except 1) 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); 2) if you have consented to the disclosure, including for your medical treatment and related administrative activities; or 3) if it is used for other scientific research, as allowed by federal regulations protecting research subjects. This information will be available to doctors, nurses and other authorized staff who may not be part of the research team but who are involved in providing you medical care and other health care operations. It may also be released to your insurance company in order to receive reimbursement for covered services.

The Certificate 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 by *[THE AGENCY]*, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to any other person not connected with the research, you must provide written consent to allow the researchers to release it.

[Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of *[list what will be reported, such as child abuse and neglect, or harm to self or others.]*

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, including the inclusion of research data in your medical record. Any information disclosed pursuant to your authorization may no longer be protected by the Certificate of Confidentiality.