**Guidance for Certificates of Confidentiality (COC)**

When conducting human subject research that involves sensitive identifiable information, the IRB may ask (or you may decide) to obtain a Certificate of Confidentiality (COC) for the project. Certificates of Confidentiality are granted by the Department of Health and Human Services (DHHS) Institutes, Centers or the FDA, and they are intended to prevent researchers from being compelled to release research information (thereby protecting the participating subjects’ privacy).

The application is electronic-only and must be submitted through the NIH website: <https://humansubjects.nih.gov/coc/index>

Visit the website if you are looking for information regarding:

-Filling out the COC Application Form

-Deciding to which Institute or Center to apply

-How making changes in the research may affect your COC

-Whom to contact if you need more information

-Frequently Asked Questions

This guide will provide instructions on preparing your application and what is needed by the PPHS office to support the application process.

**Time Considerations in the COC application process**

DHHS suggests that applications for Certificates should be submitted at least three months prior to the date on which enrollment of research subjects is expected to begin. Since IRB approval (or approval pending only receipt of the COC) is required before submitting the application, this means that submitting to the IRB as early as possible to begin the review process is recommended.

**What The IRB Office Needs to Support Your Application:**

-COC Application Form (you will complete a draft on the COC website and provide the IRB a PDF copy. This draft should not be sent to the NIH.)

-Consent form (Two copies- one with PPHS template language regarding COC’s included and one without). The Mount Sinai consent template has this language built into the document.

-Assurance Document signed by the PI (template language below). Please prepare the assurance on Institutional letterhead and upload a scanned version of the signed form into the application. The PPHS office will oversee receiving the signature of the Institutional Official.

**What Happens Next?**

- After receiving the above documentation, the IRB will release your project approval at this point, if you haven’t received it previously. In most cases you will also receive your stamped (non-COC) consent documents containing standard MSSM confidentiality language so that you may begin recruiting. Only if your project is of such a sensitive nature that the IRB requires that you receive your COC prior to starting will you receive a “conditional” approval letter and not have any consent forms released to you at this time.

- When the application has been signed by the Institutional Official and returned to the IRB, the IRB will contact you. The IRB will send the fully signed Assurance Document to the study team to send with the application to the NIH. The IRB will also provide you with the consent forms you submitted containing the COC language, marked by the IRB with the text “approved pending COC” across the bottom of the consent document, to indicate that these are not documents for use, but the approved consent template to send to the DHHS Institute or Center. This version of the consent document should be sent with your signed COC application. (The IRB will retain the second copy of your consent document(s) to approve after the COC is in place.)

-Your electronic application to the NIH should include a copy of your project IRB approval letter

-Send your completed COC application and supporting documents electronically to the appropriate Institute.

-Once you receive your approved Certificate, or find out that your COC was denied, please submit a copy of the approved certificate or denial letter to the IRB office. If your COC was granted, the IRB will then release the consent document containing the COC language with final approval dates. When subjects who have signed the previous (non-COC) consent form return for visits, you should inform them of the protections afforded by the Certificate (any exceptions to those protections as are explained in the confidentiality section of the consent), and have them re-consent using the COC consent. In general, subjects who are no longer actively participating in the project do not have to be contacted especially about the receipt of the Certificate of Confidentiality if it is impractical to do so, unless the IRB informs the researcher otherwise.

**What If I Need To Amend or Extend My COC?**

-In your COC application, you will be asked to indicate the beginning date and expected end date of the project. The Certificate you receive, upon approval, will state the date upon which it becomes effective and the date upon which it expires.

If you determine that the research project for which you have received a Certificate of Confidentiality will extend beyond the expiration date on the Certificate or if a significant change in your research project is proposed after a Certificate is issued, you must contact the issuing agency or NIH Institute or Center.

More information about extending or amending a COC can be found at the following website:

https://humansubjects.nih.gov/coc/extend-amend

**Assurance Document Template Language (Use this language to prepare the assurance document on Institutional Letterhead. Have the PI sign and upload a scanned copy of that signed form to the IRB. The IRB will obtain the Dean’s signature)**

This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges.

The institution and personnel involved in the conduct of the research will comply with the applicable Federal regulation for the protection of human subjects or, if no such Federal regulation is otherwise applicable, they will comply with 45 CFR Part 46.

This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS or NIH or used to coerce individuals to participate in the research project.

All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate.

Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator Signature of Institutional Official

[Insert Name] Dennis S. Charney, M.D.

[Insert position] Dean, Icahn School of Medicine at Mount Sinai

 President for Academic Affairs, Mount Sinai Health System

**Whom to contact if you need more information regarding the IRB’s role in supporting your COC application:**

Icahn School of Medicine Program for the Protection of Human Subjects (212) 824-8200