Guidance for Certificates of Confidentiality (COC)

When conducting human subject research that involves sensitive identifiable information, the IRB may ask a researcher 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 or Centers, and they are intended to prevent researchers from being compelled to release research information (thereby protecting the participating subjects' privacy). Information about COCs can be accessed at the NIH website called the “Certificate of Confidentiality Kiosk.” The NIH also has a section of the kiosk for Frequently Asked Questions which contains a wealth of information about the Certificates and the process, and you are strongly encouraged to read it. The information presented in this guidance is only a general summary of information.

This guidance will provide information on:

- What is meant by “sensitive information”
- How research may be affected
- Time Considerations in the COC application process
- Deciding to which Institute or Center to apply
- Instructions for preparing your COC application:
  - Instructions for preparing the MSSM consent document to accompany the COC application
  - Instructions for submitting the application to the IRB and DHHS Institute/Center
- COC approval periods and renewals
- How making changes in the research may affect your COC
- Whom to contact if you need more information

What is meant by “sensitive information”

According to the NIH website, sensitive information includes (but is not limited to) information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information or tissue samples.

Examples of research are eligible for a Certificate are: research on HIV, AIDS, and other STDs; studies that collect information on sexual attitudes, preferences, or practices; studies on the use of alcohol, drugs, or other addictive products; studies that collect information on illegal conduct; studies that gather information that if released could be damaging to a participant's financial standing, employability, or reputation within the community; research involving information that might lead to social stigmatization or discrimination if it were disclosed; research on participants' psychological well being or mental health; genetic studies, including those that collect and store biological samples for future use; research on behavioral interventions and epidemiologic studies.

How research may be affected

The IRB will allow most research projects that involve sensitive identifiable information to begin (or continue) prior to having an approved Certificate of Confidentiality on file at the IRB, provided that evidence of the submission to DHHS is submitted to the IRB (see instructions in “Submitting the Application” below).

A few kinds of research may be deemed too sensitive to proceed without an approved COC in place. In those rare cases, the IRB may require receipt of the approved Certificate before allowing the research to proceed. If you receive a document that states that receipt of an approved COC is required in order for the IRB to issue final approval, please contact the IRB for further instructions. Otherwise, please follow the instructions as listed below.
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.

Deciding to which Institute or Center to apply

1. If your research involves an IND (Investigational New Drug application) then you must apply to the FDA for your Certificate of Confidentiality. If it does not involve an IND, and is sponsored by an Institute or Center, you must apply to your sponsoring Institute for your Certificate.

2. If your project is not funded by a National Institute or Center, you can still apply for a COC from the Institute or Center that handles the related area of scientific research. For instance, if you are to conduct a project in which you will collect lung specimens for a repository, you would send your COC application to the National Heart, Lung, and Blood Institute (NHLBI). If there is no Institute or Center that has an area similar to your research area, you may submit your application to the central COC resources at the DHHS—the NIMH. Their contact information is listed in #3.

3. If you have any doubt about where to send your application, contact the COC Central Resource representatives at the NIMH, and ask which Institute or Center is appropriate place to send the application. The list of COC representatives at each Institute and Center is available on their website. If you need further assistance, contact the IRB.

Instructions for preparing your COC application:

1. From the main COC Kiosk, open the “Extramural Projects- Application Instructions”. Please note that an “application” is not an actual form provided to you; it is simply a document you write up on your own letterhead that contains the information requested in the application instructions.

2. Submit an “application” on institutional letterhead that contains the information covered in points 1 through 14 listed in the application instructions. A few helpful tips in covering the points:
   a. For items 5a-b: The IRB will provide the PI with a signed approval letter for the study and a “stamped” consent form that states “approved pending COC” to send with the completed application to the DHHS Institute or Center (see below for further information).
   b. For item 5c: The FWA# is 00005656
   c. After inserting the “Assurances” language (verbatim from the NIH website), please add the following information underneath the signature lines that you will put at the end of your application:

   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

Instructions for preparing the consent document to accompany the COC application:

1. For the consent form, do NOT use the suggested consent language provided on the COC application instructions. Please follow the instructions below:

   ➢ If the study involves adults

Under Maintaining Confidentiality – HIPAA Authorization:
Under Who, outside Mount Sinai, might receive your protected health information?

Replace the second paragraph beginning “In all disclosures outside of Mount Sinai..” with the following paragraph:

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Add the following paragraph before the signature page:

Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This Certificate does not mean that the Department of Health and Human Services approves of this research. Rather, it is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above. The research staff will not share any of your research information with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

- If the study involves children

Under Who, outside Mount Sinai, might receive your protected health information?

Replace the second paragraph beginning “In all disclosures outside of Mount Sinai..” with the following paragraph:

In almost all disclosures outside of Mount Sinai, your child will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to your child without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, will come to inspect your child’s records. Even if those records are identifiable when inspected, the information leaving the institution
will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your child’s name and other identifying information confidential.

Add the following paragraph before the signature page:

Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This Certificate does not mean that the Department of Health and Human Services approves of this research. Rather, it is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying your child in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above. The research staff will not share any of your child’s research information with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that your child or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect your child or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your child’s involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your child’s research participation, and you agree that they can have your child’s research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

➢ If the study involves incapacitated adults

Under Who, outside Mount Sinai, might receive your protected health information?

Replace the second paragraph beginning “In all disclosures outside of Mount Sinai..” with the following paragraph:

In almost all disclosures outside of Mount Sinai, the research subject will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to the research subject without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to the research subject’s privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, will come to inspect the research subject’s records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to the research subject’s medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep the research subject’s name and other identifying information confidential.

Add the following paragraph before the signature page:
Certificate of Confidentiality: To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This Certificate does not mean that the Department of Health and Human Services approves of this research. Rather, it is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying the research subject in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above. The research staff will not share any of the research subject’s research information with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that the research subject, or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect the research subject, or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or the research subject’s involvement in this research. This means that you and the research subject must also actively protect your own privacy. If an insurer or employer learns about the research subject’s research participation, and you agree that they can have the research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

2. Be sure to maintain a copy of your consent document without the changes made above (to be used by participants until the COC is in place).

Submitting the application to the IRB and the DHHS Institute/Center:

1. After preparing your COC application, submit the application form (signed by the PI) and the revised consent form to the IRB. After reviewing the application, the IRB will forward it to the Institutional Official for signature. If you haven’t received it previously, the IRB will also release your project approval at this point. 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.

2. When the application has been signed by Dr. Charney and returned to the IRB, the IRB will contact you. 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.)

3. Include in your application a copy of your project IRB approval letter.

4. Send your completed COC application packet to the appropriate DHHS Institute or Center address.

5. 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. If the consent has been modified during this time period, please submit the approved version of the consent document, incorporating the COC language. You should start using the new “COC consent” with all new subjects. 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.
COC approval periods, renewals, and changes
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. A Certificate of Confidentiality protects all information identifiable to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect. The protection afforded by the Certificate is permanent.

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, you may submit a written request for extension of the date. This request should be submitted to the DHHS Institute/Center issuing the certificate at least three months prior to the Certificate's expiration. It must include an explanation of the reasons for requesting an extension (e.g., new subjects continue to be enrolled in the project), a revised estimate of the date for completion of the project, documentation of the Institutional Review Board's most recent approval for the project, and a copy of the consent form which should include language explaining the Certificate's protections, specify any voluntary disclosures, and clearly state any other limitations. If your request is approved, an amended Certificate will be issued.

How making changes in the research may affect your COC
If a significant change in your research project is proposed after a Certificate is issued, you must inform the Certificate Coordinator of the Institute issuing the certificate by submitting an amended application for a Certificate of Confidentiality (in the same form and manner as your original application for a Certificate). Significant changes include: major changes in the scope or direction of the research protocol, changes in personnel having major responsibilities in the project, or changes in the drugs to be administered (if any) and the persons who will administer them.

Amended applications will be reviewed by the NIH Institute issuing the certificate and either approved or disapproved. If an amended application is approved, an amended Certificate of Confidentiality will be issued. If an amended application is disapproved, you will be notified that adoption of the proposed significant change(s) will result in prospective termination of the original Certificate. Any termination of a Certificate of Confidentiality is operative only with respect to the identifying characteristics of individuals who began their participation as research subjects after the effective date of such termination.

Whom to contact if you need more information
- Icahn School of Medicine Program for the Protection of Human Subjects (212) 824-8200
- Certificate Coordinators at the various Centers and Institutes. They are all listed on the NIH's COC Kiosk website.