

Non-Federal Funding

The following decision tree is for investigators who:

1. Are conducting biomedical, behavioral, clinical, or other research activity
2. Receive **no support** from any Federal Government agency or entity for the research activity
3. Collect or use identifiable, sensitive information about a research participant

Should I seek a Certificate of Confidentiality?

Decision Tree #1

Are you conducting Human Subjects Research?

*This includes Human Subjects Research determined to meet one of the categories of exempt research described at [45 CFR 46.104](#)

no

yes

Does your project involve research on a sensitive health-related topic?

no

yes

Are you collecting names or other identifiers (or sensitive information) pertaining to your subjects?

no

yes

Does your project involve the use or study of a product subject to FDA's jurisdiction and subject to FDA's regulatory authority?

no

yes

Do the objectives of your study involve subject matter within a mission area of the NIH or DHHS?

no

yes

You are **NOT** collecting or using identifiable, sensitive information that requires a Certificate of Confidentiality

No Further Action is Required

Your research project may be eligible to receive a Certificate of Confidentiality through the FDA. You may choose to obtain a CoC or you may consult with the IRB as to whether a CoC is necessary.

A CoC can be requested from the FDA in the form of a letter (e.g., as a PDF attachment to the email) to the email address for the appropriate FDA Center.

MOVE to Decision Tree #2

Your research project may be eligible to receive a Certificate of Confidentiality through the NIH. You may choose to obtain a CoC or you may consult with the IRB as to whether a CoC is necessary.

A CoC can be requested from the NIH using the online application system (<https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step2>)

MOVE to Decision Tree #3

What actions do I need to take if I want to pursue a Certificate through the FDA?

Decision Tree #2

myIRB application:

- 1) In the pending application for your new study respond “yes, certificate is pending” in myProject Section 4.
- 2) In the confidentiality section of your consent form add the appropriate HRPO-template language describing the protections and limitations of a Certificate of Confidentiality
- 3) The study will be approved providing you with an approval letter and an IRB approved consent form that contains the necessary CoC language for inclusion in your FDA CoC application packet.

*The consent form will be watermarked. You are not permitted to enroll participants at this time.

*If your study is already approved, submit a modification to make these changes.

Applying for a CoC through the FDA (see template letter [here](#)):

- 1) Determine the appropriate Center and submit the request in the form of a letter (e.g. as a PDF attachment to the email submission), through one of the following email addresses:
 - Center for Drug Evaluation and Research (CDER) at: CDER-CoC-Requests@fda.hhs.gov
 - Center for Biologics Evaluation and Research (CBER) at: CBERBIMONotification@fda.hhs.gov
 - Center for Devices and Radiological Health (CDRH) at: CDRH-CoC@fda.hhs.gov
 - Center for Tobacco Products (CTP) at: CTP_RIHSC@fda.hhs.gov
 - Center for Food Safety and Applied Nutrition (CFSAN) at: CFSAN-CoC-Requests@fda.hhs.gov
 - Center for Veterinary Medicine (CVM) at: AskCVM@fda.hhs.gov
- 2) The request letter should include the following information and assurances to facilitate FDA’s review and to expedite consideration of the request for the discretionary CoC.
 - Sponsor or Sponsor-Investigator Name or authorized representative (e.g. the individual who takes responsibility for or initiates the clinical investigation), their address (same as on file with FDA), and their email address
 - FDA Application Number, as applicable (e.g., IND/NDA/BLA/IDE/HDE/PMA/PMTA/ITP)
 - ClinicalTrials.gov Numerical Identifier (if applicable)
 - Research Title
 - If conducting human subject research subject to FDA’s jurisdiction but the sponsor or sponsor-investigator is exempt from submission of an investigational application (e.g., IND/IDE) submit all of the above information with the exception of the FDA application number.
 - Signature of sponsor, sponsor-investigator, or authorized representative submitting the discretionary CoC request
 - Sufficient information to allow the FDA to assess whether the requester understands its obligations to comply with the CoC statutory provisions. See example language for request letter.



The FDA’s CoC Determination is Received:

Submit a Modification form in myIRB once the FDA’s determination is received:

CoC awarded:

- 1) Change myProject Section 4 response from “yes, Certificate is pending” to “yes, Certificate is received.”
- 2) Attach a copy of the CoC to myProject Section 4.
- 3) The watermark will be removed from the consent form, and the study will be allowed to begin enrollment.

CoC denied:

- 1) Change myProject Section 4 response from “yes, Certificate is pending” to “no.”
- 2) Remove the CoC template language from your consent form
- 3) The watermark will be removed from the consent form, and the study will be allowed to begin enrollment.

What actions do I need to take if I want to pursue a Certificate through the NIH?

Decision Tree #3

myIRB application:

- 1) In the pending application for your new study respond “yes, certificate is pending” in myProject Section 4.
- 2) In the confidentiality section of your consent form add the appropriate HRPO-template language describing the protections and limitations of a Certificate of Confidentiality
- 3) The study will be approved providing you with an approval letter and an IRB approved consent form that contains the necessary CoC language for inclusion in your NIH CoC application packet.

*The consent form will be watermarked. You are not permitted to enroll participants at this time.

*If your study is already approved, submit a modification to make these changes.

Online NIH CoC application:

- 1) Determine what information needed for your CoC application: <https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step2>
- 2) Apply for the CoC online at <https://public.era.nih.gov/commonsplus/public/coc/request/init.era>
 - Enter the following for the Institutional Official (Director of OSRS):
 - Name of Institutional Official: Teri Medley
 - Email address of Institutional Official: researchgrants@wusm.wustl.edu
 - Phone number of Institutional Official: 314-747-4134
- 3) The system will e-mail the Director of OSRS to confirm the accuracy of the CoC request and affirm the Institutional Assurance statement.
- 4) Send an email to OSRS at researchgrants@wusm.wustl.edu with:
 - A subject line indicating you are applying for a CoC
 - Your grant information (funding agency, grant number, and grant title)
 - A copy of your IRB approval letter



The NIH's CoC Determination is Received:

Submit a Modification form in myIRB once the NIH's determination is received:

CoC awarded:

- 1) Change myProject Section 4 response from “yes, Certificate is pending” to “yes, Certificate is received.”
- 2) Attach a copy of the CoC to myProject Section 4.
- 3) The watermark will be removed from the consent form, and the study will be allowed to begin enrollment.

CoC denied:

- 1) Change myProject Section 4 response from “yes, Certificate is pending” to “no.”
- 2) Remove the CoC template language from your consent form
- 3) The watermark will be removed from the consent form, and the study will be allowed to begin enrollment.