Non-NIH, Non-CDC, Non-FDA, Non-HRSA, and Non-AHRQ PHS Funding

The following decision tree is for investigators who:

1. Are conducting biomedical, behavioral, clinical, or other research activity
2. Receive support, **in whole or in part**, for that activity from a non-NIH, non-CDC, non-FDA, non-HRSA, and non-AHRQ* PHS Agency
3. Collect or use identifiable, sensitive information about a research participant

*AHRQ has its own confidentiality statute that applies in lieu of Certificates of Confidentiality.

Should my research be issued a Certificate of Confidentiality?

Decision Tree #1

Are you conducting Human Subjects Research in which subjects can be identified?

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

yes →

You are required to apply for a CoC.

MOVE to Decision Tree #2.
Start at box A

no ↓

Does your research activity involve the collection or use of human biospecimens ?

no →

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

No Further Action is Required

yes ↓

Are you generating individual level human genomic data?

yes →

no ↓

Are the biospecimens you are collecting or using identifiable *to anyone*?

yes →

no ↓

Is there 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 determine the identity of any individual participant?

yes →

You are required to apply for a CoC.

MOVE to Decision Tree #2, Skip box A and start at box B

no →

Your research does not require a CoC.

No Further Action is Required

How do I ensure I am compliant with 21st Century Cures?

Decision Tree #2

Box A

myIRB application:

1) In the IRB application for your new study or your modification form 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 CoC application packet.

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

Box B

Select your funding agency

IHS or SAMHSA Funding

IHS Funding

For information about how to apply for a Certificate of Confidentiality, contact Rachael Tracy at rachael.tracy@ihs.gov or Heather McClane at heather.mcclane@ihs.gov.

SAMHSA Funding

Follow the SAMHSA's instructions to apply for a Certificate of Confidentiality.

Studies under an IND or IDE

Contact the FDA CoC coordinators for more information:

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 Soma.Kalb@fda.hhs.gov

Other PHS Funding

Determine what information is needed for your CoC application

(https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step2)

Use NIH's Online Certificate of Confidentiality System to apply for the CoC online

(https://humansubjects.nih.gov/coc/index)

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

The system will email the Director of OSRS to confirm the accuracy of the CoC request and affirm the Institutional Assurance statement.

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

Obtain institutional signature by emailing the Director of OSRS at researchgrants@wusm.wustl.edu the full application (or screen prints if an online application) and a copy of the IRB Approval letter. The Director of OSRS will review the application and provide signature on the following documents:

- The assurance page generated by the CoC online system, signed by the PI, and
- The letter prepared by the department, on department letterhead, requesting the CoC, signed and dated by the PI.

<u>The Agency's CoC Determination is Received:</u>

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

<u>CoC awarded</u>:

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.

<u>CoC denied</u>:

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.