

# 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

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

no

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

*No Further Action is Required*

yes

Your research project may be eligible to receive a Certificate of Confidentiality. 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 #2

# What actions do I need to take if I want to pursue a Certificate?

## 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 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](mailto: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](mailto: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.