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 46.101(b)(1)

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

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://humansubjects.nih.gov/coc/apply)

Request a CoC through the NIH institute or center that supports research in a scientific area similar to your research (https://humansubjects.nih.gov/coc/index)

MOVE to Decision Tree #2

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

No Further Action is Required
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) Complete the online application found at [https://humansubjects.nih.gov/coc/apply](https://humansubjects.nih.gov/coc/apply).
2) Provide OSRS with the following:
   - A print-out of your pending NIH CoC application
   - A copy of the NIH generated Assurance page, signed by the study PI.
   - A letter requesting the CoC, signed and dated by the PI, on Departmental letterhead.
1) The WU “institutional Authority” designee in OSRS will countersign both the Assurance page and the letter requesting the CoC on your Department’s letterhead.
2) Submit the completed CoC application to the NIH.

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**The NIH’s CoC Determination is Received:**

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

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**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.