Non-NIH and Non-CDC 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 and non-CDC PHS Agency
3. Collect or use identifiable, sensitive information about a research participant

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 46.101(b)(1)

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

You are required to apply for a CoC.
MOVE to Decision Tree #2. Start at box A

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

You are NOT collecting or using identifiable, sensitive information that requires a Certificate of Confidentiality.
No Further Action is Required

Are you generating individual level human genomic data?

Yes

You are required to apply for a CoC.
MOVE to Decision Tree #2, Skip box A and start at box B

no

no

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

Yes

Your research does not require a CoC.
No Further Action is Required

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?
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

**FDA Funding and studies under an IND/IDE**

Follow the FDA’s instructions to apply for a Certificate of Confidentiality.

**HRSA Funding**

Contact Lisa Wright-Solomon at lwright-solomon@hrsa.gov for information about how to apply for a Certificate of Confidentiality.

**SAMHSA Funding**

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

**Other PHS Funding**

Use the online application system through the NIH (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)

**Per CoC issuing agency requirements, if documentation from an “Institutional Authority” is required for your CoC application:**

Provide OSRS with the following:

1) A copy or print-out of your pending CoC application;

2) For NIH applications only: A copy of the NIH generated Assurance Page, signed by the PI;

3) A letter requesting the CoC, signed and dated by the PI, on departmental letterhead.

The WU “Institutional Authority” designee in the OSRS will countersign.
The Agency’s CoC Determination is Received:

Submit a Modification form in myIRB once the Agency’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.