NIH, CDC, FDA, or HRSA 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 the **NIH**, **CDC**, **FDA** or **HRSA** through any mechanism (grants, cooperative agreements, contracts, or other awards)
3. Collect or use identifiable, sensitive information.

Is my research subject to NIH, CDC, FDA, or HRSA Certificate of Confidentiality policy?

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 have been automatically awarded a CoC.

SKIP to Decision Tree #2

no ↓

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

no →

You have NOT been automatically awarded a CoC.

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 even a small risk that some combination of your biospecimen(s), a request for the biospecimen, and other available data sources could be used to deduce the identity of any individual participant?

yes →

You have been automatically awarded a CoC.

SKIP to Decision Tree #2

no →

You have NOT been automatically awarded a CoC nor do you need to apply for a CoC.

No Further Action is Required.

NIH, CDC, FDA, or HRSA Funded Certificate of Confidentiality Decision Tree #2

The following decision tree is for investigators who:

1. Are conducting biomedical, behavioral, clinical, or other research activity
2. Receive support for that activity from the NIH, CDC, FDA, or HRSA through any mechanism (grants, cooperative agreements, contracts, or other awards)
3. Collect or use identifiable, sensitive information.

How do I ensure I am compliant with NIH, CDC, FDA, or HRSA CoC-related policy?

Are you conducting Human Subjects Research with IRB approval?

no →

Use these links to learn about your responsibilities under a Certificate

NIH - (https://grants.nih.gov/faqs#/certificates-of-confidentiality.htm)

CDC - (https://www.cdc.gov/os/integrity/confidentiality/applinst.htm)

FDA - (https://grants.nih.gov/grants/guide/notice-files/NOT-FD-19-002.html)

HRSA - (https://www.hrsa.gov/sites/default/files/hrsa/about/organization/bureaus/opae/coc-policy-update.pdf)

Or contact OVCR staff at ovcrinfo@wustl.edu or HRPO staff at 314-747-6800 with questions you may have prior to sharing or disclosing your data and/or specimens.

yes ↓

In your myIRB application, have you marked "yes, certificate automatically issued by sponsor" in myProject section 4?

no →

Revise your pending New application to make this change or if your study is already approved, submit a Modification form in myIRB to make this necessary change.

yes ↓

Does the confidentiality section of your consent form describe the protections and limitations of a Certificate of Confidentiality?

no →

Revise your pending New application to make this change or if your study is already approved, submit a Modification form in myIRB to make this necessary change.

yes ↓

Use these links to learn about your responsibilities under a Certificate

NIH - (https://grants.nih.gov/faqs#/certificates-of-confidentiality.htm)

CDC - (https://www.cdc.gov/grants/additionalrequirements/ar-36.html)

FDA - (https://grants.nih.gov/grants/guide/notice-files/NOT-FD-19-002.html)

HRSA - (https://www.hrsa.gov/sites/default/files/hrsa/about/organization/bureaus/opae/coc-policy-update.pdf)

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