

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

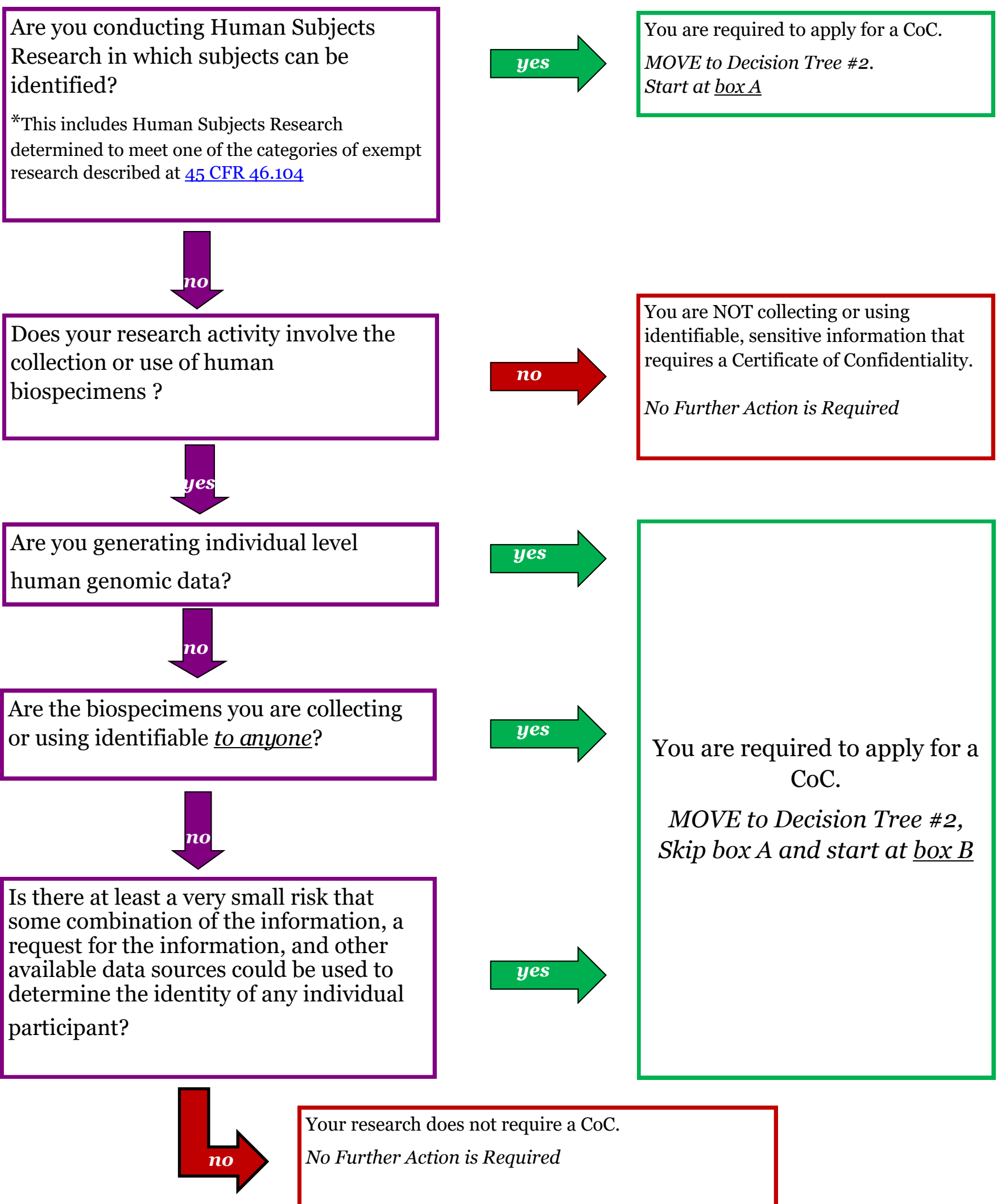
The following decision tree is for investigators who:

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, 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



# 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

### **HRSA, IHS or SAMHSA Funding**

#### **HRSA Funding**

Contact Lisa Wright-Solomon at [lwright-solomon@hrsa.gov](mailto:lwright-solomon@hrsa.gov) for information about how to apply for a Certificate of Confidentiality.

#### **IHS Funding**

For information about how to apply for a Certificate of Confidentiality, contact Rachael Tracy at [rachael.tracy@ihs.gov](mailto:rachael.tracy@ihs.gov) or Heather McClane at [heather.mcclane@ihs.gov](mailto: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](mailto:CDER-CoC-Requests@fda.hhs.gov)

Center for Biologics Evaluation and Research (CBER) at [CBERBIMONotification@fda.hhs.gov](mailto:CBERBIMONotification@fda.hhs.gov)

Center for Devices and Radiological Health (CDRH) at [Soma.Kalb@fda.hhs.gov](mailto: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](mailto: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](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

Obtain institutional signature by emailing the Director of OSRS at [researchgrants@wusm.wustl.edu](mailto: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.

**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.