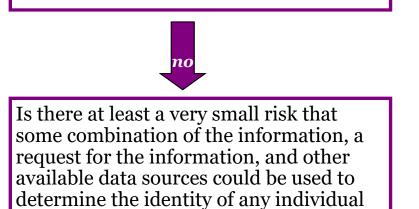
## Non-NIH, Non-CDC, Non-FDA, Non-HRSA, and Non-AHRQ PHS Funding The following decision tree is for investigators who: 1. Are conducting biomedical, behavioral, clinical, or other research activity 2. Receive support, in whole or in part, for that activity from a non-NIH, non-CDC, non-FDA, non-HRSA, 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 Are you conducting Human Subjects You are required to apply for a CoC. Research in which subjects can be *MOVE to Decision Tree #2.* yes identified? Start at <u>box A</u> \*This includes Human Subjects Research determined to meet one of the categories of exempt research described at 45 CFR 46.104 no You are NOT collecting or using Does your research activity involve the identifiable, sensitive information that collection or use of human requires a Certificate of Confidentiality. no biospecimens? No Further Action is Required Are you generating individual level yes human genomic data? Are the biospecimens you are collecting

yes Yo

yes

You are required to apply for a



or using identifiable to anyone?

participant?



MOVE to Decision Tree #2, Skip box A and start at <u>box B</u>



Your research does not require a CoC.

No Further Action is Required

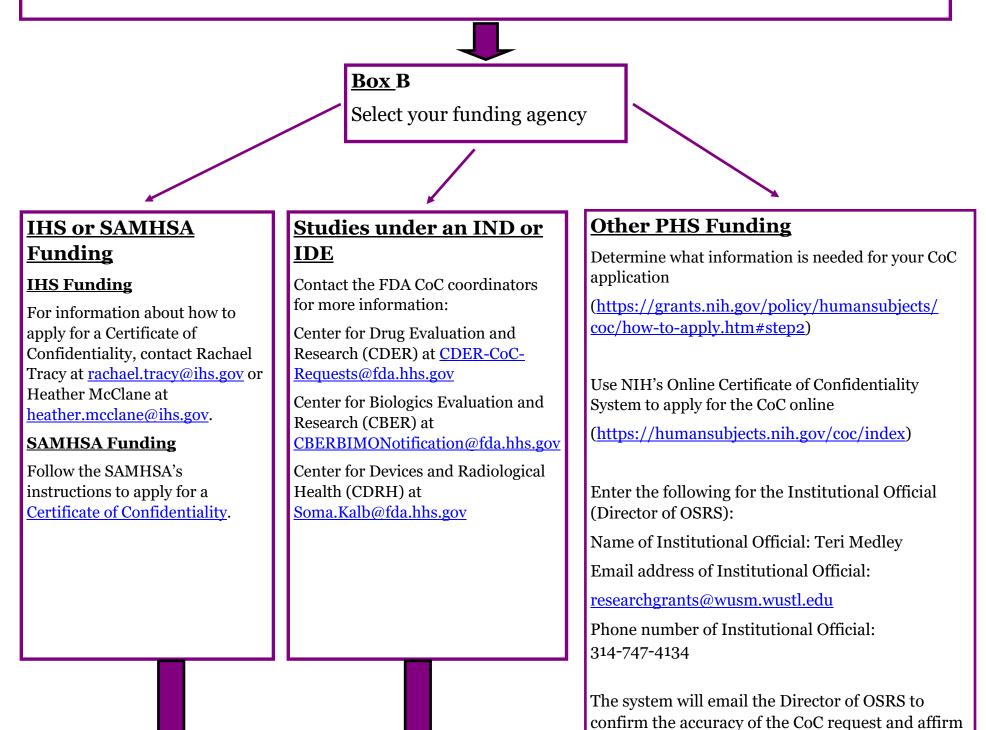
Decision Tree #2

### 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.



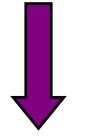
Obtain institutional signature by emailing the Director of OSRS at researchgrants@wusm.wustl.edu the full application (or screen prints if an online application) and a copy of the IRB Approval letter. The Director of OSRS will review the application and provide signature on the following documents:

- 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 Institutional Assurance statement.

# Send an email to OSRS at <u>researchgrants@wusm.wustl.edu</u> 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 Agency's CoC Determination is Received:

Submit a Modification form in myIRB once the Agency's determination is received:

### CoC awarded:

- 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.