



Certificates of Confidentiality (CoCs) Requirements for Human Subjects Research, including Biospecimens, Genomic Data, and Non-Anonymous Research

Requirements

Certificates of Confidentiality (CoCs) are required, under the [21st Century Cures Act](#), for any *biomedical, behavioral, clinical, or other research*, in which **identifiable, sensitive information** is collected where the research is funded *wholly or in part by [Public Health Service \(PHS\) Agencies](#)* (or as required by a sponsoring agency).

What do I need to know?

You are collecting **identifiable, sensitive information** if you are:

- Collecting or using biospecimens derived from a human
- Using or creating individual level genomic data
- Conducting Human Subjects Research, including exempt research, and data are not collected anonymously

The [National Institutes of Health \(NIH\)](#) and/or the [Center for Disease Control \(CDC\)](#) are automatically issuing CoCs; however, other agencies may require you to apply for a CoC.

What should I do?

Visit WashU's [CoC Website](#) for guidance as to whether the CoC requirements apply to your research, how to comply with the requirements, and how to request a CoC.

For *ongoing* human studies applications where CoC requirements apply:

The Human Research Protections Office (HRPO) will be contacting you via email with instructions as to what actions are needed for your HRPO application.

When did this become effective?

The changes to the CoC requirements took effect October 1, 2017.

If you have questions, please email ovcrinfo@wustl.edu or call HRPO's SWAT line at 314.747.6800.

Sincerely,
Jennifer Lodge, PhD
Vice Chancellor for Research