For detailed instructions on the CoC IRB submission process, please see SOP: Certificates of Confidentiality (HRP-027).

Harvard’s policy on CoCs may be found here https://vpr.harvard.edu/files/ovpr-test/files/harvard_coc_guidance_4-9-2018.pdf?m=1526931505.

Still want to know more?
Check out the NIH policy overview video which may be found here - https://grants.nih.gov/policy/clinical-trials/overview-policies-resp/story_html5.html

Questions?
Contact the IRB Office

Harvard University IRB
Smith Campus Center
1350 Massachusetts Ave
Suite 935 (9th floor)

617-496-3985
cuhs@harvard.edu

Guidance on NIH regulations that may affect your research

Part I: Requirements that apply to all NIH-funded research
Is your study funded by the NIH? This could be through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program. If so, there are additional requirements that you must be compliant with.

**NIH REQUIREMENTS FOR ALL RESEARCH INVOLVING HUMAN SUBJECTS**

**Use of a Single IRB for Multi-Site Studies**

Historically, in many multi-site studies, each site has its own IRB which conducts an independent review of studies involving human research participants. The use of a single IRB (sIRB) of record for multi-site studies that are conducting the same protocol will help streamline the IRB review process by eliminating the unnecessary repetition of those reviews across sites.

For applications with due dates on or after January 25, 2018, and contract solicitations published on or after January 25, 2018, NIH expects that all sites participating in multi-site studies, which involve non-exempt human subjects research funded by the NIH, will use a sIRB to conduct the ethical review required for the protection of human subjects.

NIH funding applicants are expected to include a plan for the use of a sIRB in the grant applications and contract proposals they submit to the NIH (for due dates on or after January 25, 2018).


If you are interested in pursuing a sIRB for your research, see the IRB website for more information - [https://cuhs.harvard.edu/ins-and-outs-forging-reliance-agreement](https://cuhs.harvard.edu/ins-and-outs-forging-reliance-agreement).

**Certificates of Confidentiality for all research that uses “identifiable, sensitive information”**

Does your research collect or use identifiable, sensitive information? The term “identifiable, sensitive information” means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where the following may occur:

- An individual is identified; or
- For which there is 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 deduce the identity of an individual.

If your research includes identifiable, sensitive information, then a Certificates of Confidentiality will be issued as part of the Terms and Conditions of the award.

Effective October 1, 2017 all NIH-funded research commenced or on-going as of December 13, 2016, were issued a CoC as a term and condition of the NIH award. The researcher does not have to apply to the NIH for the CoC nor does the NIH issue a separate CoC document.

A Certificate of Confidentiality (CoC) protects the privacy of research subjects by prohibiting forced disclosure of their individually identifiable, sensitive research information, records, or data to anyone not associated with the research, except when the subject consents to such disclosures or in other limited specific situations. CoCs are issued by different federal agencies, most typically by the National Institutes of Health (NIH).

- For NIH-funded research, the CoC is automatically included as a term and condition of the NIH award.
- For other HHS agencies (that do not have a CoC application process) or for research without federal funding, researchers may apply for an NIH CoC if a primary focus of the research is within the NIH mission (i.e., health/mental health-related).
- For research funded by other HHS agencies such as the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), or funded by or operating under the authority of the Food and Drug Administration (FDA), researchers should apply for a CoC to the applicable funding agency.