



Human Research News

Subject: NIH Policy on Certificates of Confidentiality

February 16, 2018

Dear UCLA Research Community,

The National Institutes of Health (NIH) has significantly expanded the use of Certificates of Confidentiality (CoCs) for research that it funds. Based on the 21st Century Cures Act, human subjects research funded by NIH (as well as some non-human subjects research) is now **automatically** covered by a CoC regardless of how sensitive the data are.

This expansion is **retroactive for research that was active on or after December 13, 2016** and is unrelated to whether or not a project fits under the NIH definition of “clinical trial.”

While some research teams are already experienced with the protections and responsibilities associated with CoCs, this expansion affects research teams that have not previously dealt with CoCs.

This [FAQ document](#) includes information about the policy change along with links to NIH websites. The FAQ is primarily for research teams conducting or planning NIH-funded research, regardless of the type of research or the sensitivity of the data involved. However, research teams who obtain CoCs for sensitive research funded by entities other than NIH should take note of the sections about updated consent language and non-NIH research.

Updated versions of the OHRPP consent template documents will be posted on the OHRPP website along with an updated version of the OHRPP guidance document about CoCs. In the meantime, a Word document with the [new suggested language](#) is available for copy-and-pasting.

Sincerely,
UCLA Office of the Human Research Protection Program

This message was originally sent via the Human Research News mailing list. If you would like to subscribe to future announcements, please send an e-mail to: investigators-l+subscribe@lists.ucla.edu. The subject line and body of the e-mail can be blank.