If you are already familiar with the concept and use of a Certificate of Confidentiality then be aware that the NICHD system is no longer accepting new applications. All previously issued Certificates of Confidentiality from the NICHD can still be modified or extended by directly contacting me through e-mail. All new Certificates are now issued through a central NIH system found at http://grants.nih.gov/grants/policy/coc/index.htm

The processing is still Institute specific, so applicants must designate the NICHD to review the proposed study. All applications still come to me and I continue to remain available for questions and guidance.

If you wish to know a bit more about Certificates of Confidentiality, read on.

What is a Certificate of Confidentiality?

A Certificate of Confidentiality is intended as a recruitment aid to provide additional assurance to prospective applicants that their identity will be protected based on procedures outlined in the study plan and the Certificate. The Certificate concept originated to facilitate enrollment of substance abusers into studies without fear of recrimination or arrest if the study records were subpoenaed by a court of law.

The legal authority comes from the United States Code Title 42 › Chapter 6A › Subchapter II › Part A › paragraph 241 (d)
“(d) Protection of privacy of individuals who are research subjects
The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.”

Given the legal language, Is the authority for granting Certificates of Confidentiality delegated?
Yes. Initially only the Assistant Secretary for Health reviewed and signed off on Certificates, but as the use proliferated, that responsibility was delegated to individual agencies, and in the case of the NIH, delegated to Institutes and Centers.

What is the purpose of a Certificate of Confidentiality?
A Certificate states an intent and mechanism to protect the identity of study participants when disclosure may become an unacceptable risk. A Certificate, however, is not a guarantee that disclosure of study participant identity cannot occur.
As medical records note study participation and as electronic health records proliferate and data aggregation and triangulation techniques become more powerful, the ability to assure non-disclosure of participant identity continues to erode.
How do potential participants learn about a Certificate of Confidentiality?
Language about a Certificate is embedded in the consent form and is expected to be discussed as part of the consent process. A Certificate is not issued without clear language written in the consent form stating the goals, procedures, limits and responsibilities related to a Certificate.

Does a Certificate of Confidentiality provide federal protection for all collected study data?
In brief, no. The confidentiality of all other study data outside personal identifiers is governed by the security policies and practices of the study specific informatics systems and data support systems. This is a point that many Institutional Review Boards tend to conflate with protecting identifiable information and stipulate that a Certificate be used to “protect” study data until a study is completed.

What is the significance of the expiration date for a Certificate of Confidentiality?
Given the primary purpose of an aid to recruitment, the expiration date is typically suggested by the study team to cover the enrollment period. I usually extend the date when issuing the Certificate anticipating that not everything will happen on schedule. Once all participants are enrolled and if the enrollment occurred prior to the Certificate expiration date, the participants are covered as long as study records are kept. That is, while the Certificate may expire, the protection it offers does not as long as vulnerable disclosure records that are study specific exist. To restate the principle, a Certificate is intended to protect the identity of participants who are enrolled in a study during the active enrollment period.

What happens if the study reopens enrollment?
A Certificate can be extended to cover the new enrollment period.

What happens if a study is amended and enrollment is not complete?
A Certificate can be amended to indicate any major design changes.

How long does it take to issue a Certificate once an application is submitted?
The NICHD was the pioneer in semi-automated processing of Certificates and brought the review time from many weeks to usually seven to ten days. About a dozen other NIH ICs used the NICHD system until it was replaced a few weeks ago by the new NIH OD system. The NIH OD system is built upon the logic and principles of the NICHD system. The review time within the NICHD remains the same with the new system of about a seven to ten day turn around. The actual application review including all related documents and generation of a paper copy of the Certificate and mailing it to the appropriate institution all factor into the processing time.

Who can apply for an NIH Certificate of Confidentiality?
Anyone doing health related research where the study goals are aligned with the mission of an NIH IC can apply for a Certificate. The study need not be funded by the NIH, but the goals must align with an NIH related mission. Intramural investigators apply through their IC point of contact.

What is a good source for further information?
The NIH Certificate of Confidentiality Kiosk, listed above, is the best first stop. After that feel encouraged to contact me directly.

Thank you.

Kind regards,

Steven H.

Steven Hirschfeld, MD PhD
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