

DEPARTMENT: Yale University Human Investigation Committee
POLICY NUMBER:
SECTION:
REVIEW RESPONSIBILITY: HIC Leadership Committee
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Yale University School of Medicine HIC Policy Regarding: Certificate of Confidentiality

Definitions:

1. **Certificate of Confidentiality:** A Certificate of Confidentiality is issued by National Institutes of Health (NIH), the US Food and Drug Administration (FDA) or the Department of Health and Human Services (DHHS) to protect subjects' privacy and ensure the confidentiality of their study data and participation in a study. The Certificate prevents researchers from having to involuntarily disclose, in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings, names and other identifying information about any individual who participates as a research subject. This protection is afforded by the Public Health Service Act §301(d), 42 U.S.C. §241(d).

It does not protect against voluntary disclosures by the researcher, but those disclosures must be specified in the informed consent form. A researcher may not rely on the Certificate to withhold data if the participant consents in writing to the disclosure.

2. **National Institutes of Health (NIH):** Founded in 1887, the National Institutes of Health today is one of the world's foremost medical research centers, and the Federal focal point for medical research in the United States. The NIH, comprising 27 separate Institutes and Centers, is one of eight health agencies of the Public Health Service which, in turn, is part of the U.S. Department of Health and Human Services.

Simply described, the goal of NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability, from the rarest genetic disorder to the common cold. The NIH mission is to uncover new knowledge that will lead to better health for everyone. NIH works toward that mission by: conducting research in its own laboratories; supporting the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad; helping in the training of research investigators; and fostering communication of medical and health sciences information.

3. **Food and Drug Administration (FDA):** The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines

and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

4. **Department of Health and Human Services (DHHS)**: The United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

Policy:

Yale University School of Medicine Human Investigation Committee Guidance on Certificates of Confidentiality

A. When does the HIC suggest applying for a Certificate?

Any person engaged or intending to engage in research that will collect “sensitive” information should apply for a Certificate. Sensitive information consists of (but is not restricted to):

- information regarding sexual practices or preferences;
- information regarding the use of alcohol, illegal drugs or other addictive products;
- information concerning illegal behavior;
- information that can be destructive to the subject’s financial standing, employability or reputation within the community or might lead to social disgrace or prejudice;
- information regarding the subject’s psychological state or mental health; and
- sensitive genetic information or tissue samples, those that collect and store biological samples for future use.
- Information regarding HIV, AIDS, and other STDs;
- Information regarding behavioral interventions and epidemiologic studies.

B. How long does a Certificate’s protection last?

A Certificate protects in perpetuity the identity of subjects participating in a research study during a distinct period of time that the Certificate was in force (i.e. the duration of the study). It is the responsibility of the researcher to ensure that the Certificate remains valid. If a study's duration needs to be extended, and data collection will continue past the expiration date of the Certificate, the researcher must submit a written request to the appropriate agency for an extension of the Certificate expiration date. NIH and other agencies request that this proposal be submitted at least 3 months prior to the expiration date. Extension applications should include a rationale for the extension request, a revised estimate of the study duration, the most recent HIC approval of the study, and a copy of the approved consent form which states a Certificate has been obtained.

C. How do I apply for a Certificate?

Certificates of Confidentiality are issued by agencies within the Department of Health and Human Services (such as the Centers for Disease Control and Prevention, Food and Drug Administration, or National Institutes of Health), and the FDA and researchers should apply to the particular agency involved in the funding or regulation of the study. A Certificate application must be signed by the Principal Investigator of the study and the authorized institutional official. The designated institutional official for the Yale University School of Medicine is the Assistant Director of the Grant and Contract Administration.

Contact information for Certificate of Confidentiality applications is available at: <http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm>.

Please Note: For multi-site protocols, the coordinating center is strongly encouraged to apply for a Certificate to cover all sites. The coordinating institution must retain on file the IRB approvals from all sites and make them available upon request to the NIH. All consent forms from all sites should include appropriate language regarding the Certificate.

D. HIC requirements relating to Certificates of Confidentiality

Please note that the Certificate application and approval process may take up to three months. The HIC may either approve or withhold approving research until the investigator has obtained a Certificate, depending on the perceived need for this protection in relation to the type of sensitive information collected. Therefore it is possible that a research study may begin to enroll subjects without the protection provided by the Certificate. **In these instances it is imperative to inform potential subjects that their records may not be protected until such time that the Certificate has been acquired.** Investigators must clarify in protocols, consent forms and during the consent process that a Certificate of Confidentiality has either been applied for or obtained. The consent form must also explain the protections offered by the Certificate, and any conditions of or limitations to these protections.

Suggested wording for the consent form to assure that subjects are fully aware of this circumstance is below.

“If you decide to take part in this research study, you will be required to give us information about your substance use/genetic information/criminal behavior. We have applied for/obtained a Certificate of Confidentiality (COC) issued by the DHHS/FDA/NIH. The COC is issued to protect the investigators on this study from being forced to tell people that are not connected with this study about your participation in this study, even under a subpoena. However, we cannot know for

certain how much protection the Certificate provides as it has rarely been challenged in the courts. This protection will not apply until the researcher has obtained the COC, which may take a few months. The investigator will inform you when the COC has been obtained.”

“You should understand that a COC does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you are going to discuss your participation in this study with members of your family you should ensure that they can keep it confidential. If an insurer or employer learns about your participation and obtains your consent to receive such information, then we may not use the COC to withhold this information. This means that you and your family members must actively protect your own privacy.”

“We are committed to protecting your privacy but we are ethically obligated to disclose your identity in some cases. For example, the protection offered by the COC does not stop the researchers from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject’s threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities.”

E. What do I do once I have obtained the Certificate?

Once the Certificate has been obtained the researcher must 1) submit a copy to the HIC and 2) inform all subjects already enrolled that it is now in effect. This may be done via a letter to the subject (e.g. if their participation is no longer required) or face-to-face (e.g. if the subject will return in the near future). The PI must also submit an amendment to the consent form to state that the Certificate has been obtained rather than applied for.

Researchers planning to collect sensitive information must obtain a Certificate of Confidentiality within 6 months of the study being approved by the HIC. Failure to do so may result in the temporary suspension of enrollment. For additional information on COC’s please see <http://grants.nih.gov/grants/policy/coc/>

F. Do I have to amend my Certificate if I amend my study?

If a significant change in your research project is proposed after a Certificate is issued, you must inform the Certificate Coordinator of the Institute issuing the certificate by submitting an amended application for a Certificate of Confidentiality (in the same form and manner as your original application for a Certificate).

G. Can a study be designed without the use of a Certificate?

Studies are often designed without the need for a Certificate of Confidentiality. Investigators are encouraged to consider the need for a Certificate of Confidentiality when designing their research studies. In some instances pre-screening procedures may have occurred outside of the protocol screening process, e.g. urinalysis in conjunction with hospital admission to determine illicit or illegal drug use rather than being part of the protocol.

References:

Certificate of Confidentiality Kiosk at <http://grants.nih.gov/grants/policy/coc/>

March 15, 2002 Frequently asked Questions at

<http://grants.nih.gov/grants/policy/coc/faqs.htm>

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Protecting Study Volunteers in Research; McGuire Dunn, C. and Chadwick, G.L.;