UNM | Office of the Institutional Review Board

Guideline for Obtaining and Maintaining a Certificate of Confidentiality

Background

The National Institutes of Health (NIH) issues Certificates of Confidentiality to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality (COCs) may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, COCs help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants.

There is a growing trend for investigators to apply for a COC regardless of the details of the study or the study risks. However, there are costs to applying for a COC. Each COC application receives a thorough review by NIH staff whose time is limited. Because of numerous applications, the backlog of applications awaiting review continues to grow and the wait time can be as long as 1 year. Thus, it is important to develop guidelines defining when a COC is appropriate based on the risk of a breach in confidentiality as well as the nature of the information that may be compromised.

For more information regarding the protections and limitations of COCs: https://docs.google.com/a/mrn.org/fileview?id=0BwTfSWYT9SbVMWQ5ZGVkOGItNGU2YS00ODNiLThkYWEtZmVm ZDJlNDNmYjQz&hl=en

Considerations

- "Sensitive" research, as defined by NIH, includes, but is not limited to, that which is:
  - Related to sexual attitudes, preferences, or practices;
  - Related to the use of alcohol, drugs or other addictive substances pertaining to illegal conduct;
  - If released, might lead to social stigmatization or discrimination;
  - Pertaining to individual's psychological well-being or mental health;
  - Genetic information or genetic specimens;
  - Studies where participants may be involved in litigation related to exposures under study (e.g. breast implants, environmental exposures
- COCs are not limited to federally supported research; any study collecting sensitive information may apply.
- COCs are issued for individual studies; a separate application is required for each study.
- COCs come with an expiration date (as originally identified by the researcher) so they must be renewed if the study remains open past the expiration date.
- If a COC is obtained, the study must be reviewed under the federal regulations (aka Common Rule), even if the study is not federally funded.

- Individuals who participate in the specified research project during any time the COC is in effect are permanently protected - even if the participant gave the researcher data before the COC is issued.

Recommended Guidelines

- A COC is appropriate when identifiable research information is maintained (for any length of time) AND that information could be damaging to participants if disclosed.
- A study that does not involve the collection of sensitive information (as defined above) would not be appropriate for a COC because a COC would only provide minimal benefit given the nature of the information collected.
- The consent form must tell participants that a COC is in effect and it must provide a fair and clear explanation of the COC's protections, limitations and exceptions (see sample language below).
- All research staff must be trained on privacy considerations related to maintaining a COC. The COC cannot protect data comprised by study personnel or the institution.

IRB Requirements when obtaining a COC

1. It is important for investigators to inform the IRB if they intend to apply for a COC in their study protocol.
2. Before the COC is obtained, the consent form should state "the researcher will apply for a certificate of confidentiality".
3. Researchers are required to apply for a COC <u>within one month of obtaining IRB approval</u>.
4. Once a COC is granted, the researcher must submit an amendment to the IRB to change the protocol and consent language from "will apply for a COC" to "have obtained a COC". Unless required by the IRB, participants enrolled prior to this change will not need to be re-consented.
5. If a COC is not granted, the IRB should be immediately notified to consider whether other additional confidentiality protections are necessary.

Sample Consent Form Language

Confidentiality of your information:

To help us further protect the confidentiality of your data, the investigators ***(will apply for or have obtained)*** a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we cannot be forced (for example by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure of coded data (your name will not be on it) will be necessary, however, upon request of DHHS (Dept. of Health and Human Services) or other federal agencies for audit or evaluation purposes.

You should understand that a Certificate of Confidentiality does not prevent you or a family member from voluntarily releasing information about yourself or your involvement

in this research. Note, however, that if an insurer or employer learns about your participation, and obtains your consent to receive research information, then the researcher may not use the Certificate to withhold this information. This means that you and your family must also actively protect your own privacy and the confidentiality of your data. Finally, you should understand that if you are currently planning to harm yourself or someone else, we are required to notify the appropriate authorities.