2007

Certificate of confidentiality guideline

Sarah Fowler-Dixon
Washington University School of Medicine in St. Louis

Certificate of Confidentiality Guideline

Sarah Fowler-Dixon, PhD

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What is a CoC?

- Certificates of Confidentiality are issued by the National Institutes of Health (NIH) or the Food Drug Administration (FDA) **to protect identifiable research information from forced disclosure (subpoena).**

CoC is ineffective when:

1. the information is already in the medical record.

2. no sensitive information is being collected.

3. when disclosure is mandated by state or federal law. Examples include: suspected child abuse, threat of harm to self or others, reportable communicable diseases, FDA or DHHS audit or program evaluation

4. the participant discloses the information to his/her insurance company, primary care provider or other clinician, any other voluntary disclosure, etc.

5. Data maintained outside the U.S.

The Future

- HRPO will request a CoC when it is thought that the study design and University research protections are not sufficient.

- Investigators, or the sponsor, are always free to obtain a CoC if they wish to have one for their study.

Examples of University Research Protections

- All subpoenas are fought whether or not a CoC is in place
- HIPAA regulations
- WU Confidentiality Guidelines found at http://hrpo.wustl.edu under Guidelines

Examples of Other Protections not utilizing a CoC

- Keep information as de-identified as much as possible. Examples include: anonymizing or coding data without the use of master lists, or with master lists and use of the “honest broker” mechanism.

- Use of confidentiality agreements in some research teams/studies.

- Keep information in locked locations, behind two keys, with limited access

- Maintain clinical records separate from research records

Examples of Protections not utilizing a CoC

- Obtain permission for gathering the sensitive information by putting what is being collected and shared explicitly in the consent document under Participation and allowing the participant to read and sign the consent document prior to gathering the sensitive information.

- Avoid collecting sensitive information

- Educate your research participants on how to protect their confidentiality.

Does it require a CoC?

- Longitudinal study using a small research population. Questions are being asked concerning sexual preferences, illicit drug use, and familial history of abuse. The PI may wish to obtain a CoC to provide added protections to this small population.

Does it require a CoC?

- A study screens for substance abuse as indicators of potential non-compliance with prescribed medications and disease relapse. The investigator asks the participant for permission to share relevant clinical information with treatment providers (e.g. if the clinical information has the potential to benefit the participant medically). Thus, the information enters the medical record. A CoC would afford no protections.

Does it require a CoC?

- The study uses only clinically derived information. All information is obtained from the medical record. The CoC affords no protections.

Does it require a CoC?

- A short term study collects sensitive information that may damage the participant's reputation, livelihood or well-being if the information were divulged in a court of law. Information is coded and the master list is kept in a separately locked cabinet. Only the PI and study coordinator have access to the master list. Depending on the nature of the questions, the protections in place could be sufficient.

Does it require a CoC?

- A study uses an investigational drug. The sponsor has not applied for a CoC as all screening information is part of the medical history and therefore in the clinical record. A CoC would not afford any additional protections.

Does it require a CoC?

- A study asks questions regarding illegal activities within a family. Questions are worded so that members of the family may or may not be readily identified. In either case, the answers would be regarded legally as hearsay and the answers to the questions are recorded in a completely anonymous fashion. The CoC would not afford any additional protections.

Does it require a CoC?

- A study will use drug screening and sensitive questions. Both are outlined in the consent document together with a statement of risks and will only occur once the participant has agreed to participate. The CoC is not necessary.

Does it require a CoC?

- Information regarding screen failures will be sent to the sponsor with identifiers. The information collected is sensitive such as HIV or drug testing results. If this information is already known and in the medical record, a CoC is not necessary. If this information is not already known then we need to consider how identifiable and sensitive the information is that is being sent.

Does it require a CoC?

- A study is using classifications found in the the DSM IV. The need for a CoC would depend on the nature of the study, protections afforded in the study and the population being targeted. A CoC would not automatically be required because a certain standardized instrument is being used.