

Certificate of Confidentiality

Background

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) and other HHS agencies to protect identifiable research information from forced or compelled disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in civil, criminal, administrative, legislative, or other proceedings, whether federal, state, or local.

The privacy of the research subjects is protected through the issuance of Certificates of Confidentiality. These certificates of Confidentiality provide protection against compelled disclosure of identifying information about subjects enrolled in sensitive biomedical, behavioral, clinical, or other research. This protection is not limited to federally supported research.

Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help to minimize risks to subjects by adding an additional level of protection for maintaining confidentiality of private information.

Certificates of Confidentiality protect subjects from compelled disclosure of identifying information but do not prevent the voluntary disclosure of identifying characteristics of research subjects. Researchers, therefore, are not prevented from voluntarily disclosing certain information about research subjects, such as evidence of child abuse or a subject's threatened violence to self or others.

However, if a researcher intends to make such voluntary disclosures, the consent form should clearly indicate this. Furthermore, Certificates of Confidentiality do not prevent other types of intentional or unintentional breaches of confidentiality. As a result, investigators and IRBs must ensure that other appropriate mechanisms and procedures are in place to protect the confidentiality of the identifiable private information to be obtained in the proposed research.

How does this affect VA Research Projects?

When a VA research study is protected by a Certificate of Confidentiality, the IRB's initial approval memo will include a reminder of the medical record documentation requirements.

Participants who are enrolled in a VA research study that is protected by a Certificate of Confidentiality should not be simultaneously enrolled in other interventional studies unless it is absolutely clear that this enrollment does not raise safety issues. The IRB Office will facilitate a discussion with the PIs of both studies to assess potential safety and confounding issues

References:

1. Office for Human Research Protections Guidance on Certificates of Confidentiality, (2/25/2003), <http://www.hhs.gov/ohrp/policy/certconf.html>
2. VHA Handbook 1200.05 REQUIREMENTS FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH (11/12/2014)