

GUIDANCE ON CERTIFICATES OF CONFIDENTIALITY

VHA Office of Research and Development (ORD) has issued guidance on Certificates of Confidentiality (CoC) in VA research.

The main topics covered in the guidance are:

1. What is a CoC?
2. What are identifiable characteristics or information?
3. What types of studies are eligible for a CoC?
4. How do VA Investigators apply for a CoC?
5. Why should information about the study not be placed in the VHA health record?
6. If the informed consent document approved by the Institutional Review Board (IRB) and signed and dated by the VA subject includes a statement that subjects' participation in the study will be included in the VHA Health Record, could VA Investigators include information protected by the CoC in the VHA Health Record?
7. What can be in a CPRS Progress Note entry that does not compromise the protections afforded by the CoC but can be communicated to non-research related clinical health care providers?
8. If a VA study involving investigational drugs has been issued a CoC, are VA Investigators required to follow the requirements in VHA 1108.04 (Investigational Drugs and Supplies)?
9. Are VA subjects' informed consent documents and written HIPAA authorizations required to be placed in the VHA Health Record?
10. Can VA Investigators or VA Facilities apply for a waiver from VHA Handbook 1200.05 requirements regarding health record documentation for VA studies issued a Certificate of Confidentiality?
11. Are VA Investigators required by ORD to follow the revised VHA Handbook 1200.05's requirements for studies issued a CoC and approved prior to March 12, 2015?

The full text of this ORC guidance is attached and is available on [ORD's website](#).

NOTE. Regarding Item 8 and information on investigational drugs placed into CPRS: At VAMHCS, the Research Subject Clinical Warning (RSCW) is our equivalent to VA Form 10-9012. Therefore, the RSCW is required even if a CoC is in place. If possible, modify the study title so that it can be identified by a clinician but that it does not explicitly state the nature of the topic for which the CoC was issued.

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:

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