

**OFFICE OF RESEARCH AND DEVELOPMENT (ORD)  
VETERANS HEALTH ADMINISTRATION (VHA)**

**ORD Guidance on Certificates of Confidentiality**

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**SCOPE:** This guidance applies to VA research involving human subjects conducted under a Certificate of Confidentiality (CoC) as described in VHA Handbook 1200.05.

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?

**1. What is a Certificate of Confidentiality?**

A Certificate of Confidentiality (CoC) is issued for applicable Department of Veterans Affairs (VA) research by several Department of Health and Human Services (DHHS) agencies to protect research subjects by preventing investigators and institutions from being forced or compelled to release identifiable information or identifiable characteristics of research subjects. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. The CoC helps to minimize risks by adding an additional level of protection for maintaining the privacy and confidentiality of research subjects in a VA study.

## 2. What are identifiable characteristics or information?

NIH defines identifying characteristics as such things as: name, address, social security or other identifying number, fingerprints, voiceprints, photographs, genetic information or tissue samples, or any other item or combination of data about a research participant which could reasonably lead, directly or indirectly by reference to other information, to identification of that research subject.

## 3. What types of studies are eligible for a CoC?

Generally, a human subjects research project that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible to apply for a CoC. Sensitive information for purposes of a CoC is not synonymous with the definition of sensitive information in VA and Veterans Health Administration (VHA) Handbooks. Research areas collecting sensitive information that may be eligible for a CoC include, but are not limited to, the following examples:

- Research on HIV, Acquired Immune Deficiency Syndrome (AIDS), and other sexually transmitted diseases (STD)
- Studies that collect information on sexual attitudes, preferences, or practices
- Studies on the use of alcohol, drugs, or other addictive products
- Studies that collect information on illegal conduct
- Studies that gather information that if released could be damaging to a participant's financial standing, employability, or reputation within the community
- Research involving information that might lead to social stigmatization or discrimination if it were disclosed
- Research on participants' psychological well-being or mental health
- Genetic studies, including those that collect and store biological samples for future use
- Research on behavioral interventions and epidemiologic studies

## 4. How do VA Investigators apply for a CoC?

- VA does not issue CoCs. The Federal law authorizing CoCs only allows several Department of Health and Human Services (DHHS) operating agencies to issue them. A flowchart is available at [http://grants.nih.gov/grants/policy/coc/coc\\_flow\\_chart\\_062011.pdf](http://grants.nih.gov/grants/policy/coc/coc_flow_chart_062011.pdf).
- For a VA-funded study, you may apply for a Certificate through the National Institutes of Health (NIH) Institute or Center (IC) that supports research in a scientific area similar to your project. Detailed application instructions can be found at [http://grants.nih.gov/grants/policy/coc/appl\\_extramural.htm](http://grants.nih.gov/grants/policy/coc/appl_extramural.htm). Some ICs have an online application process. See <http://grants.nih.gov/grants/policy/coc/contacts.htm> for a list of contacts at NIH and other HHS agencies that issue CoCs. Additional information regarding the process for applications to NIH is found at <http://grants.nih.gov/grants/policy/coc/faqs.htm>.
- If NIH funds the research project for which you would like to request a CoC, you should apply through the respective IC.
- The Food and Drug Administration (FDA) handles requests for CoCs for studies that obtain an Investigational New Drug (IND) authorization, Investigational Device Exemption (IDE), or other FDA authorization. Projects with INDs or IDEs should apply to the FDA (see [http://grants.nih.gov/grants/policy/coc/appl\\_extramural.htm](http://grants.nih.gov/grants/policy/coc/appl_extramural.htm), paragraph 2 for FDA contact information).

An Agency which can issue CoCs can either approve or not approve a CoC application. The Common Rule contains no requirements for human subjects studies collecting sensitive information to have a CoC in order for the IRB approval criteria to be met, and the IRB does not have the authority to require an Agency to issue a CoC for a study under the IRB's oversight.

Additional information regarding CoCs issued by NIH can be found at the Certificates of Confidentiality Kiosk located at <http://grants.nih.gov/grants/policy/coc/index.htm> .

#### **5. Why should information about the study not be placed in the VHA health record?**

It is important to remember what the CoC is protecting when it is issued for a given study by the issuing Agency. With a few exceptions and limitations, it binds the research team and the Institution to protecting the privacy of the individuals who are the subjects of the study for which the CoC has been issued by withholding those subject names and other identifying characteristics from all persons not connected with that research. Personally identifiable information protected by a CoC may only be disclosed under the following circumstances:

- Voluntary disclosure of information by study subjects themselves or any disclosure that the study subject has consented to in writing, such as to insurers, employers, or other third parties;
- Voluntary disclosure by the researcher of information on such things as child abuse, reportable communicable diseases ([http://grants.nih.gov/grants/policy/coc/cd\\_policy.htm](http://grants.nih.gov/grants/policy/coc/cd_policy.htm)), possible threat to self or others, or other voluntary disclosures provided that such disclosures are spelled out in the informed consent form;
- Voluntary compliance by the researcher with reporting requirements of state laws, such as knowledge of communicable disease, provided such intention to report is specified in the informed consent form; or
- Release of information by researchers to DHHS as required for program evaluation or audits of research records or to the FDA as required under the federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

If a research note is entered into CPRS, one cannot include in the title or within the research note the name of the study or identifying information of the subject that would allow someone outside of the study to associate the subject who is a patient with that specific study.

#### **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?**

No. Even though VHA considers the medical record to be confidential, the information placed in the medical record is available to anyone who has access to the VHA Health Record. Therefore, the information is being placed in a location where it is not considered to be protected for purposes of the CoC. VHA is not considered to be upholding the CoC's protections when the protected information is available to anyone who has access to the VHA Health Record.

**7. What can be in a CPRS Progress Note entry so as to not compromise the protections afforded by the CoC but can be communicated to non-research related clinical health care providers?**

It is the clinician/researcher that must make the determination of what should be placed in the CPRS Progress Notes regarding the impact of the research on care of patients who are VA research subjects. When a study is covered by a CoC, the Principal Investigator is responsible for subjects entered into the study and part of this responsibility is identifying what research related information would be needed in the subject's VHA Health Record to ensure appropriate clinical care of the subject, including any details that would affect the subject's clinical care for such studies. Patient safety is always first and foremost our priority. If it is necessary to disclose to other members of the subject's/patient's healthcare team information about the subject's participation in a study that would be protected under a CoC, then a CoC should not be pursued for the study.

The specifics of the study dictate what can or cannot be placed in a progress note or other parts of the VHA Health Record. ORD cannot give exact phrasing that can be included in every type of progress note. The information placed in CPRS is very specific to the protocol, the clinical issues involved with the patient's clinical care, and emergent care that must be given to the subject if an emergency arises. It is only the PI who should be an MD or other clinician (NP, PA, etc.), that would be able to make the determinations of what information is necessary to ensure the safety and appropriate clinical care of the subject/patient. Remember also, that if the outpatient visit is only for research purposes, it would need to be coded in such a way that the visit can be billed back to research. The code does not need to include the name of the study.

**8. If a VA study involving investigational drugs has been issued a CoC, are VA Investigators required to follow the requirements in VHA Handbook 1108.04 (Investigational Drugs and Supplies) regarding scanning of the informed consent document and the VA Form 10-9012 (Investigational Drug Information Record) into CPRS?**

VHA Handbook 1200.05's requirements regarding studies involving a medical intervention with a CoC refer to what must be in the CPRS progress note as well as the requirement that the subject's informed consent document and HIPAA authorization document are not to be included in the subject's VHA Health Record. VHA Handbook 1200.05 does not state that VHA Handbook 1108.04 is not to be followed for VA studies involving investigational drugs.

VHA Handbook 1108.04 does not require that the informed consent document of the VA subject must be scanned into the subject's VHA Medical Record. As described in VHA Handbook 1108.04, Paragraph 10(d)(4), prior to dispensing the drug, the dispensing VA Pharmacy Service must receive: "(4) The initial order or prescription for each new subject on an investigational protocol must be accompanied by a signed informed consent or written assurance, by the provider, that the signed consent is available for viewing and printing in the electronic medical record. **NOTE:** Pharmacy does not need to physically have a copy of the consent if it can be viewed in the electronic medical record. If there is not a physical copy of the consent maintained in pharmacy there must be a mechanism by which the pharmacist can document that the signed consent was seen before dispensing to the subject for the first time."

As noted above, the VA Pharmacy Service dispensing the investigational drug can either be given a signed informed consent document from the participating VA subject OR a written assurance that the VA subject's informed consent document has been scanned into the

patient's VHA Health Record and can be viewed prior to the Pharmacist dispensing the investigational drug. Therefore, if the study does have a CoC, the informed consent document should not be scanned into the VHA Health Record per VHA Handbook 1200.05, Paragraph 21.d(2) but, rather, should be presented in physical form to the VA Pharmacy Service, as allowed by VHA Handbook 1108.04, Paragraph 10(d)(4).

The VA Form 10-9012 must be scanned into the subject's VHA Health Record for studies requiring a VA Form 10-9012 as described in VHA Handbook 1108.04, Paragraph 11(b)(2). This section states:

- “ b. **VA Form 10-9012, Investigational Drug Information Record.** VA Form 10-9012 must be provided to the pharmacy by the PI prior to the time of first dispensing of the investigational drug. Once on file, additional copies are required only if the form requires revision.
- (1) VA Form 10-9012 informs the authorized prescribers and other clinical personnel of the side effects and any known antidote of the investigational agent, as well as whom the designated contact person is for questions. VA Form 10-9012 is required on all investigational agents where a drug manufacture's [sic] package insert in [sic] not available.
  - (2) VA Form 10-9012, or an electronic equivalent, must be placed in the subject's medical record by the PI or LSI.”

#### **9. Are VA subjects' informed consent documents and written HIPAA authorizations required to be placed in the VHA Health Record?**

There is no ORD or VHA requirement to place VA subjects' informed consent documents and written HIPAA authorizations into the VHA Health Record. The Joint Commission requires hospitals to maintain the research consent document in the medical record or the investigator's research file. If a local VA Facility wishes to create local policy requiring research informed consent documents and written HIPAA authorizations to be placed into the VHA Health Record, the local VA Facility can choose to do so except for VA studies issued a CoC.

#### **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?**

VA does not have the ability to waive requirements applying to the Certificate's protections for which the Certificate is issued under the authority in the Secretary of Health and Human Services by Section 301(d) of the Public Health Service Act 42 U.S.C. 241(d). VHA Handbook 1200.05's requirements regarding health record documentation for VA studies issued a CoC uphold those protections.

#### **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?**

No, VHA Handbook 1200.05's requirements in the revised policies issued November 12, 2015 must be applied to human subjects studies approved after March 12, 2015. There is no ORD requirement to apply the revised ORD policies in VHA Handbook 1200.05 to studies approved by the IRB of Record for studies under the previous Handbook.

**REGULATORY AND VHA POLICY REFERENCES:**

- Section 301(d) of the Public Health Service Act (42 U.S.C. 241(d))
- VHA Handbook 1108.04, Investigational Drugs and Supplies.
- VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.