Veterans Health Administration
Research & Development
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VA Consent Addendum for National Cancer Institute (NCI) Studies Under the Oversight of the NCI Central Institutional Review Board (NCI CIRB)

(January 6, 2020)

Office of Research and Development (ORD) policy in VHA Directive 1200.05 (January 7, 2019), Paragraph 22.c. requires specific information to be given to Department of Veterans Affairs (VA) subjects as part of the informed consent when the approved VA study has a Certificate of Confidentiality (CoC). All NCI studies involving human subjects have a CoC because the research involves the collection of identifiable, sensitive information.

ORD policy requires the following for VA studies with Certificates of Confidentiality:

> VHA Directive 1200.05, Paragraph 22: Certificates of Confidentiality
>
> *c. When VA conducts a study that is protected by a Certificate of Confidentiality, the following requirements apply:*
>
> *(1) For studies in which information about the subject's participation will be included in the subject's VHA medical record, information must be given to the prospective subjects as part of the informed consent process that information regarding study participation will be included in the medical record; and*
>
> *(2) For studies in which the IRB requires a written informed consent, the informed consent document approved by the IRB must include a statement that the study has a Certificate of Confidentiality. NOTE: The HHS agencies that issue Certificates of Confidentiality usually have guidance specific to the issuing agency on statements that must be included in informed consent documents describing Certificates of Confidentiality.*

Use of the NCI CIRB Approved VA Consent Addendum:

ORD and the Office of Research Oversight (ORO) have worked with the NCI CIRB to create a VA informed consent addendum to be used by local VA Facilities in order to meet ORD informed consent policy requirements in VHA Directive 1200.05 for VA studies with a Certificate of Confidentiality. The NCI CIRB has approved the addendum document titled: "Department of Veterans Affairs Informed Consent Addendum" on December 22, 2019. The VA informed consent addendum form has been uploaded to the NCI Central IRB SharePoint Site established by ORD and ORO at: vaww.vha.vaco.portal.va.gov/sites/comm/admin/projects/ncicirb/default.aspx.

This Addendum is to be used for all new NCI studies approved by the NCI CIRB until revisions are approved by the NCI CIRB to the VA boilerplate language containing the VA specific requirements for informed consent documents. This addendum will no longer be used once the NCI IRB approves the revised VA boilerplate language. ORD and ORO will send an update to notify VA Facilities when the NCI CIRB has approved the revised VA boilerplate language.

Note:

1. The VA Informed Consent Addendum must be used by all VA facilities for all new NCI studies approved by the NCI CIRB.
2. VA Facilities must update their local standard operating procedures to include a statement that the VA Informed Consent Addendum will be used.
3. The VA Informed Consent Addendum is not to be used for studies already approved at VA Facilities by the NCI CIRB. There is no requirement for previously consented VA subjects to sign the VA Informed Consent Addendum.
4. The VA Informed Consent Addendum's text cannot be modified. This language has been approved by the NCI CIRB.
5. The VA Informed Consent Addendum includes lines for signatures and dates for the study participant and the person(s) conducting the informed consent discussion. The VA Informed Consent Addendum must be signed and dated.

Please send any questions regarding use of the VA Informed Consent Addendum for the NCI studies to Dr. Karen Jeans at c.karen.jeans@va.gov.