

**Guidance on Revision of the VA Boilerplate Language for National Cancer Institute (NCI) Studies under the Oversight of the NCI Central IRB**

**Date Issued: April 6, 2022**

**Updated: May 12, 2022**

**Scope**: The following update from ORPP&E applies to all VA Facilities approved to use the NCI Institutional Review Board (NCI CIRB):

**Purpose**: The purpose of this Guidance is to inform VA Facilities on revisions to the VA boilerplate language replacing the VA ICF Addendum.

**Background:**

On January 3, 2020, ORD informed the VA research community that ORD and the Office of Research Oversight (ORO) had worked with the NCI CIRB to create a VA informed consent form (VA ICF) 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 approved the VA ICF addendum titled: “Department of Veterans Affairs Informed Consent Addendum” on December 22, 2019. This document was uploaded to the NCI Central IRB SharePoint Site established by ORD and ORO at: <https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/ncicirb/default.aspx>. This addendum has been required for all new NCI studies approved by the NCI CIRB pending boilerplate revision approvals by the NCI CIRB.

**NCI CIRB Approval of the Revised VA Boilerplate Language and Requirements to Revise VA Facility’s NCI CIRB Boilerplate Language**

The NCI CIRB has approved the revisions to the VA boilerplate language, resolving the VA ORD national policy issue requiring the use of the VA ICF addendum. The revised VA NCI template boilerplate language with a date of 04-21-2022 has been placed on the ORD-ORO NCI SharePoint site located at <https://dvagov.sharepoint.com/sites/vacovhacomm/admin/projects/ncicirb/default.aspx>.

The revised VA boilerplate language contains additional language for the section, “Who will see my medical information?” to address both ORD policy requirements regarding certificates of confidentiality as well as adding both ORO and the VA Office of the Inspector General (OIG) as agencies that may see records. It also clarifies the signature section to reinforce that while the consent form signature lines cannot be replaced, additional lines may be added.

**Actions Required by VA Facilities to Revise the VA Facility’s Boilerplate Language:**

VA Facilities must do the following to revise their VA Facility’s boilerplate:

A. Revise the Annual Signatory Institution Worksheet to include the language in the revised VA NCI template boilerplate language with a date of 04-21-2022. VA Facilities will continue to use the VA Addendum until the new boilerplate document has been approved for their site.

B. Once the language has been approved for your VA Facility by the NCI CIRB, update as applicable your local standard operating procedures to include a statement that the VA Informed Consent Addendum will not be used.

**Additional Information:**

ORD will be planning a webinar at the end of April 2022 to update the VA research community of different topics related to human subjects protections. One of the topics will include discussion of the updates to the VA NCI CIRB boilerplate language and the process for VA Facilities to rely upon the NCI CIRB for NCI studies under their oversight. The webinar announcement will be sent out with the date and time.

Please send any questions regarding this information in this guidance to Dr. Karen Jeans at [c.karen.jeans@va.gov](mailto:c.karen.jeans@va.gov) and Dr. Don Workman at [don.workman@va.gov](mailto:don.workman@va.gov).