**REQUIREMENT FOR ALL VA STUDY SUBMISSIONS TO AN ORD-APPROVED COMMERCIAL INSTITUTIONAL REVIEW BOARD (IRB) REVIEW:**

**VA FACILITY COMMERCIAL IRB ENDORSEMENT LETTER**

Any research study submitted by a VA Investigator to a commercial IRB approved by ORD must include the following letter: “VA Facility Commercial IRB Endorsement Letter.” The purpose of the letter is to ensure that the VA Facility is aware that the VA Investigator is submitting a cooperative study to the ORD-approved commercial IRB and confirmed that neither the VA nor the VA NPC is contracting directly for the IRB review services provided by the commercial IRB. The letter also provides verification that the preliminary privacy and information security reviews have been completed prior to submission to the commercial IRB in addition to including a reminder that the study team is to include required informed consent and VA specific authorization language if the informed consent document and HIPAA authorization are combined. The commercial IRBs have requested this institutional documentation as part of standard processing of investigator applications.

The “VA Facility Endorsement Letter” must be signed by one of the following:

* the Associate Chief of Staff for Research and Development (ACOS/R&D),
* Administrative Officer for Research & Development (AO/R&/D), or
* the VA Facility’s Liaison for the commercial IRB

The VA Principal Investigator is not authorized to sign the VA Facility Commercial IRB Endorsement Letter. This letter must be included with the VA Investigator’s study application materials to the commercial IRB. **Any VA study application submitted without the signed VA Facility Commercial IRB Endorsement letter will not be processed by the applicable commercial IRB.**

Please contact Dr. Don Workman (Don.Workman@va.gov), with questions about this requirement.

The [ORD VA Facility Commercial IRB Endorsement Letter](https://www.research.va.gov/programs/orppe/VA-Facility-Endorsement-Letter-Template-for-Commercial-IRB-Submission.pdf) template is available for download on the ORD website at (<https://www.research.va.gov/programs/orppe/single_irb.cfm>). VA Facilities are encouraged to check the ORD website for frequent updates to information, instructions and templates.