Table of Changes to Veterans Health Administration (VHA) Directive 1058.03

Topic	VHA Handbook 1058.03	VHA Directive 1058.03	Comments
FWA for exempt research	[E]ach Department of Veterans Affairs (VA) medical facility engaged in research involving human subjects or human biological specimens must hold an effective Federalwide Assurance (FWA) approved by Office for Human Research Protections (OHRP) with an effective VA FWA Addendum approved by Office of Research Oversight (ORO).	[E]ach VA medical facility engaged in non-exempt human subjects research covered by the requirements of 38 CFR 16 must hold a valid FWA approved by the U.S. Department of Health and Human Services (HHS)-OHRP with an effective VA FWA Addendum approved by ORO. [§6.a.]	Only VA medical facilities engaged in non-exempt human subjects research must hold an assurance.
Designation of IRBs on FWAs	Institutional Review Boards (IRBs) used by VA medical facilities, whether operated by VA or by another entity, must be registered with OHRP and designated as an IRB of Record on the facility's FWA.	(a) All IRBs operated by a VA medical facility (internal IRBs) must be designated on the VA medical facility's FWA. (b) If a VA medical facility does not operate its own internal IRB, the external IRB that oversees the greatest percentage of the VA medical facility's non-exempt human subjects research studies must be designated on the VA medical facility's FWA. [§6.a.(3.)]	Only IRBs operated by the VA medical facility must be designated on the FWA or, in the absence of an IRB operated by the VA medical facility, only the primary external IRB relied upon must be designated on the FWA.
VA FWA Addendum Signatories	The VA FWA Addendum must be signed by the facility Director, the Director of the appropriate Veterans Integrated Service Network (VISN), and the ORO Chief Officer, or designee, prior to approval by OHRP.	The VA FWA Addendum must … be signed by the VA medical facility Director and the ORO Executive Director, or designee, in conjunction with approval of the FWA by HHS-OHRP. [§6.a.(4)]	Only the medical facility Director and the ORO Executive Director, or designee need to sign the VA FWA Addendum.
Changes to FWAs	All changes to FWAs must be submitted promptly as they occur to ORO through OHRP. Modifications other than telephone, address, or email changes require a revised VA FWA Addendum signed by the facility Director, the VISN Director, and the ORO Chief Officer or designee, prior to approval by OHRP.	All administrative and programmatic changes necessitating a change to a VA medical facility's FWA, as required by HHS-OHRP, must be submitted within 60 days to ORO FWA staff for review so as to ensure timely submission to HHS-OHRP through ORO FWA staff within 90 days of the change. [§6.c.]	Only changes that OHRP requires necessitate an update to the FWA: changes in the legal name of the institution, Signatory Official or Human Protections Administrator.

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VA FWA Addendum	The VA FWA Addendum must be signed by the facility Director, the Director of the appropriate VISN, and the ORO Chief Officer, or designee, prior to approval by OHRP….	A VA medical facility's initial FWA and VA FWA Addendum submission to ORO must include:… The VA FWA Addendum signed by the Institutional Official (IO); … [§6.b.]	Only the Institutional Official needs to sign the VA FWA Addendum
FWA training	All personnel signing the FWA and the VA FWA Addendum must complete the OHRP Assurance Training Modules, as well as any other training required for this purpose by the Office of Research & Development.	[language re training removed]	The medical facility Director is responsible for being familiar with the requirements in the Common Rule and the ethical principles governing human subjects research in the Belmont Report. [§5.f.(2)]
Suspending/ Restricting FWAs	Where the ORO Chief Officer determines that restriction or suspension of a VA medical facility's Assurance is necessary to safeguard the safety, rights, or welfare of human subjects, the ORO Chief Officer so notifies the Under Secretary for Health and the facility's IO, and provides the IO with a written statement of the reasons for the restriction or suspension.	Where the ORO Executive Director (ED) determines that restriction or suspension of a VA medical facility's Assurance or associated VA FWA Addendum is necessary because the ORO ED reasonably believes the action is necessary to safeguard the safety, rights, or welfare of human subjects, the ORO ED must recommend such restriction or suspension to the Under Secretary for Health. [(§6.f.)]	Responsibility for approving the restriction or suspension of a VA medical facility's Assurance or VA FWA Addendum, based on a recommendation by the ORO Executive Director, has been assigned to the Under Secretary for Health.
Reporting IRB Roster Changes	Regardless of whether the IRB of Record is operated by the VA medical facility or by another entity, the VA medical facility holding the FWA must provide ORO with an updated roster within 30 days of any change in membership.	[Language removed]	The previous requirement for VA medical facilities to report IRB membership changes to ORO has been eliminated.

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Memoranda of Understanding (MOUs)	MOUs must be revised promptly as conditions change and must be submitted to ORO within 30 working days of any revision…. VA facilities designating the IRB(s) of another entity as their IRB(s) of Record must review their MOU(s) carefully at the time of FWA renewal….	Existing MOUs must be revised promptly by the VA medical facility Director as conditions outlined in the MOU change and must be submitted to ORO within 30 days of being revised as final. [§7.d.(2)]	Drafts of changes to MOUs are no longer required to be reviewed by ORO prior to finalization. VISN Directors are no longer required to sign MOUs. Final MOUs (new or revised) for external IRBs required to be designated on the FWA must be submitted to ORO within 30 days of execution.