OFFICE OF RESEARCH OVERSIGHT Summary of Major Changes VHA Directive 1058.03 "Assurance of Protection for Human Subjects in Research" Dated September 17, 2020

*The revision of VHA Handbook 1058.03, dated September 17, 2020, generally reduces burden for Department of Veterans Affairs (VA) medical facilities. This summary **only** lists **major** changes resulting from the revision. It is **not** a comprehensive list of **all** changes.*

6. ASSURANCES FOR VA MEDICAL FACILITIES

a. Federalwide Assurances (FWAs). A previous requirement that all VA medical facilities must hold a recognized assurance if engaged in human subjects research, regardless of whether such research meets certain regulatory exemption criteria, has been changed such that only VA medical facilities engaged in non-exempt human subjects research must hold such an assurance**.** "[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 [U.S. Department of Health and Human Services Office for Human Research Protections] HHS-OHRP with an effective VA FWA Addendum approved by [the Office of Research Oversight] ORO."

f. Restriction or Suspension of Assurances. Responsibility for approving the restriction or suspension of an FWA based on recommendation by the ORO Executive Director, has been assigned to the Under Secretary for Health. "Where the ORO Executive Director determines that restriction or suspension of a VA medical facility's Assurance or associated VA FWA Addendum is necessary because the ORO Executive Director reasonably believes the action is necessary to safeguard the safety, rights, or welfare of human subjects, the ORO Executive Director must recommend such restriction or suspension to the Under Secretary for Health."

7. INSTITUTIONAL REVIEW BOARD (IRB) REVIEW ARRANGEMENTS FOR VA MEDICAL FACILITIES

b. IRB Registration. The requirement for all IRBs used by a VA medical facility to be designated on the VA medical facility's FWA has been changed such that only IRBs operated by the VA medical facility must be designated or, in the absence of an IRB operated by the VA medical facility, only the primary external IRB relied upon must be designated. "The VA IRB(s) operated by the VA medical facility (internal IRB(s)), or if there are no internally-operated IRBs, at least 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 as the IRB(s) of Record."

c. IRB Membership Rosters. The previous requirement for VA medical facilities to report IRB roster changes to the VHA ORO has been eliminated.