VHA Office of Research Oversight - VHA Handbook 1058.01 – Interpretation #1

Title: Clarification of the VHA Office of Research Oversight's (ORO) Requirements for the Review of Reportable Events Involving Exempt Human Subjects Research

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Purpose:

VHA Handbook 1058.01, §6 sets forth requirements for the reporting and review of certain events (unanticipated problems, noncompliance, suspensions and terminations, etc.) involving human subjects research. Further, this section of the Handbook establishes responsibilities for reporting of such events to the appropriate Institutional Review Board (IRB) that provides oversight of the human subjects research associated with the event, and review of such events by that IRB. However, the Handbook does not differentiate between non-exempt and exempt human subjects research, the latter of which may not fall under the purview of an IRB. Thus, the purpose of this interpretation is to clarify reporting and review requirements involving exempt human subjects research that is not overseen by an IRB.

Reference(s):

VHA Handbook 1058.01, "Research Compliance Reporting Requirements" (issued June 15, 2015), §6. "Human Research"

Interpretation/Clarification:

For an event otherwise required by VHA Handbook 1058.01, §6 to be reported to an IRB and that is associated with *exempt* human subjects research that falls under the oversight of a committee other than an IRB, the event shall be reported instead to the committee with primary oversight responsibility for the research (e.g., Research & Development Committee (R&DC), R&DC designated subcommittee for the oversight of exempt human subjects research, etc.). Under the aforementioned circumstances, responsibilities ascribed by VHA Handbook 1058.01, §6 to the IRB for reviewing or otherwise acting upon such events shall instead be carried out by the committee with primary oversight responsibility for the research.