OFFICE OF RESEARCH OVERSIGHT (ORO)

Examples of Noncompliance in VA Human Subjects Research that ORO Typically Considers to Meet the Definition of Serious or Continuing Noncompliance under VHA Directive 1058.

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VHA Directive 1058, "OFFICE OF RESEARCH OVERSIGHT," sets forth requirements for the reporting to ORO of serious or continuing noncompliance and other events involving VA research. The directive covers reporting requirements for the various types of research conducted by VA investigators, including research involving the participation of human subjects, research involving the use of laboratory animals, and basic benchtop research conducted in laboratories. With regard to VA human subjects research, and more specifically, VA human subjects research to which the requirements of the Federal Policy for the Protection of Human Subjects apply (i.e., non-exempt human subjects research) or that is otherwise under the oversight of an Institutional Review Board (IRB), VHA Directive 1200.05(3) requires IRBs to establish and follow written SOPs for, among other things, ensuring prompt reporting to the appropriate IRB any serious or continuing noncompliance with the directive or the requirements or determinations of the IRB, involving such research.[1] VHA Directive 1058 provides details and timelines for reporting such serious or continuing noncompliance to ORO. Examples are provided in this guidance document to assist in identifying noncompliance that ORO would typically consider to constitute serious or continuing noncompliance under VHA Directive 1058.[2] This guidance in *not* intended to provide an exhaustive list of examples of serious or continuing noncompliance.

Pertinent Definitions in VHA Directive 1058:

§8.c. Continuing Noncompliance. *For purposes of this directive, continuing noncompliance means repeated instances of noncompliance with applicable laws, regulations, policies, agreements, or determinations of a research review committee or the prolonged persistence of noncompliance occurring after its identification, awareness, or implementation of a corrective action intended to effectively resolve the noncompliance.*

§8.e. Noncompliance. For purposes of this directive, *noncompliance is any failure to adhere to applicable requirements for overseeing, reviewing, approving, or conducting VA research set forth in law, regulation, policy, or study agreements (such as reliance agreements, memoranda of understanding, data use agreements), including any failure to conduct research in accordance with a VA study protocol approved by a research review committee.*

§8.m. Serious Noncompliance. *For purposes of this directive, serious noncompliance is any failure to adhere to requirements for conducting human research that may reasonably be regarded as:*

(1) Presenting a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, or others, including their rights to privacy and confidentiality of

[1] Directive 1058 also addresses reporting requirements for other types of research (exempt human subjects research, laboratory animal research, basic laboratory benchtop research, etc.) under the oversight of a committee other than an IRB (such as a Research & Development Committee, Institutional Animal Care and Use Committee, or Subcommittee on Research Safety).

[2] Although the focus of this guidance document is on events involving human subjects research under the purview of an IRB, the examples provided in this document of events typically constituting serious or continuing noncompliance involving such research may have parallels with events that occur in other types of research (exempt human subjects research, laboratory animal research, basic laboratory benchtop research, etc.) and that would be similarly reportable to ORO.

identifiable private information;

(2) Presenting a genuine risk of substantive harm to the safety of research personnel who conduct research;

(3) Presenting a genuine risk of substantive harm to the health or welfare of animals used in research;

(4) Presenting a genuine risk of substantive reputational harm to VA; or

(5) Substantively compromising a VA medical facility's Animal Care and Use Program (ACUP), Human Research Protection Program (HRPP), Research Safety and Security Program (RSSP), or research information security processes.

A. Examples of Noncompliance in Human Subjects Research that May Constitute Serious Noncompliance under VHA Directive 1058:

(1) Initiation of non-exempt human research without required IRB approval.
(2) Initiation of non-exempt human research without required Research and Development (R&D) Committee approval.
(3) Failure to obtain required informed consent, or documentation of informed consent prior to conducting research.
(4) Failure to obtain required Health Insurance Portability and Accountability Act (HIPAA) authorization for one or more subjects that led to use and/or disclosure of protected health information (PHI) without proper legal authority.
(5) Other substantive informed consent or HIPAA authorization deficiencies, including HIPAA authorization deficiencies that have led to use and disclosure of PHI without proper legal authority (e.g., a valid HIPAA authorization or a valid waiver of HIPAA authorization).
(6) Substantive deviations from IRB-approved protocols (except to eliminate apparent immediate hazards to subjects), such as violations of inclusion or exclusion criteria, failure to institute research procedures that provide safeguards to subjects or others, or addition of research procedures that add unnecessary risks to subjects or others.
(7) Failure to promptly notify the IRB of unanticipated problems in human subjects research involving risks to subjects or others (UPIRTSO), including serious adverse events that are unanticipated and related or possibly related to participation in VA research.
(8) Conduct of non-exempt human research without required credentialing, privileging, or adequate training of research staff.
(9) Continuation of interventions/interactions with subjects in non-exempt human research beyond the specified IRB approval period.
(10) Noncompliance that substantively compromises the HRPP (e.g., violation of IRB quorum requirements; improper approval or documentation of waivers; misapplication of exempt research determinations, failure to ensure IRB approval criterion are met). *NOTE: Serious or continuing noncompliance on the part of the IRB must be reported to the facility R&D Committee.*
(11) Any combination of noncompliant actions that collectively present a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects (including their rights to

privacy and confidentiality of identifiable private information), research personnel, or others, or substantively compromise a facility's HRPP.

B. Some Examples of Noncompliance in Human Subjects Research that May Constitute Continuing Noncompliance under VHA Directive 1058:

(1) Repeated failure by the relevant investigator(s) to ensure timely remediation of any noncompliance, identified by or made known to the investigator(s), with requirements for the conduct of human research.
(2) Repeated failure by the responsible official(s) to ensure timely remediation of any programmatic noncompliance, identified by or made known to the official(s), with requirements for the conduct or oversight of human research.
(3) Any noncompliance that, due to its persistence over time, results in a genuine risk of substantive harm to the safety, rights, or welfare of human research subjects, research personnel, or others, or substantively compromises a facility's HRPP.
(4) Persistence of noncompliance occurring after the implementation of a corrective action intended to effectively resolve the noncompliance.