Table of Changes to VHA Directive 1058.01- Research Compliance Reporting Requirements

Topic	VHA Handbook 1058.01	VHA Directive 1058.01	Comments
Definition of Continuing Noncompliance	Continuing noncompliance is the persistent failure to adhere to the legal and policy requirements governing human research.	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. [§3.c]	Added the prolonged persistence of noncompliance occurring after its identification, awareness, or implementation of a corrective action intended to effectively resolve the noncompliance
Definition of Serious Accident, Injury, Illness or Exposure of a Human	Serious accidents/injuries include those that require medical attention or treatment, other than basic first aid provided at the site where the accident/injury occurred; those that require extended medical surveillance of the affected individual(s) that may include sequential serology or other medical testing; and those that lead to a serious long term health complication or death.	Serious accidents, injuries, illnesses or exposures of a human are incidents that: (1) require medical attention or treatment, other than basic first aid provided at the site where the accident, injury, illness or exposure occurred; (2) require time away from work or restricted work activities; (3) require medical surveillance of the affected individual(s) that may include sequential serology or other medical testing; or (4) lead to serious long term health complications or death. [§3.m]	Added illnesses and exposures and incidents that require time away from work or restricted work activities.
Definition of Serious accidents, injuries…	Serious accidents/injuries include those that require medical attention or treatment, other than basic first aid provided at the site where the accident/injury occurred; those that require extended medical surveillance of the affected individual(s) that may include sequential serology or other medical testing; and those that lead to a serious long term health complication or death.	Serious accidents, injuries, illnesses or exposures of a human are incidents that: (1) require medical attention or treatment, other than basic first aid provided at the site where the accident, injury, illness or exposure occurred; (2) require time away from work or restricted work activities; (3) require medical surveillance of the affected individual(s) that may include sequential serology or other medical testing; or (4) lead to serious long term health complications or death. [§3.m]	Added illnesses and exposures and incidents that require time away from work or restricted work activities.

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Definition of Serious Noncompliance	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, research personnel, or others, including their rights to privacy and confidentiality of identifiable private information; or (2) Substantively compromising a facility's HRPP. ***NOTE:*** *For examples, see the ORO SharePoint/Web sites at http://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/default.aspx and http://www.va.gov/oro/. The first link is to an internal Web site and is not available to the public.*	Serious noncompliance is any failure to adhere to requirements for conducting 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 identifiable private information; (2) Presenting a genuine risk of substantive harm to the safety, rights, or welfare 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. [§3.o]	Added Presenting a genuine risk of substantive reputational harm to VA and substantively compromising a facility's ACUP, RSSP, or research information security processes. Also added Presenting a genuine risk of substantive harm to the health or welfare of animals used in research.
Definition of Unanticipated Problem in Human Subjects Research Involving Risks to Subjects or Others	[No analogous provision]	An unanticipated problem involving risks to subjects or others (UPIRTSO) in human subjects research is an incident, experience or outcome that is: unexpected; related or possibly related to participation in the research; and indicative of the research placing subjects or others at substantively greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized. [§3.q]	New terminology introduced

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Definition of Related and Possibly Related	A related AE, death, or problem is an AE, death, or problem that may reasonably be regarded as caused by, or probably caused by, the research. ***NOTE:*** *For more information, see 21 CFR 312.64.*	The phrase "related to participation in the research" means a logical sequence of cause and effect shows that the study procedures were the reason for the incident, experience, or outcome. The phrase "possibly related to participation in the research" implies a lesser degree of certainty about causality and refers to an incident, experience, or outcome for which there is some evidence to reasonably suggest a causal relationship between study procedures and the incident, experience, or outcome. [§3.q.(2)]	Substantive change to definition
Reporting for External Committees	[No analogous provision]	If the procedures of the non-VA operated committee [overseeing a VA medical facility's research] differ from, or the timeframes exceed those of, this Directive, the Director must consult with the VHA Office of Research & Development (ORD) and the appropriate [Office of Research Oversight (ORO)] workgroup (as specified on ORO's website) as to the adequacy of those procedures to protect the interests of VA and those involved in VA research. [§5.g.(2)]	***NOTE:*** *In the event that a non-VA operated research review committee is unable or unwilling to review an event required to be reviewed under this directive, the VA medical facility's [Research & Development Committee (R&DC)] will either review the event or designate another applicable VA research review committee to review the event as would otherwise occur if the event were subject to review by a VA-operated research review committee under the requirements of this directive.*

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Timeframe for Remedial Actions	Except where remediation requires substantial renovation or fiscal expenditure, hiring, legal negotiations, or other extenuating circumstances, remedial actions must be completed within 120 calendar days after any determination of noncompliance. (2) Where remedial actions cannot be completed in 120 calendar days, the VA facility Director must provide ORO with an acceptable written justification and an acceptable timeline for completion.	(a) Remedial actions to correct noncompliance identified by ORO or that is otherwise required to be reported to ORO must be completed within 180 calendar days after any determination of noncompliance, except where extenuating circumstances exist (e.g., remediation requires substantial renovation or fiscal expenditure, hiring, or legal negotiations). (b) Where remedial actions cannot be completed in 180 calendar days, the VA medical facility Director must provide the appropriate ORO workgroup(s) with written justification and a reasonable timeline for completion. [§§5.g.(6)(a)&(b)]	Timeframe for completion of remedial actions changed from 120 days to 180 days
Approval of Waiver for the Requirement of a full-time Research Compliance Officer (RCO)	The VA facility Director must appoint at least one full-time RCO to conduct annual informed consent and triennial regulatory audits unless the Under Secretary for Health approves a waiver to permit a part-time appointment.	Each VA medical facility Director whose VA medical facility has a research program is responsible for: … Appointing at least one full-time Research Compliance Officer (RCO) to conduct research informed consent and regulatory audits unless ORD and ORO jointly approve a waiver to permit appointing of a part-time RCO. [§5.g.(8)]	The Under Secretary for Health no longer is responsible for reviewing and approving RCO full-time waivers; ORO and ORD now have responsibility for reviewing and approving such waivers.
Flexibility to Whom the RCO Reports	The lead RCO must report directly to the VA facility Director. RCO activities may not be determined or managed by the Associate Chief of Staff (ACOS) for Research and Development (R&D) or any other research entity.	The RCO, or a lead RCO …, must report directly to and be supervised by either the VA medical facility Director or a senior individual who reports directly to and is supervised by the VA medical facility Director and whose primary responsibilities at the VA medical facility pertain directly to compliance. [§5.g.(8)(a)]	Provides flexibility to allow, but does NOT mandate, RCO reporting to another individual who reports directly to the facility Director.

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Ensuring RCO Access to Records	[No analogous language]	The VA medical facility Director must ensure that the VA medical facility RCO(s) has ready access to research program and study documentation so that the RCO can effectively fulfill the responsibilities of the position. This includes access to documentation (e.g., research review committee meeting minutes, study approval letters, investigator study documentation) necessary to fulfill requirements related to auditing of informed consents and study protocols. [§5.g.(8)(d)]	
Ensuring RCO Access to Records (External review committees)	[No analogous language]	***NOTE:*** *In situations where the VA medical facility relies upon a research review committee operated by a non-VA entity, the VA medical facility Director must ensure that agreements to rely on such committees or other documents (e.g., the committee's SOPs) require that the VA medical facility's RCO has access to the committee's records to the extent necessary for the RCO to fulfill research auditing requirements.* [§5.g.(8)(d)]	
Reporting of Human Deaths	The [Institutional Review Board (IRB)] must alert ORO by e-mail or telephone within 2 business days after receiving such notification and provide relevant information as requested…. VA personnel, including WOC and IPA appointees, must ensure written notification of the IRB within 5 business days of becoming aware of the death. Within 5 business days after receiving written notification of the death, the IRB Chair or a qualified IRB member-reviewer must determine and document whether any actions are warranted to eliminate apparent immediate hazards to subjects.	VA personnel must also ensure that follow-up written notification is provided to the [appropriate review committee] of Record within one (1) business day of becoming aware of such a death. The ACOS/R&D, or designee, must alert the VA medical facility Director and appropriate ORO workgroup by email or telephone within one (1) business day after receiving the initial oral notification and provide relevant information as requested. Within one (1) business day after receiving written notification of the death, the [committee] Chair or another qualified [committee] voting member must assess and document whether any actions are warranted to eliminate apparent immediate hazards [to individuals] and, if so, initiate those actions. [§§7.a.(1)&(2); 9.a.; 10.a.]	Report to VA medical facility Director & ORO of local human deaths—2 days changed to 1 day. Review committee chair's assessment whether actions are warranted to eliminate hazards–added "if so, initiate actions"; deadline for this requirement changed from 5 days to 1 day.

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Notifying Facility Staff of Events	The [Research Review Committee] must notify the VA facility Director and the ACOS/R&D of its determinations….	The [Research Review Committee] must notify the VA medical facility Director, the RCO, and the ACOS/R&D in writing of its determinations…. [§§6.c.; 7.a.(4) & (6); 7.b.(3) & (5); 7.c.(2); 7.d.; 9.a.(4) & (6); 9.b.(3) & (5); 9.c.(2); 9.d.(2); 9.e.; 10.a.(4) & (6); 10.b.(3) & (5); 10.c.(2); 10.d.]	Added requirement to notify the RCO.
When Review by the Convened Research Review Committee Must Occur	The [Research Review Committee] must review … at its next convened meeting….	The [Research Review Committee] must … review the written notification … at its next convened meeting, not to exceed 30 calendar days after the date of the written notification. [multiple §]	Clarify the Research Review Committee is reviewing the written notification and that convened meeting must be within 30 calendar days.
New Section 8 on Exempt Human Subjects Research	[No analogous language]	For an event that would otherwise be required by paragraph 7 of this directive to be reported to and reviewed by an IRB, but that is associated with exempt human subjects research that falls under the oversight of a committee other than an IRB, the event must instead be reported to the committee with primary oversight responsibility for the research (e.g., R&DC, R&DC-designated subcommittee for the oversight of exempt human subjects research). …	Responsibilities ascribed to the IRB in §7 for reviewing and acting upon such events is carried out by the committee with primary oversight responsibility for the research. All other associated reporting and review requirements for such events must be carried out as specified in paragraph 7 (Non-exempt Human Subjects Research).