

Version Number: 4	Research & Development Policy 151-17	Supersedes Document Dated: 04/13/2010
Effective Date: 03/11/2013	REQUIREMENTS FOR REPORTING RESEARCH EVENTS INVOLVING HUMAN SUBJECT RESEARCH	Expiration Date: 03/10/2017

I. PURPOSE

This policy describes the types of events (unanticipated problems involving risks to participants or others, serious or continuing non-compliance, or suspension or termination of Institutional Review Board (IRB) approved research) that must be reported to appropriate regulatory agencies, and how such reports are to be prepared and sent.

2. SCOPE

This Policy:

- a. Identifies the research events that must be reported to facility research oversight committees, Associate Chief Of Staff Research and Development (ACOS R&D) and Medical Center Director.
- b. Identifies the research events that must be reported to Office of Research Oversight (ORO) Northeastern Regional Office,
- c. Identifies the research events that must be reported to ORO Central Office,
- d. Provides the methods and timelines for reporting such events, and
- e. Indicates what information must be provided in reports of these events.

3. DEFINITIONS : See R&D SOP 151-01 Appendix B

4. GENERAL REQUIREMENTS FOR REPORTING RESEARCH EVENTS TO ORO

a. **Applicability.** The reporting requirements of this policy apply only to VA research. Appendices summarize the research events that must be reported to ORO.

b. **Contents of Initial Reports to ORO.** Initial reports to ORO of reportable research events must (as applicable) include:

- (1) The name and any relevant Assurance number of the reporting VA facility.
- (2) The title of the research project(s).
- (3) The number(s) used by the facility's Research Service or relevant research review committee(s) to identify the project(s).
- (4) The name of any external sponsor(s) of the project(s).
- (5) The funding source(s) for the project(s).
- (6) The name of any agencies or organizations external to VA that were notified, or need to be notified, of the event.
- (7) A description of the event being reported, including (where applicable) the nature of the research

study (e.g., retrospective chart review; prostate cancer treatment study; post-traumatic stress disorder behavioral intervention study).

(8) A description of any immediate actions taken to address or investigate the reported event.

c. **Contents of Follow-Up Reports to ORO.** After the initial report, additional investigation and review are frequently needed to obtain a complete understanding of the facts associated with the case. Interim and final reports must be provided as directed by ORO to incorporate the full scope of relevant determinations and remedial actions, including programmatic actions as warranted.

d. **Implementation of Remedial Actions.** The relevant research review committee is responsible for determining the appropriate remedial action(s) in response to identified noncompliance and for verifying that the remediation is implemented as required.

(1) Except in extraordinary circumstances, remedial actions related to specific research projects must be completed within 90-120 days of the research review committee's determination of noncompliance (or of such a determination by ORO).

(2) Except where remediation requires substantial renovation, fiscal expenditure, hiring, legal negotiations, or other extenuating circumstances, remedial actions related to programmatic noncompliance must be completed within 120-180 days of the noncompliance determination.

(3) Where completion of remedial actions extends beyond the periods described in the preceding subparagraphs, the facility must provide ORO with a written justification for the delay and an acceptable timeline for completion.

e. **Secure Transmission to ORO.** Reports to ORO may include VA sensitive information as defined in VA Directive 6500. Electronic transmissions of such reports must be encrypted in accordance with applicable requirements of the VA Office of Information and Technology (OI&T), and hard copies of such reports must be sent by secure carrier in accordance with VA requirements in VA Directive and Handbook 6500 and VA Directive 6609.

f. **Other Reporting Requirements.** In addition to the requirements described, VA facilities and investigators are required to comply with all applicable reporting requirements of relevant Federal and state oversight agencies, funding entities, and the sponsor. Examples include, but are not limited to: the Food and Drug Administration (FDA), the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP), the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Nuclear Regulatory Commission (NRC), and the VA Network and Security Operations Center (VA-NSOC). In all cases, reporting must be based on the requirements established by the relevant entity. **NOTE:** *Contact information for reporting to ORO RO and CO oversight groups is posted prominently on ORO's Web site at: <http://www.va.gov/oro/>.*

5. FACILITY DIRECTOR RESPONSIBILITIES.

The Facility Director is responsible for:

a. Ensuring that detailed SOPs are developed and implemented to satisfy all requirements of Handbook 1058.01, including requirements affecting the facility's academic affiliates.

b. Ensuring that all persons working in research or performing any research activities have been officially appointed by Human Resources Management.

c. Appointing one or more RCOs to conduct annual research informed consent audits and triennial regulatory audits in accordance with a written audit plan or SOP, and to assist in facility assessments of regulatory compliance. **NOTE:** *Procedures and materials related to RCO training requirements and RCO audit requirements are updated periodically and posted prominently on ORO 's Web site at: <http://www.va.gov/oro/>.*

(1) Unless a waiver for a part-time RCO is approved by the Under Secretary for Health, each VA research facility must designate at least one full-time RCO.

(2) A VA research facility's lead RCO must report directly to the facility Director. RCO activities may not be determined or managed by the Research Service, research investigators, or any other research personnel.

(3) In addition to conducting required audits, the RCO may serve as a non-voting consultant, as needed, to the facility's R&D Committee, IRB, SRS, and other research review committees. The RCO may not serve as a voting or non-voting member of these committees. The RCO may attend meetings of these committees when requested by the committee.

(4) The RCO may participate in research compliance education activities and perform related duties as determined by the facility Director.

(5) The facility Director must report any appointment, resignation, or change in status of the facility RCO to ORO CO, with a copy to the relevant ORO RO, within 5 business days after the appointment, resignation, or change takes effect.

d. Ensuring that the results of all RCO informed consent audits, regardless of outcome, are reported to the IRB and the R&D Committee in a timely fashion.

e. Ensuring that the results of all RCO regulatory audits, regardless of outcome, are reported to the R&D Committee and all other relevant research review committees (e.g., IRB, SRS) in a timely fashion.

f. Reporting to ORO in writing within 5 business days after being notified of a research problem or event for which such reporting is required.

(1) The facility Director's written report is required regardless of whether disposition of the event has been resolved at the time of the report.

(2) Follow-up reports detailing any additional findings and appropriate remedial actions must be provided to the relevant ORO office at intervals and in a manner specified by that office.

g. Completing the annual facility Director's Certification of Research Oversight. **NOTE:** *Prior to the official due date procedures and materials related to the facility Director's Certification are updated annually and posted prominently on ORO 's Web site (<http://www.va.gov/oro/>).*

h. Providing a copy of any ORO compliance reports regarding the research program to the ACOS for Research, R&D Committee, any relevant research review committee(s), and the RCO in a timely fashion.

6. REQUIREMENTS RELATED TO HUMAN RESEARCH:

a. **Unanticipated Problems Involving Risks to Subjects or Others.** Members of the VA research community are required to ensure that unanticipated problems involving risks to subjects or others in research are reported promptly to the IRB.

b. **Serious Unanticipated Problems Involving Risks to Subjects or Others.** Within 5 business days of becoming aware of any serious unanticipated problem involving risks to subjects or others in VA research, members of the VA research community are required to ensure that the problem has been reported in writing to the IRB. Serious unanticipated problems involving risks to subjects or others include:

(1) Interruptions of subject enrollments or other research activities due to concerns about the safety, rights, or welfare of human research subjects, research staff, or others.

(2) Any work-related injury to personnel involved in human research, or any research-related injury to any other person, that requires more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individual(s), or leads to serious complications or death.

(3) Any VA National Pharmacy Benefits Management (PBM) Bulletins or Communications (sometimes referred to as PBM Safety Alerts) relevant to one or more of the facility's research projects. **NOTE:** *Reference R&D SOP 151-23*

(4) Any DMC, DSMB, or DSMC report describing a safety problem.

(5) Any sponsor analysis describing a safety problem for which action at the facility level is warranted. **NOTE:** *Sponsor AE reports lacking meaningful analysis do not constitute "problems" under this paragraph.*

(6) Any unanticipated problem involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others;

(7) Any problem reflecting a deficiency that substantively compromises the effectiveness of a facility's human research protection or human research oversight programs.

c. **Local Unanticipated SAEs.** Within 5 business days of becoming aware of any local (i.e., occurring in the reporting individual's own facility) unanticipated SAE in VA research, members of the VA research community are required to ensure that the SAE has been reported in writing to the IRB. **NOTE:** *This requirement is in addition to other applicable reporting requirements (e.g., reporting to the sponsor under FDA requirements). The unfounded classification of an SAE as "anticipated" constitutes serious noncompliance.*

d. **IRB Review of Serious Unanticipated Problems and Unanticipated SAEs.** Within 5 business

days after a report of a serious unanticipated problem involving risks to subjects or others, or of a local unanticipated SAE, the convened IRB or a qualified IRB member-reviewer must determine and document whether or not the reported incident was serious, unanticipated, and related to the research. **NOTE:** *Related means the event or problem may reasonably be regarded as caused by, or probably caused by, the research.*

(1) If the convened IRB or the qualified IRB member-reviewer determines that the problem or event is serious and unanticipated and related to the research, the IRB Chair or designee must notify ORO via telephone or e-mail within 48 hours and report the problem or event directly (without intermediaries) to the facility Director within 5 business days after the determination.

(a) The report must be made in writing, with a simultaneous copy to the ACOS for Research and the R&D Committee.

(b) The facility Director must report the problem or event to the appropriate ORO RO within 5 business days after receiving such notification.

(2) If the convened IRB or the qualified IRB member-reviewer determines that the problem or event was serious, unanticipated, and related to the research, a simultaneous determination is required regarding the need for any action (e.g., suspension of activities; notification of subjects) necessary to prevent an immediate hazard to subjects in accordance with VA regulations in 38 CFR 16.103(b)(4)(iii).

(3) All determinations of the qualified IRB member-reviewer (regardless of outcome) must be reported to the IRB at its next convened meeting.

(4) If it was determined that the problem or event is serious, unanticipated, and related to the research, the convened IRB must determine and document whether or not a protocol or informed consent modification is warranted.

(5) If the convened IRB determines that a protocol or informed consent modification is warranted, the IRB must also determine and document the following:

(a) Whether or not previously enrolled subjects must be notified of the modification and, if so,

(b) When such notification must take place and how such notification must be documented. **NOTE:** *Decision charts related to reporting SAEs and problems involving risks to subjects or others see Appendix B*

e. **Apparent Serious or Continuing Noncompliance.** Within 5 business days of becoming aware of any apparent serious or continuing noncompliance with applicable human research protection requirements (e.g., 38 CFR 16, VHA Handbook 1200.05, FDA regulations), members of the VA research community are required to ensure that the apparent noncompliance has been reported in writing to the IRB. **NOTE:** *The determination that noncompliance is serious or continuing rests with the IRB; hence, individuals are required to report apparent serious or continuing noncompliance. Decision charts related to such reporting see Appendix C*

f. **Examples of Apparent Serious Noncompliance.** Examples of apparent serious

noncompliance that must be reported to the IRB within 5 business days include, but are not limited to:

- (1) Any finding of noncompliance with human research requirements by any VA office (other than ORO), any other Federal or State entity (e.g., FDA), or any external monitor. Reports to ORO based on findings made by entities external to the facility must include a copy of the official findings.
- (2) Initiation of VA human subject research, regardless of level of risk or number of subjects, without written notification from the ACOS for Research that the project may begin.
- (3) Initiation of VA human subject research, regardless of level of risk or number of subjects, without approval by the IRB.
- (4) Initiation of research interactions or interventions with one or more subjects prior to obtaining required informed consent.
- (5) Lack of a required, signed informed consent document or lack of a required, signed Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule authorization for one or more subjects.
- (6) Use of an informed consent document, for one or more subjects, whose content was not approved by the IRB.
- (7) Failure to report one or more unanticipated SAEs or unanticipated serious problems involving risks to subjects or others as required by this Handbook.
- (8) Participation by one or more members of the research team in the conduct of an active protocol without the required credentialing, privileging, or scope of practice, or engaging in activities outside the approved scope of practice.
- (9) Continuation of interactions or interventions with human subjects beyond the specified IRB approval period.
- (10) Implementation of substantive protocol changes without IRB approval, except where necessary to prevent immediate hazard to a subject.
- (11) Involvement of prisoners or children in VA research, or conduct of international VA research without the required approval by the VHA Chief Research and Development Officer (CRADO).
- (12) Any noncompliance involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others;
- (13) Any noncompliance that substantively compromises the effectiveness of the facility's human research protection or human research oversight programs.
- (14) Serious programmatic noncompliance. Examples include, but are not limited to:

- (a) The conducting of IRB business by an improperly constituted committee or with less than a quorum of voting members present;
- (b) Improper designation of research as exempt under 38 CFR 16.101(b);
- (c) IRB approval of a waiver of informed consent, a waiver of documentation of informed consent, or a waiver of HIPAA Privacy Rule Authorization when the respective approval criteria at 38 CFR 16.116(c), 16.116(d), 38 CFR 16.117(c), or 45 CFR 164.512(i)(1)(i) are not met or are not documented;
- (d) Programmatic failure to provide for and document Privacy Officer (PO) and Information Security Officer (ISO) review of proposed human subject research;
- (e) Any programmatic noncompliance involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; and
- (f) Any programmatic noncompliance that substantively compromises the effectiveness of the facility's human research protection or human research oversight programs.

g. **Examples of Apparent Continuing Noncompliance.** Examples of apparent continuing noncompliance that must be reported to the IRB within 5 business days include, but are not limited to:

- (1) Failure to implement IRB-required changes to an on-going protocol within the time period specified by the IRB;
- (2) Deficiencies in informed consent or HIPAA authorization procedures or documentation for ten or more subjects (e.g., outdated informed consent or HIPAA content; lack of required informed consent elements; lack of information required by VA; lack of signature of individual obtaining consent);
- (3) Failure to maintain documentation required by the IRB or by the IRB-approved protocol for ten or more subjects (e.g., inadequate medical record documentation where required; inadequate case report forms where required); or
- (4) Failure to implement remedial actions within the periods specified within subparagraph 4d(1) or 4d(2) in the absence of the justification described within subparagraph 4d(3).

h. **RCO Reports of Apparent Serious or Continuing Noncompliance.** Within 5 business days of identifying apparent serious or continuing noncompliance based on an informed consent audit, regulatory audit, or other systematic audit of VA research, an RCO must report the apparent noncompliance directly (without intermediaries) to the facility Director.

- (1) The report must be made in writing, with a simultaneous copy to the ACOS for Research, the R&D Committee, the IRB, and any other relevant research review committee.
- (2) The facility Director must report the apparent serious or continuing noncompliance to the appropriate ORO RO, with a simultaneous copy to the Veterans Integrated Service Network (VISN) Director and the ORD, within 5 business days after receiving such notification.

(3) An initial report of apparent serious or continuing noncompliance based on an RCO informed consent audit, RCO regulatory audit, or other systematic RCO audit is required regardless of whether disposition of the matter has been resolved at the time of the report.

i. **IRB Review of Apparent Serious or Continuing Noncompliance.** The IRB must review any report of apparent serious or continuing noncompliance, according to subparagraph 6e through 6h, at its next convened meeting. *NOTE: The IRB Chair, or designee, must consult the relevant ORO RO if the significance of a reported event is not clear.*

(1) If the IRB determines that the reported incident constitutes serious noncompliance or continuing noncompliance, the IRB Chair, or designee must report the determination directly (without intermediaries) to the facility Director within 5 business days after the determination.

(2) The IRB Chair's report must be made in writing, with a simultaneous copy to the ACOS for Research, the R&D Committee, and any other relevant research review committee.

(3) The facility Director must report the determination to the appropriate ORO RO, with a simultaneous copy to the VISN Director and the ORD, within 5 business days after receiving such notification, unless the noncompliance has already been reported in accordance with the RCO reporting requirements.

(4) An initial report of an IRB determination that serious noncompliance or continuing noncompliance occurred is required, even where the determination is preliminary or disposition of the matter has not been resolved at the time of the report. *NOTE: The IRB must reach a determination that serious or continuing noncompliance did or did not occur within 30-45 days after receiving a report of apparent noncompliance. According to subparagraph 5d, remedial actions involving a specific study or research team must be completed within 90-120 days after the IRB's determination. Remedial actions involving programmatic noncompliance must be completed within 120-180 days after the IRB's determination, unless remediation requires substantial renovation, fiscal expenditure, hiring, or legal negotiations.*

j. **Terminations or Suspensions of Research.** Any termination or suspension of research (e.g., by the IRB or other research review committee, or by the ACOS for Research or other facility official) related to concerns about the safety, rights, or welfare of human research subjects, research staff, or others must be reported directly (without intermediaries) to the facility Director within 5 business days after the termination or suspension occurs.

(1) The report must be made in writing with simultaneous copies, as applicable, to the ACOS for Research, the R&D Committee, the IRB, and any other relevant research review committee.

(2) The facility Director must report the termination or suspension to the appropriate ORO RO within 5 business days after receiving such notification.

k. **Program Changes.** The facility Director must report the following research events to the ORO CO, with a simultaneous copy to the appropriate ORO RO:

(1) **Assurance Changes.** Assurance changes are proposed changes to the facility's Federal-wide Assurance (FWA), or other human research Assurance that must be submitted to ORO prior to submission to OHRP and in accordance with VHA Handbook 1058.03.

(2) **IRB Changes.** IRB changes are proposed addition or removal of the IRB(s) of records designated in a facility's FWA and must be submitted to ORO prior to submission to OHRP and in accordance with VHA Handbook 1058.03. Any change in IRB membership rosters must be reported to ORO in accordance with VHA Handbook 1058.03.

(3) **Substantive MOU Changes.** Substantive MOU changes are any substantive change in an MOU with an affiliate institution or other entity related to the designation of the IRB(s) or other human research protection arrangements that must be reported to the ORO within 5 business days.

(4) **Accreditation Problems.** Failure of the VA facility to achieve the accreditation status required by ORD for human research protections, any change in the facility's accreditation status, or any change in the accreditation status of an affiliate involved in the facility's human research protection program must be reported to ORO within 5 business days.

(5) **RCO Changes.** Any appointment, resignation, or change in status of the facility RCO must be reported to ORO CO, with a copy to the relevant ORO RO, within 5 business days.

7. REQUIREMENTS RELATED TO RESEARCH INFORMATION PROTECTION

a. **Research Information Incidents – Immediate Reporting.** Within one hour of becoming aware of any situation members of the VA research community are required to ensure that the situation has been reported to the ACOS for Research, the facility ISO, and the facility PO.

(1) **Reportable Incidents.** Any unauthorized use, disclosure, transmission, removal, theft, loss, or destruction of VA research-related protected health information (PHI), individually identifiable private information, or confidential information, as defined by the HIPAA Privacy Rule, the Common Rule, the Privacy Act, or 38 U.S.C. §§5701, 5705, and 7332.

(2) **Notification.** In case of loss of VHA sensitive data: **At a minimum**, the following should occur as soon as a loss is discovered

- Report the loss or theft to security/police officers immediately
 - If employee is in a VA facility, notify the VA police
 - If employee are on travel or at another institution, notify the security/police officers at the institution such as hotel security, university security, etc. as well as the police in the jurisdiction where the event occurred
 - Obtain the case number and the name and badge number of the investigating officer(s). If possible, obtain a copy of the case report.
- Immediately call or email the following regarding the incident:
 - Employee's supervisor
 - Local Information Security Officer
 - VA facility's Privacy Officer
 - VA facility's Security Officer (VA Police Chief)
- Notify others such as the Medical Center Director or the Chief of Staff

The ACOS for Research must immediately notify the facility Director, the R&D Committee, and any relevant research review committee upon discovering, receiving, or otherwise becoming aware of a credible report of an incident described above and must ensure that the facility ISO and facility PO have also been notified.

(3) **Written Report.** Any oral report or notification by the ACOS for Research as described in preceding must be followed as quickly as possible by a written report.

b. **Research Information Protection Incidents – Regular Reporting.** Independent of the reporting requirements, within 5 business days of discovering, receiving a credible report of, or otherwise becoming aware of any situation described above, the ACOS for Research must report the situation directly (without intermediaries) to the facility Director, the R&D committee, and any relevant research review committees, and must ensure that the facility ISO and the facility PO have also been notified.

(1) **Findings of Noncompliance.** Any findings of noncompliance related to research information security or privacy by any VA office (other than ORO) or any other Federal or state entity. Reports to ORO based on findings made by entities external to the facility must include a copy of the official findings.

(2) **Other Deficiencies.** Other deficiencies are any other deficiency that substantively compromises the effectiveness of the facility's research information protection program.

(3) **Suspensions or Terminations.** Suspensions or Terminations are any suspension or termination of research (e.g., by the ACOS for Research or other facility official or committee) related to concerns about research information protection.

c. **Reports to ORO.** Within 5 business days of being notified of them, the facility Director must report the research information incidents to ORO (as specified below) and must ensure that the facility ISO and facility PO have also been notified.

(1) Uses and disclosures of PHI under an invalid (or nonexistent) HIPAA authorization or waiver of HIPAA authorization, and deficient (or nonexistent) ISO or PO protocol review practices that substantively compromise the effectiveness of the facility's research information protection program, must be reported to the relevant ORO RO.

(2) All other research information protection incidents (for example, unauthorized transmission, removal, theft, loss, or destruction of VA PHI related to research) must be reported to ORO CO.

8. REQUIREMENTS RELATED TO RESEARCH MISCONDUCT

a. **Procedures.** The full procedures for handling research misconduct allegations are found in R&D SOP 151-07.

8. REFERENCES

VHA Directive 1058.01, Requirements For Reporting Research Events To Facility Oversight Committees And The Office Of Research Oversight.

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MARK E. POLHEMUS, MD, FACP
ACOS/Research & Development

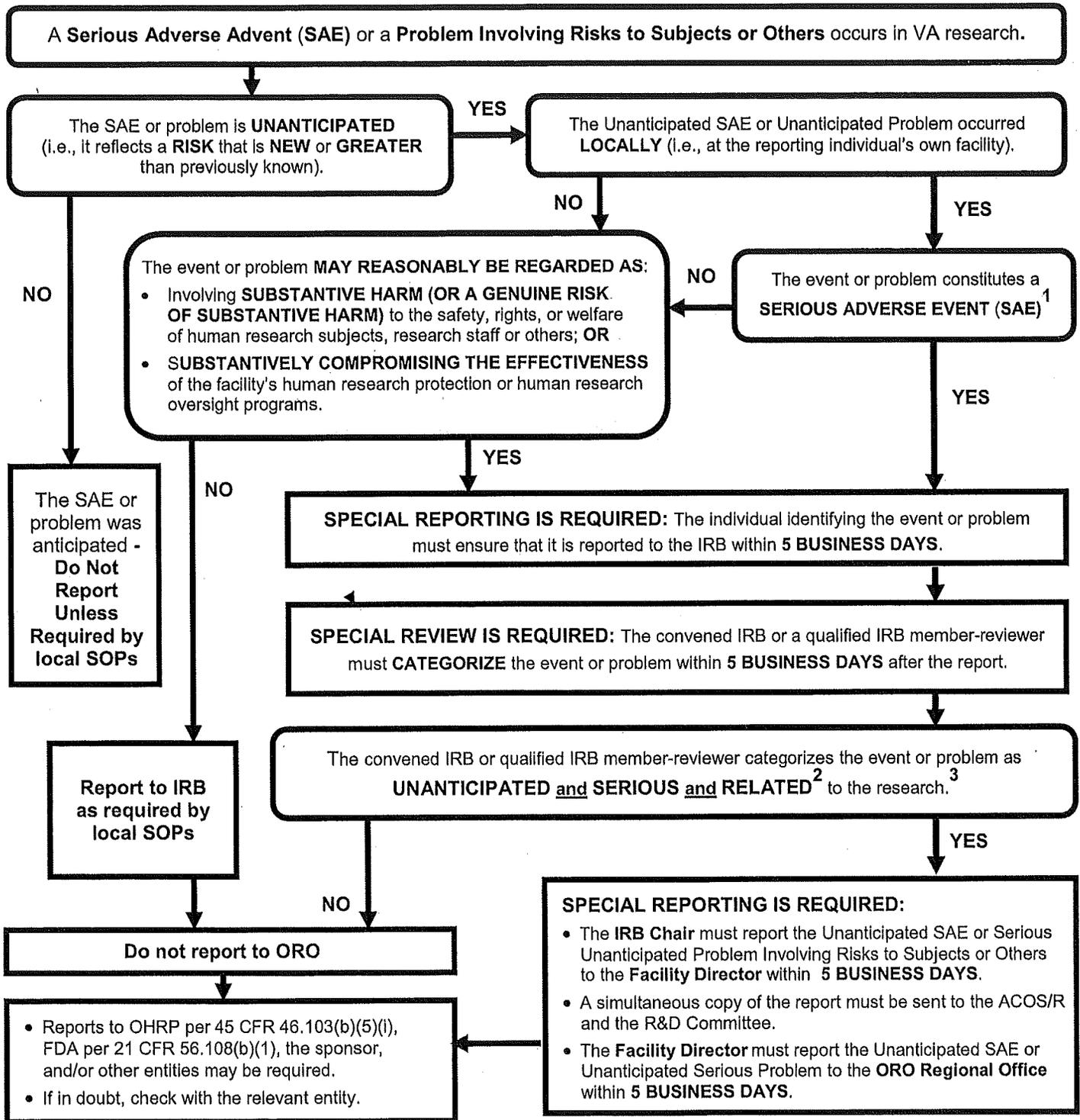
SUMMARY OF REQUIREMENTS FOR REPORTING RESEARCH EVENTS TO ORO

Human Research: Report to RO *	Animal Welfare: Report to CO RSAW *	Research Safety: Report to CO RSAW *	Laboratory Security: Report to CO RSAW *	Research Information Protection *
<p>1. Problems involving risks to subjects or others that are unanticipated <u>and</u> serious <u>and</u> related to the research, e.g., work-related injuries requiring more than minor medical intervention or extended surveillance or leading to serious complications or death; interruptions related to safety, rights, or welfare of subjects/others; Nat'l Pharm Benefits Mgt (PBM), Data Monitoring Cmte (DMC), or sponsor safety reports.</p> <p>2. Local Serious AEs (SAEs) that are unanticipated <u>and</u> serious <u>and</u> related to the research.</p> <p>3. Research Compliance Officer (RCO) audit findings of apparent serious or continuing noncompliance (also report to ORD).</p> <p>4. Institutional Review Board (IRB) findings of serious or continuing noncompliance (also report to ORD).</p> <p>5. Suspensions or terminations of study activities related to safety, rights, or welfare of subjects or others.</p> <p>6. Any proposed change in facility's Federalwide Assurance (FWA) or other ORO-approved Assurance.</p> <p>7. Notify ORO CO RCEP with copy to RO):</p> <ul style="list-style-type: none"> ° Assurances changes ° IRB designation changes ° IRB roster changes ° Substantive MOU changes ° RCO changes ° Changes in accreditation status 	<p>1. Unanticipated loss of animal life.</p> <p>2. Animal theft or potentially dangerous escape.</p> <p>3. Work-related or research-related injury to any person requiring more than minor medical intervention or extended surveillance or leading to serious complications or death.</p> <p>4. Incidents reportable under applicable standards, including noncompliance or deficiency that substantively compromises the effectiveness of facility's animal research protection/oversight programs.</p> <p>5. Suspensions or terminations of research activities related to animal safety, health, or welfare; safety, rights, or welfare of research staff or others; or operations problems causing research interruptions.</p> <p>6. Any change in facility's Public Health Service (PHS) Animal Welfare Assurance.</p> <p>7. Any change PHS Animal Welfare Assurance of an affiliate or other entity on which the facility relies.</p> <p>8. Any new MOU or substantive change in an MOU related to laboratory animal welfare or animal care and use arrangements.</p> <p>9. Facility failure to gain full accreditation or change in facility accreditation or in affiliate accreditation affecting facility research protections.</p>	<p>1. Work-related or research-related injury or exposure to hazardous, toxic, or infectious materials at greater than routine levels or any exposure or injury requiring more than minor medical intervention or extended surveillance or leading to serious complications or death.</p> <p>2. Reportable incidents under applicable standards, including any deficiency that substantively compromises the effectiveness of facility research safety programs.</p> <p>3. Suspensions or terminations of research activities related to the safety, rights, or welfare of research staff or others.</p> <p>4. Unauthorized laboratory decommissions or reassignments requiring identification and disposal of hazardous materials, infectious agents, or equipment.</p> <p>5. Any substantive change in an MOU related to research safety arrangements.</p>	<p>1. Injury or harm to any human being or laboratory animal related to a break-in, security breach, or other security problem involving a VA research facility.</p> <p>2. Any break-in or security breach involving a VA Biosafety Level-3 (BSL-3) research laboratory.</p> <p>3. Any break-in or security breach involving a VA research facility that results in loss of any quantity of a select agent or toxin or of a highly hazardous agent, substantial damage to the facility, or substantial loss of equipment or resources.</p> <p>4. Findings of noncompliance by entities external to the facility.</p> <p>5. Any noncompliance or other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program.</p> <p>6. Suspensions of terminations of research related to laboratory security concerns.</p> <p>7. Any substantive change in an MOU related to research laboratory security arrangements.</p>	<p>1. Report to ACOS for Research, Privacy Officer (PO), and Information Security Officer (ISO) Required Within 1 Hour:**</p> <p>Any unauthorized use, disclosure, transmission, removal, theft, loss, or destruction of VA research-related protected health information (PHI), individually identifiable private information, or confidential information, as defined by the HIPAA Privacy Rule, the Common Rule, the Privacy Act, or 38 U.S.C. §§5701, 5705, and 7332.</p> <p>2. Report to ACOS for Research, PO, and ISO Required Within 5 Business days: **</p> <p>a. Findings of non-compliance related to research information security or privacy by entities external to the facility.</p> <p>b. Any other deficiency that substantively compromises the effectiveness of the facility's research information protection program.</p> <p>c. Suspensions or terminations of research related to information protection concerns.</p> <p>** Uses and disclosures of PHI under invalid or nonexistent HIPAA authorization or waiver or deficient ISO or PO review must be reported to the ORO RO. All other research information protection incidents must be reported to CO RIPP.</p>

* **NOTE:** RO = ORO Regional Office CO = ORO Central Office RCEP = Research Compliance Education and Policy Group
 RSAW = Research Safety and Animal Welfare Group RIPP = Research Information Protection Group

Except for Information Protection Item 1, the relevant research review committee(s) must be notified of these events within 5 business days. The facility Director must notify ORO within 5 business days of being informed of these events and must send a copy of the notification to the Network Director. Decision charts for reporting research events are available on the ORO Web site at <http://www.va.gov/oro/>

REPORTING SERIOUS ADVERSE EVENTS (SAEs) AND PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS IN VA RESEARCH

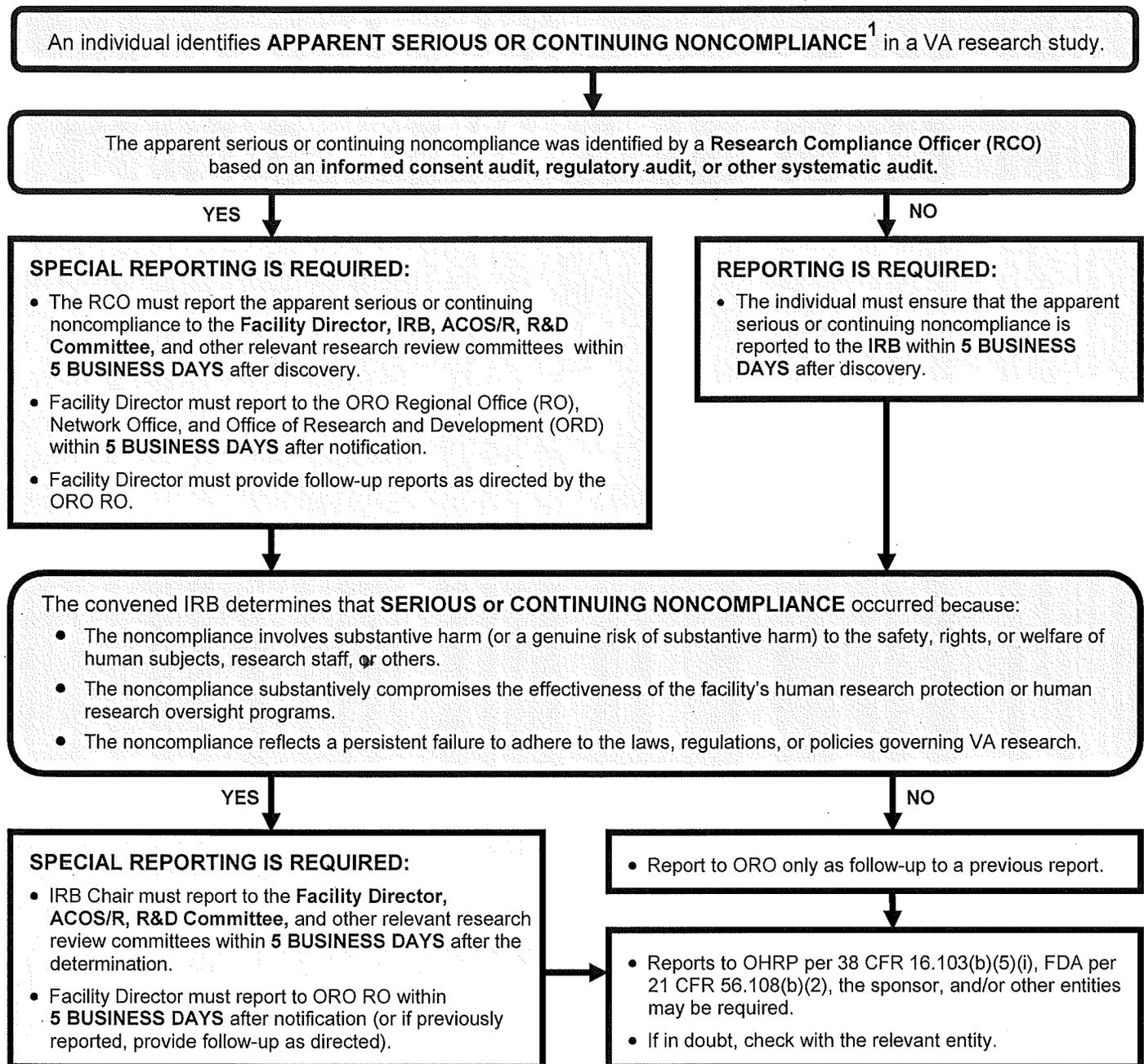


¹ An SAE is an untoward physical or psychological occurrence in human subject participating in research that results in death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly, or birth defect, or that requires medical, surgical, behavioral, social, or other intervention to prevent such an outcome [VHA Handbook 1058.01 §§4b & 4w].

² "Related" means the event or problem may reasonably be regarded as caused by, or as probably caused by, the research [VHA Handbook 1058.01 §4p].

³ The convened IRB or qualified IRB member-reviewer must also document whether or not action is needed to prevent an immediate hazard to subjects. If consent or protocol modifications are required, the convened IRB must determine whether previously enrolled subjects must be notified, and if so, when and how notification must occur and be documented [VHA Handbook 1058.01 §6d].

REPORTING NONCOMPLIANCE IN VA HUMAN RESEARCH



¹ See 38 CFR 16.103(b)(5)(i), 21 CFR 56.108(b)(2), and VHA Handbook 1058.01 §6. Examples considered by VA to reflect **apparent serious or continuing noncompliance** that must be reported to the IRB within 5 business days include, but are not limited to:

- External findings of noncompliance by any VA office or other Federal or State oversight agency
- Initiation of VA research without written notification from the ACOS/R, without IRB approval, or prior to obtaining required informed consent
- Lack of a required, signed informed consent document or required, signed HIPAA Privacy Rule authorization for one or more subjects
- Use for one or more subjects of an informed consent document whose content was not approved by the IRB
- Failure to report one or more unanticipated SAEs or serious unanticipated problems involving risks to subjects or others as required
- Conduct of research by one or more persons without the required credentialing, privileging, or scope of practice or outside the approved scope of practice.
- Continuation of interactions or interventions with human subjects beyond the specified approval period
- Implementation of substantive protocol changes without IRB approval, except to prevent immediate hazard to a subject
- Failure to obtain CRADO approval for VA research involving prisoners or children or for international VA research
- Serious programmatic noncompliance, eg, conduct of IRB business by an improperly constituted IRB or with less than a quorum of voting members, improper designation of research as exempt, noncompliant approval or noncompliant documentation by the IRB of an informed consent waiver, documentation waiver, or HIPAA authorization waiver, failure to provide for PO and ISO review of proposed research
- Failure to implement IRB-required changes within the IRB-specified time period
- Deficiencies in informed consent or HIPAA authorization procedures or documentation for 10 or more subjects
- Failure to maintain documentation required by the IRB or the IRB-approved protocol
- Failure to implement remedial actions within the time periods specified by VA policy without acceptable justification