

OFFICE OF RESEARCH OVERSIGHT (ORO)
GUIDANCE ON INFORMATION TO BE INCLUDED IN REPORTS TO ORO
February 1, 2022

The Office of Research Oversight (ORO) receives hundreds of incident reports annually from VA medical facilities that conduct research. To assist facilities with fulfilling their reporting responsibilities as described in VHA Directive 1058.01, “Research Compliance Reporting Requirements” (dated October 22, 2020), this document provides guidance on information that should be included in reportable event notifications sent to ORO. The guidance describes the information most commonly needed by ORO to effectively exercise its oversight responsibilities when reviewing such events. In many instances, it is anticipated that adherence to the guidance will reduce the need for ORO follow-up requests for information, thereby reducing burden on VA medical facility personnel.

VHA Directive 1058.01 describes requirements for reporting select events involving VA research to research review committees, VHA medical facility leadership, and ORO. Events are categorized in the Directive according to the type of research involved and the nature of the event. Specific processes for the review and reporting of events are delineated in the following six sections of the Directive:

- Systemic Deficiencies (§6)
- Non-Exempt Human Subjects Research (§7)
- Exempt Human Subjects Research (§8)
- Animal Research (§9)
- Research Laboratory Safety and Security (§10)
- Research Information Security and Privacy (§11)

Using a parallel structure to the Directive, this guidance provides a description of information that should be included in notifications to ORO of reportable events in each section of the Directive (see **Appendices A through F** of this guidance document). During the course of its oversight, ORO may request additional information not addressed in this guidance (such as meeting minutes from when the event was reviewed by a research review committee, documentation of completion of remedial actions, etc.).

Notifications of events reportable to ORO should be directed to the ORO workgroup with the appropriate subject matter expertise and assigned oversight responsibilities that encompass the research oversight area that the event falls within. In some instances, an event may fall under the oversight auspices of more than one ORO workgroup. In such instances, facility personnel need only send the initial notification to one of the ORO workgroups with applicable oversight responsibilities.

- Reportable events pertaining to noncompliance with VHA Directive 1200.01, including Research & Development Committee (R&DC) operations, research solely under the oversight of the R&DC, and Research Compliance Officer (RCO) responsibilities, should be reported to [ORO’s Comprehensive Research Oversight Workgroup \(CROW\)](#).
- Reportable events pertaining to human subjects research and Institutional Review Board (IRB) operations should be reported to [ORO’s Human Research Protection \(HRP\) Workgroup](#).

NOTE: *The Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) requires submission of the OHRP Incident Report Form for any incident report made to OHRP in accordance with 45 CFR part 46. The form and the associated instructions may be found on the HHS-OHRP website [here](#). VA facilities who utilize the OHRP Incident Report Form for reporting to HHS-OHRP may also submit that form to ORO for incidents*

involving VA non-exempt human subjects research provided that the additional information indicated in Appendix B (which is marked with an asterisk) accompanies the submission to ORO.

- Reportable events pertaining to animal research and Institutional Animal Care and Use Committee (IACUC) operations should be reported to [ORO's Research Safety and Animal Welfare \(RSAW\) Workgroup](#).
- Reportable events pertaining to research laboratory safety and security and Subcommittee on Research Safety (SRS) or Institutional Biosafety Committee (IBC) operations should be reported to [ORO's RSAW Workgroup](#).
- Reportable events pertaining to research information security and privacy should be reported to [ORO's Research Information Security \(RIS\) Workgroup](#).

APPENDIX A. Information to be included in reports to ORO involving systemic deficiencies.

1. Name of the reporting VA facility.
2. A detailed description of the systemic deficiency, including whether and how the deficiency:
 - a. Poses a genuine risk of harm to the safety, rights, or welfare of human research subjects or others as a result of participation in VA research, including their rights to privacy and confidentiality;
 - b. Poses a genuine risk of harm to the safety, rights, or welfare of VA personnel conducting VA research;
 - c. Compromises the care and welfare of animals used in VA research; and/or
 - d. Compromises the effectiveness of a VA medical facility's research oversight program.
3. A description of how the deficiency was identified, including whether identified internally (by VA medical facility personnel or entities acting as agents of the facility such as a research review committee operated by another entity but relied upon by the facility through a formal agreement) or externally (by individuals *not* associated with or acting as agents of the facility such as by a VHA Program Office, external monitoring/auditing/accreditation organization, etc.).
4. Name of the research review committee that reviewed the reported deficiency, date reported to the committee, resulting determination(s) made by the committee, and the date of the committee's determination(s).
5. Actions the facility has taken or plans to take to address the systemic deficiency and anticipated deadlines for completing any pending or proposed actions.
6. Indication of whether the systemic deficiency represents a repeat of the same type of systemic deficiency and/or noncompliance involving the facility's research program within the past three (3) years.
7. Names of other Federal agencies or entities notified, or to be notified, of the systemic deficiency and when notification occurred.
8. Documents *relevant* to the determination (e.g., review committee minutes where issue was discussed, related protocol documents, and applicable Standard Operating Procedures (SOPs), policies, Memoranda of Understanding (MOUs), or agreements).
9. Name and contact information (telephone number and email address) of the VA medical facility point of contact with whom ORO can follow-up for additional information.
10. If the systemic deficiency pertains to a particular protocol/project or a limited set of related protocols/projects:
 - a. Title and identification number of the research protocol(s)/project(s) involved, as well as the name of the principal investigator(s)/local site investigator(s) for the research protocol(s)/project(s);
 - b. Sponsor(s) and grant number(s) associated with support for the research protocol(s)/project(s) involved;
 - c. Indication of whether the research protocol(s)/project(s) involved are being conducted as part of a multi-site study and, if so, the name of the institution serving as the coordinating center;
 - d. Risk level associated with the research protocol(s)/project(s) involved (e.g., whether minimal risk or more than minimal risk for human subjects research; assigned biosafety level for laboratory research; animal species involved); and
 - e. Indication of whether the deficiency involves noncompliance by a same individual or study team responsible for other research noncompliance within the past three (3) years.

APPENDIX B. Information to be included in reports to ORO involving non-exempt human subjects research.

1. Name of the reporting VA facility.
2. Title and identification number of the research protocol(s)/project(s) involved, as well as the name of the principal investigator(s)/local site investigator(s) for the research protocol(s)/project(s).
3. Sponsor(s) and grant number(s) associated with support for the research protocol(s)/project(s) involved.
4. Indication of whether the research protocol(s)/project(s) involved are being conducted as part of a multi-site study and, if so, the name of the institution serving as the coordinating center.*
5. Risk level associated with the research protocol(s)/project(s) involved (e.g., whether minimal risk or more than minimal risk for human subjects research).*
6. Indication of whether investigational drugs and/or devices are used in the research and, if so, the associated Investigation New Drug (IND)/Investigational Device Exemption (IDE) number.*
7. Clinicaltrials.gov number.*
8. A detailed description of the event, including:
 - a. The date of the event;
 - b. The type of reportable event (serious adverse event (SAE), unanticipated problem involving risk to subjects or others (UPIRTSO), serious or continuing noncompliance, suspension or termination, etc.);
 - c. Number of research subjects affected; and*
 - d. Underlying cause and outcome of the event.
9. A description of how the event was identified, including whether identified internally (by VA medical facility personnel or entities acting as agents of the facility such as a research review committee operated by another entity but relied upon by the facility through a formal agreement) or externally (by individuals *not* associated with or acting as agents of the facility such as by a VHA Program Office, external monitoring/auditing/accreditation organization, etc.).*
10. Name of the Institutional Review Board (IRB) that reviewed the event, date reported to the IRB, resulting determination(s) made by the IRB, and the date of the IRB determination(s).*
11. Actions the facility is taking or plans to take to address the event (protocol or informed consent document revisions, subject enrollment suspensions, protocol terminations, enrolled subjects notifications, increased monitoring, education/training, return/transition to clinical care and/or standard of care management of disease or condition, etc.) and anticipated deadlines for completing any pending or proposed actions.
12. Indication of whether the event represents a repeat of the same type of noncompliance involving the facility's research program within the past three (3) years.*
13. Indication of whether the event involves noncompliance by a same individual or study team responsible for other research noncompliance within the past three (3) years.*
14. Names of other Federal agencies or entities notified, or to be notified, of the event and when notification occurred (U.S. Department of Health and Human Services Office for Human Research Protections (OHRP);¹ Food and Drug Administration (FDA);² etc.).*
15. Documents *relevant* to the determination (e.g., Privacy Officer (PO) reports, review committee minutes where issue was discussed, related protocol documents, and applicable SOPs, policies, MOUs, or agreements).*
16. Name and contact information (telephone number and email address) of the VA medical facility point of contact with whom ORO can follow-up for additional information.

**Denotes information that ORO requests which is not included in the OHRP Incident Report Form for reporting to HHS-OHRP. VA facilities may also submit the OHRP Incident Report form to ORO for incidents in VA non-exempt human subjects research, with the additional information requested.*

¹ See HHS-OHRP reporting guidance at <https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html>.

² See FDA contact information for mandatory IRB reporting at <https://www.fda.gov/science-research/report-problems-fda/mandatory-irb-reporting-fda-contacts>.

APPENDIX C. Information to be included in reports to ORO involving exempt human subjects research.

1. Name of the reporting VA facility.
2. Title and identification number of the research protocol(s)/project(s) involved, as well as the name of the principal investigator(s)/local site investigator(s) for the research protocol(s)/project(s).
3. Sponsor(s) and grant number(s) associated with support for the research protocol(s)/project(s) involved.
4. Indication of whether the research protocol(s)/project(s) involved are being conducted as part of a multi-site study and, if so, the name of the institution serving as the coordinating center.
5. A detailed description of the event, including:
 - a. The date of the event;
 - b. The type of reportable event (serious adverse event (SAE), unanticipated problem involving risk to subjects or others (UPIRTSO), serious or continuing noncompliance, suspension or termination, etc.);
 - c. Number of research subjects affected; and
 - d. Underlying cause and outcome of the event.
6. A description of how the event was identified, including whether identified internally (by VA medical facility personnel or entities acting as agents of the facility such as a research review committee operated by another entity but relied upon by the facility through a formal agreement) or externally (by individuals *not* associated with or acting as agents of the facility such as by a VHA Program Office, external monitoring/auditing/accreditation organization, etc.).
7. Name of the research review committee that reviewed the event, date reported to the committee, resulting determination(s) made by the committee, and the date of the committee's determination(s).
8. Actions the facility is taking or plans to take to address the event (protocol or informed consent document revisions, subject enrollment suspensions, protocol terminations, enrolled subjects notifications, increased monitoring, education/training, return/transition to clinical care and/or standard of care management of disease or condition, etc.) and anticipated deadlines for completing any pending or proposed actions.
9. Indication of whether the event represents a repeat of the same type of noncompliance involving the facility's research program within the past three (3) years.
10. Indication of whether the event involves noncompliance by a same individual or study team responsible for other research noncompliance within the past three (3) years.
11. Names of other Federal agencies or entities notified, or to be notified, of the event and when notification occurred.
12. Documents *relevant* to the determination (e.g., Privacy Officer (PO) reports, review committee minutes where issue was discussed, related protocol documents, and applicable SOPs, policies, MOUs, or agreements).
13. Name and contact information (telephone number and email address) of the VA medical facility point of contact with whom ORO can follow-up for additional information.

APPENDIX D. Information to be included in reports to ORO involving animal research.

1. Name of the reporting VA facility.
2. Title and identification number of the research protocol(s)/project(s) involved.
3. Sponsor(s) and grant number(s) associated with support for the research protocol(s)/project(s) involved.
4. Indication of risks/risk level associated with the research protocol(s)/project(s), including assigned biosafety level for animal/laboratory research and whether the research involves use of recombinant DNA or select agents or toxins.
5. A detailed description of the event, including:
 - a. The date and location of the event;
 - b. Species and number of animals involved in the event;
 - c. The type of reportable event (human accident, injury, or exposure, serious or continuing noncompliance, suspension or termination, etc.); and
 - d. Underlying cause of the event and outcome of the event.
6. A description of how the event was identified, including whether identified internally (by VA medical facility personnel or entities acting as agents of the facility such as a research review committee operated by another entity but relied upon by the facility through a formal agreement) or externally (by individuals *not* associated with or acting as agents of the facility such as by a VHA Program Office, external monitoring/auditing/accreditation organization, etc.).
7. Name of the Institutional Animal Care and Use Committee (IACUC) that reviewed the event, date reported to the IACUC, resulting determination(s) made by the IACUC, and the date of the IACUC's determination(s).
8. Actions the facility is taking or plans to take to address the event (protocol revisions, increased monitoring of animal research activities, education/training, etc.) and anticipated deadlines for completing any pending or proposed actions.
9. Indication of whether the event represents a repeat of the same type of noncompliance involving the facility's research program within the past three (3) years.
10. Indication of whether the event involves noncompliance by a same individual or study team responsible for other research noncompliance within the past three (3) years.
11. Names of other Federal agencies or entities notified, or to be notified, of the event and when notification occurred (U.S. Department of Health and Human Services (HHS), National Institutes of Health (NIH), Office of Laboratory Animal Welfare (OLAW); the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International; VHA Office of Research & Development (ORD), Office of the Chief Veterinary Medical Officer (CVMO); etc.).
12. Name and contact information (telephone number and email address) of the VA medical facility point of contact with whom ORO can follow-up for additional information.

APPENDIX E. Information to be included in reports to ORO involving research laboratory safety and security.

1. Name of the reporting VA facility.
2. Title and identification number of the research protocol(s)/project(s) involved, as well as the name of the principal investigator(s)/local site investigator(s) for the research protocol(s)/project(s).
3. Sponsor(s) and grant number(s) associated with support for the research protocol(s)/project(s) involved.
4. Indication of risks/risk level associated with the research protocol(s)/project(s), including assigned biosafety level for animal/laboratory research and whether the research involves use of recombinant DNA or select agents or toxins.
5. A detailed description of the event, including:
 - a. The date and location of the event;
 - b. Indication of whether recombinant DNA, select agents, or toxins were involved in the event;
 - c. The type of reportable event (human accident, injury, or exposure, serious or continuing noncompliance, security-related, suspension or termination, etc.);
 - d. Indication of whether required safety equipment, containment, personal protective equipment, and safe handling practices were being followed at the time of the event; and
 - e. Underlying cause of the event and outcome of the event.
6. A description of how the event was identified, including whether identified internally (by VA medical facility personnel or entities acting as agents of the facility such as a research review committee operated by another entity but relied upon by the facility through a formal agreement) or externally (by individuals *not* associated with or acting as agents of the facility such as by a VHA Program Office, external monitoring/auditing/accreditation organization, etc.).
7. Name of the Subcommittee on Research Safety (SRS) (or equivalent) that reviewed the event, date reported to the SRS, resulting determination(s) made by the SRS, and the date of the SRS' determination(s).
8. Actions the facility is taking or plans to take to address the event (protocol revisions, increased monitoring of laboratory research activities, education/training, medical surveillance, occupational health follow-up, etc.) and anticipated deadlines for completing any pending or proposed actions.
9. Indication of whether the event represents a repeat of the same type of noncompliance involving the facility's research program within the past three (3) years.
10. Indication of whether the event involves noncompliance by a same individual or study team responsible for other research noncompliance within the past three (3) years.
11. Names of other Federal agencies or entities notified, or to be notified, of the event and when notification occurred (National Institutes of Health, Office of Science Policy (NIH-OSP); Occupational Safety and Health Administration (OSHA); VA Police Services; etc.).
12. Name and contact information (telephone number and email address) of the VA medical facility point of contact with whom ORO can follow-up for additional information.

APPENDIX F. Information to be included in reports to ORO involving research information security and privacy.

1. Name of the reporting VA facility.
2. Title and identification number of the research protocol(s)/project(s) involved, as well as the name of the principal investigator(s)/local site investigator(s) for the research protocol(s)/project(s).
3. Sponsor(s) and grant number(s) associated with support for the research protocol(s)/project(s) involved.
4. Indication of whether the research protocol(s)/project(s) involved are being conducted as part of a multi-site study and, if so, the name of the institution serving as the coordinating center.
5. Indication of risks/risk level associated with the research protocol(s)/project(s) involved (e.g., whether minimal risk or more than minimal risk for human subjects research; assigned biosafety level for laboratory research; animal species involved).
6. A detailed description of the event, including:
 - a. The date of the event;
 - b. The type of reportable event (unanticipated problem involving risk to subjects or others (UPIRISO), serious or continuing noncompliance, suspension or termination, etc.);
 - c. Number of research subjects and/or research records affected;
 - d. Description of any VA Sensitive Information (VASI) involved, including specific elements of Protected Health Information (PHI) involved;
 - e. Indication of whether unauthorized use, disclosure and/or transmission of VASI/PHI occurred;
 - f. Indication of whether the event being reported is related to any existing or previously submitted reports; and
 - g. Underlying cause and outcome of the event.
7. A description of how the event was identified, including whether identified internally (by VA medical facility personnel or entities acting as agents of the facility such as a research review committee operated by another entity but relied upon by the facility through a formal agreement) or externally (by individuals *not* associated with or acting as agents of the facility such as by a VHA Program Office, external monitoring/auditing/accreditation organization, etc.).
8. Name of the research review committee that reviewed the event, date reported to the research review committee, resulting determination(s) made by the research review committee, and the date of the research review committee's determination(s).
9. Indication of whether a review of the event has been conducted, and a resulting determination made, by the Information System Security Officer (ISSO), Privacy Officer (PO), and Data Breach Response Service (DBRS).
10. Actions the facility is taking or plans to take to address the event (protocol or informed consent document revisions, subject enrollment suspensions, protocol terminations, issuance of notifications to subjects impacted including issuance of credit monitoring letters, education/training, etc.) and anticipated deadlines for completing any pending or proposed actions.
11. Indication of whether the event represents a repeat of the same type of noncompliance involving the facility's research program within the past three (3) years.
12. Indication of whether the event involves noncompliance by a same individual or study team responsible for other research noncompliance within the past three (3) years.
13. Names of other Federal agencies or entities notified, or to be notified, of the event and when notification occurred (U.S. Department of Health and Human Services Office for Human Research Protections (OHRP); Food and Drug Administration (FDA); etc.).
14. Name and contact information (telephone number and email address) of the VA medical facility point of contact with whom ORO can follow-up for additional information.