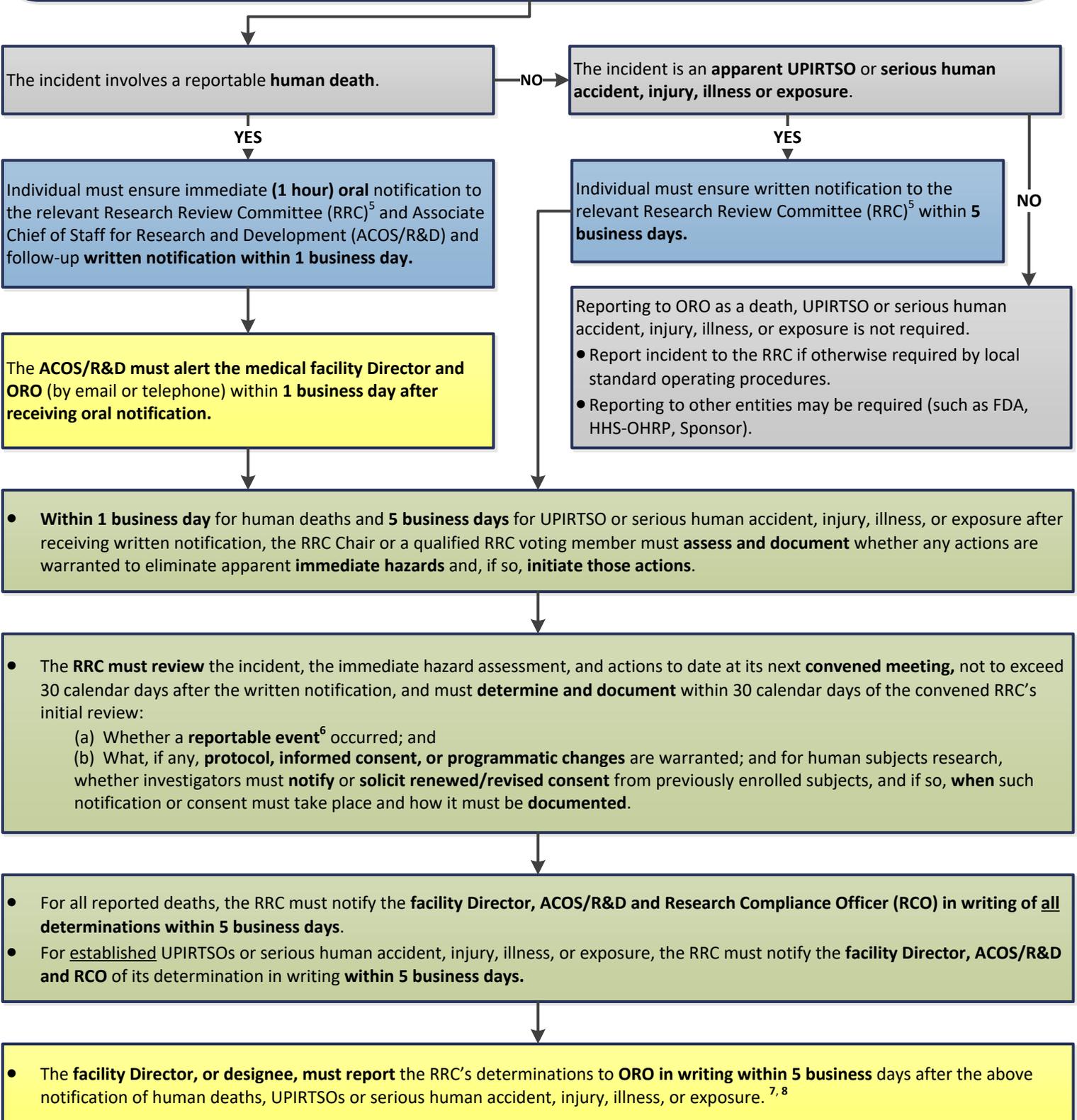


Office of Research Oversight (ORO)

Reporting Human Deaths, Unanticipated Problems and Accident, Injury, Illness or Exposure in VA Research¹ March 12, 2021

VA personnel become aware of a reportable human death², an apparent unanticipated problem involving risks to subjects or others (UPIRTSO)³ or serious human accident, injury, illness, or exposure⁴ in VA research.



Office of Research Oversight (ORO)

Reporting Human Deaths, Unanticipated Problems and Accident, Injury, Illness or Exposure in VA Research March 12, 2021

Notes:

[Return to flowchart](#)

¹For complete details, see VHA Directive 1058.01, Research Compliance Reporting Requirements, dated October 22, 2020. **NOTE:** *This chart does not cover other reportable situations (e.g., program changes, suspensions/terminations).*

²Reportable **Human Death** includes the local research death of a human subject that is believed to be both unexpected and related or possibly related to participation in a VA human subjects research study; any human death that may be the result of working with, caring for, or having other contact with animals used in VA research; any human death that may be the result of work (or other activity) in a VA research laboratory or dedicated VA research area (e.g., research specimen storage area), or involving VA-approved research conducted in a research laboratory or dedicated research area owned or operated by a non-VA entity. (VHA Directive 1058.01 §7.a, §8, §9.a, & §10.a)

³An **unanticipated problem involving risks to subjects or others (UPIRTSO)** in human subjects research is an incident, experience, or outcome that is: unexpected; and 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. For purposes of VHA Directive 1058.01 and this guidance, an unexpected serious adverse event (SAE) that is related or possibly related to participation in human subjects research constitutes a UPIRTSO. (VHA Directive 1058.01 §3.q)

- **Unexpected** refers to an incident, experience, or outcome that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population. (VHA Directive 1058.01 §3.q.(1))
- 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. (VHA Directive 1058.01 §3.q.(2))

⁴**Serious Human Accident, Injury, Illness, or Exposure** includes any serious accident, injury, illness or exposure of a human (not involving a death) that may be the result of working with, caring for, or having other contact with research animals or otherwise may be the result of a research activity (1) in a VA research laboratory or dedicated VA research area (e.g., research specimen storage area), (2) in a research laboratory or dedicated research area owned or operated by a non-VA entity, or (3) that requires research laboratory safety events to be reportable under applicable federal requirements, including Occupational Safety and Health Administration (OSHA) and relevant VHA policy requirements. (VHA Directive 1058.01 §9.b & §10.b)

⁵**Research Review Committee (RRC)** is any committee or subcommittee designated by a VA medical facility to review, approve and provide oversight of VA research. For purposes of this directive, research review committees include Institutional Animal Care and Use Committees (IACUCs), Institutional Biosafety Committees (IBCs), Institutional Review Boards (IRBs), Research & Development Committees (R&DCs), and Subcommittees on Research Safety (SRS), or the equivalents of any such committees, that are relied upon by a VA medical facility, regardless of whether the committees are operated by a VA or a non-VA entity. (VHA Directive 1058.01 §3.k)

[Return to flowchart](#)

Office of Research Oversight (ORO)

Reporting Human Deaths, Unanticipated Problems and Accident, Injury, Illness or Exposure in VA Research
March 12, 2021

Notes:

[Return to flowchart](#)

⁶Whether a Reportable Event Occurred:

- For UPIRTSOs: whether the incident, experience, or outcome constituted an actual UPIRTSO;
- For human subject deaths in human subjects research: whether the death was both unexpected and related or possibly related to participation in the research;
- For human deaths in animal research: whether the human death was the result of working with, caring for, or having other contact with animals;
- For animal research events involving serious accident, injury, illness or exposure: whether a serious accident, injury, illness or exposure of a human (not involving a death) resulting from working with, caring for, or having other contact with research animals occurred;
- For human deaths in laboratory research: whether the human death was the result of hazards used in, or hazardous conditions related to, the conduct of VA research;
- For research laboratory events: whether a serious accident, injury, illness, or exposure of a human (not involving a death) resulted from work (or other activity) in a research laboratory or dedicated research area (e.g., research specimen storage area); and whether a research safety event reportable under applicable federal requirements has occurred. (VHA Directive 1058.01 §3.q, §7.a.(3).(b)1, §7.b.(2).(b)1, §8, §9.a.(3).(b)1, §9.b.(2).(b)1, §10.a.(3).(b)1, §10.(b).(2).(b)1, & §10.(b).(2).(b)2)

⁷For animal research events including those reportable to NIH-OLAW, a copy of the IACUC's determinations must be provided to the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International and the Office of Research and Development Chief Veterinary Medical Officer. (VHA Directive 1058.01 §9.a.(5), §9.b.(4), §9.c.(3), & §9.d.(3))

⁸If the RRC is unable to make a determination on the matter within 30 calendar days of the convened RRC's initial review due to insufficient information or due to a lack of sufficient time to complete its review, the RRC must notify the medical facility Director, the RCO, and the ACOS/R&D in writing no later than 5 business days after the determination was due. The VA medical facility Director, or designee, must notify the appropriate ORO workgroup within five (5) business days after receiving the IRB's written notification that it is unable to make a determination. (VHA Directive 1058.01 §7.a.(6), §7.b.(5), §9.a.(6), §9.b.(5), §10.a.(6), & §10.b.(5))

[Return to flowchart](#)