CONTENT AND SUBMISSIONS OF NOTIFICATIONS TO ORO

1. PURPOSE

This appendix sets forth the minimum information that should be included, if and as applicable, in Department of Veterans Affairs (VA) medical facility notifications sent to the Veterans Health Administration (VHA) Office of Research Oversight (ORO). ***NOTE:*** *In some instances, it may be necessary for a VA medical facility Director to submit an initial report, which does not contain all the information stipulated in paragraph 2 of this appendix, to fulfill the requirements for prompt reporting to ORO within the deadlines stipulated in paragraph 3 of the body of the directive. In such instances, subsequent reports must be submitted when the information becomes available or as otherwise directed by ORO. During its oversight, ORO may request additional information not addressed in this appendix (such as research review committee meeting minutes from when an event was reviewed by the committee, or documentation of completion of remedial actions).*

2. MINIMUM CONTENT TO BE INCLUDED IN NOTIFICATIONS TO ORO

a. **Systemic Deficiencies.** Notifications to ORO required by this directive pertaining to systemic deficiencies must include, as applicable and to the extent known at the time of notification:

(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 of VA personnel conducting VA research.

(c) Compromises the care or welfare of animals used in VA research.

(d) Compromises the effectiveness of a VA medical facility's research oversight program.

(3) Date that VA medical facility personnel first identified or otherwise became aware of the event.

(4) 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 (e.g., by individuals *not* associated with or acting as agents of the facility such as by a VHA program office, external monitoring/auditing/accreditation organization).

(5) Name of the research review committee(s) that reviewed the reported deficiency and any resulting determination(s) made by the committee.

(6) Actions the facility has taken or plans to take to address the systemic deficiency and anticipated dates for completing any pending or proposed actions.

(7) Indication of whether the systemic deficiency represents a repeat of the same type of systemic deficiency or noncompliance involving the facility's research program within the past 3 years.

(8) Names of other Federal agencies or entities notified, or to be notified, of the systemic deficiency and the date(s) of notification.

(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, providing the following additional information:

(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; and animal species involved).

(e) Indication of whether the deficiency involves noncompliance by a same individual or study team responsible for other research noncompliance within the past 3 years.

b. **Human Subjects Research.** Notifications to ORO required by this directive pertaining to human subjects research must include as applicable and to the extent known at the time of notification:

(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 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) Date that VA medical facility personnel first identified or otherwise became aware of the event.

(9) A detailed description of the event, including:

(a) The date(s) of the event.

(b) The type of reportable event (e.g., serious adverse event, unanticipated problem involving risk to subjects or others (UPIRTSO), serious or continuing noncompliance, suspension or termination).

(c) Number of research subjects affected.

(d) Underlying cause(s) and outcome(s) of the event.

(10) 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 (e.g., by individuals *not* associated with or acting as agents of the facility such as by a VHA program office, external monitoring/auditing/accreditation organization).

(11) Name of the Institutional Review Board (IRB) or other research review committee(s) that reviewed the event and any resulting determination(s) made by the committee(s).

(12) Actions the facility is taking or plans to take to address the event (e.g., protocol or informed consent document revisions, subject enrollment suspensions, protocol

terminations, enrolled subjects notifications, increased monitoring, education/training, return/transition to clinical care or standard of care management of disease or condition) and anticipated dates for completing any pending or proposed actions.

(13) Indication of whether the event represents a repeat of the same type of noncompliance involving the facility's research program within the past 3 years.

(14) Indication of whether the event involves noncompliance by the same individual or study team responsible for other research noncompliance within the past 3 years.

(15) Names of other Federal agencies or entities (e.g., U.S. Department of Health and Human Services Office for Human Research Protections (HHS-OHRP), U.S. Food and Drug Administration (FDA)) notified, or to be notified, of the event and the date(s) of notification.

(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.

c. **Animal Research.** Notifications to ORO required by this directive pertaining to animal research must include as applicable and to the extent known at the time of notification:

(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 non-exempt recombinant DNA or select agents or toxins.

(5) Date that VA medical facility personnel first identified or otherwise became aware of the event.

(6) A detailed description of the event, including:

(a) The date(s) and location(s) of the event.

(b) Species and number of animals involved in the event.

(c) The type of reportable event (e.g., human accident, injury, or exposure, serious or continuing noncompliance, suspension or termination).

(d) Underlying cause(s) of the event and outcome(s) 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 (e.g., by individuals *not* associated with or acting as agents of the facility such as by a VHA program office, external monitoring/auditing/accreditation organization).

(8) Name of the Institutional Animal Care and Use Committee (IACUC) or other research review committee(s) that reviewed the event and any resulting determination(s) made by the committee(s).

(9) Actions the facility is taking or plans to take to address the event (e.g., protocol revisions, increased monitoring of animal research activities, education/training) and anticipated dates for completing any pending or proposed actions.

(10) Indication of whether the event represents a repeat of the same type of noncompliance involving the facility's research program within the past 3 years.

(11) Indication of whether the event involves noncompliance by a same individual or study team responsible for other research noncompliance within the past 3 years.

(12) Names of other Federal agencies or entities (e.g., National Institutes of Health Office of Laboratory Animal Welfare (NIH-OLAW); AAALAC, International; VHA Office of Research & Development (ORD), Office of the Chief Veterinary Medical Officer (CVMO)) notified, or to be notified, of the event and the date(s) of notification.

(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.

d. **Research Laboratory Safety and Security.** Notifications to ORO required by this directive pertaining to research laboratory safety and security must include as applicable and to the extent known at the time of notification:

(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 non-exempt recombinant DNA or select agents or toxins.

(5) Date that VA medical facility personnel first identified or otherwise became aware of the event.

(6) A detailed description of the event, including:

(a) The date(s) and location of the event.

(b) The type of reportable event (e.g., human accident, injury, or exposure, serious or continuing noncompliance, security-related, suspension or termination).

(c) Indication of whether required safety equipment, containment, personal protective equipment, and safe handling practices were being followed at the time of the event.

(d) Underlying cause(s) of the event and outcome(s) 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 (e.g., by individuals *not* associated with or acting as agents of the facility such as by a VHA program office, external monitoring/auditing/accreditation organization).

(8) Name of the Subcommittee on Research Safety (SRS), Institutional Biosafety Committee (IBC), or other research review committee(s) that reviewed the event and any resulting determination(s) made by the committee(s).

(9) Actions the facility is taking or plans to take to address the event (e.g., protocol revisions, increased monitoring of laboratory research activities, education/training, medical surveillance, occupational health follow-up) and anticipated dates for completing any pending or proposed actions.

(10) Indication of whether the event represents a repeat of the same type of noncompliance involving the facility's research program within the past 3 years.

(11) Indication of whether the event involves noncompliance by a same individual or study team responsible for other research noncompliance within the past 3 years.

(12) Names of other Federal agencies or entities (e.g., National Institutes of Health Office of Science Policy (NIH-OSP), Centers for Disease Control and Prevention (CDC), Occupational Safety and Health Administration (OSHA), VA Police Services) notified, or to be notified, of the event and the date(s) of notification.

(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.

e. **Research Information Security and Privacy.** Notifications to ORO required by this directive pertaining to research information security or research privacy must include as applicable and to the extent known at the time of notification:

(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) Indication of whether investigational drugs 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) Date that VA medical facility personnel first identified or otherwise became aware of the event.

(9) A detailed description of the event, including:

(a) The date(s) of the event.

(b) The type of reportable event (e.g., UPIRTSO, serious or continuing noncompliance, suspension or termination).

(c) Number of research subjects and 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 or transmission of VASI/PHI occurred.

(f) Indication of whether the event being reported is related to any existing or previously submitted reports.

(g) Underlying cause(s) and outcome(s) of the event.

(10) 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 (e.g., by individuals *not* associated

with or acting as agents of the facility such as by a VHA program office, external monitoring/auditing/accreditation organization).

(11) Name of the research review committee(s) that reviewed the event and any resulting determination(s) made by the committee(s).

(12) 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).

(13) Actions the facility is taking or plans to take to address the event (e.g., protocol or informed consent document revisions, subject enrollment suspensions, protocol terminations, enrolled subjects notifications, issuance of notifications to subjects impacted including issuance of credit monitoring letters, education/training) and anticipated dates for completing any pending or proposed actions.

(14) Indication of whether the event represents a repeat of the same type of noncompliance involving the facility's research program within the past 3 years.

(15) Indication of whether the event involves noncompliance by a same individual or study team responsible for other research noncompliance within the past 3 years.

(16) Names of other Federal agencies or entities (e.g., HHS-OHRP, HHS Office for Civil Rights (OCR)) notified, or to be notified, of the event and the date(s) of notification.

(17) 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.

3. SUBMISSION OF NOTIFICATIONS TO ORO

a. Notifications of events reportable to ORO must be directed to the relevant ORO workgroups described below. In some instances, where an event may be overseen by more than one ORO workgroup, VA medical facility personnel need only send the initial notification to one of the ORO workgroups with applicable oversight responsibilities. ***NOTE:*** *Contact information for ORO workgroups is available on ORO's website at https://www.va.gov/ORO/ORO_Contact_Information.asp. The reporting of events to ORO does not otherwise obviate the additional reporting of such events by VA medical facility personnel to pertinent Federal agencies (such as HHS-OHRP, FDA, NIH-OLAW, NIH-OSP, CDC, and OSHA), research sponsors, and accrediting bodies in accordance with the requirements of those entities.*

(1) Reportable events pertaining to noncompliance with VHA Directive 1200.01(1), Research and Development Committee, dated January 24, 2019, including Research & Development Committee (R&DC) operations and research solely under the oversight of the R&DC should be reported to ORO's Comprehensive Research Oversight Workgroup (CROW).

(2) Reportable events pertaining to noncompliance with Research Compliance Officer (RCO) responsibilities should be reported to ORO's CROW.

(3) Reportable events pertaining to human subjects research and IRB operations should be reported to ORO's Human Research Protection (HRP) Workgroup.

(4) Reportable events pertaining to animal research and IACUC operations should be reported to ORO's Research Safety and Animal Welfare (RSAW) Workgroup.

(5) Reportable events pertaining to research laboratory safety and security and SRS or IBC operations should be reported to ORO's RSAW Workgroup.

(6) Reportable events pertaining to research information security and privacy should be reported to ORO's Research Information Security (RIS) Workgroup.