Department of Veterans Affairs

Memorandum

Date: NOV 12 2003

From: Acting Chief Officer, Office of Research Oversight (ORO) (10R)

Thru: Deputy Under Secretary for Health (10A) 11-12-03
Deputy Under Secretary for Health for Operations and Management (10N) 11-12-03

Subj: What to Report to ORO: ACTION

To: Institutional Officials of VHA Facilities Conducting or Supporting Research

1. I am reissuing the memorandum "What to Report to ORCA," dated October 28, 2002, to acknowledge the name change of the office and to make minor revisions in reporting requirements.

2. Effective May 2003, the Office of Research Oversight (ORO) serves as the primary Veterans Health Administration (VHA) office to advise the Under Secretary for Health on matters of compliance and assurance in human subjects protections, animal welfare, research safety, and research misconduct.

3. ORO prefers to fulfill its mandates by working with facilities prospectively so that potential problems can be averted and quality of research maintained. This memorandum identifies issues which a VHA facility (VA Medical Centers, VA Health Care Systems, and VA Medical and Regional Office Centers) must report to ORO as required by various Federal regulations and VHA policies. It addresses reporting requirements to ORO only. Your facility may also be required to report information to other organizations such as the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), and the Office of Laboratory Animal Welfare (OLAW) in the Department of Health and Human Services (DHHS), and the Office of Research and Development in VHA.

4. Each VA facility must provide written information about events listed in Attachment A of this memorandum to the appropriate ORO Regional Office (RO). Exceptions are found in paragraphs A4 and D of Attachment A that require direct reporting to ORO's Central Office (CO). In reporting an event or situation, the facility should describe its actions to address the issue. Information on the event must be reported to ORO promptly, even if the facility has not come to a final determination about the disposition of the issue. ORO staff is available for consultation on these or related matters by e-mail or telephone.

5. In addition to what is listed at Attachment A, VHA facilities are required to report to ORO any citations by external oversight agencies related to human subjects protections, animal welfare, research safety, and research misconduct. The facility must specify how the citations will be promptly addressed.

6. When you provide ORO with any of the above information you should simultaneously notify your Network Director.

7. Please refer to Attachment B for the appropriate ORO contact.

David A. Weber, PhD
Acting Chief Officer, ORO (10R)

Attachments: A-What to Report to ORO
B-ORO Contact List

cc: Under Secretary for Health (10)
Chief Officer for Research and Development (12)
Network Directors
ACOSs for Research and Development/Research Coordinators

VA FACILITIES REPORT TO ORO

A. Protection of Human Subjects in Research:

1. Findings of serious or continuing noncompliance with the regulations for the protection of human subjects or with the requirements of the Institutional Review Board (IRB) (38CFR16.103(b)(5) and VHA Handbook 1200.5).

2. a. All adverse events (AEs) and imminent threats of AEs in research that result in:

   1) An IRB taking substantive action(s), as defined in ORO Handbook 1058.X (in preparation). The Institutional Official or designee facilitates the submission of a completed VA Adverse Events (AEs) report to the ORO RO in a specified format within 10 working days of the IRB's determination to take such action(s).

   2) An unexpected death of a research subject, regardless of IRB action. The Institutional Official or designee facilitates reporting of such deaths to the ORO RO no later than two (2) working days after the IRB is informed of the death.

   b. Definitions:

   1) An AE in research is defined for purposes of Handbook 1058.X, as any untoward occurrence (physical, psychological, social, or economic) in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom, disease, or death associated with the research or the use of a medical investigational test article. An AE may or may not be related to an error or protocol deviation. An AE does not necessarily have to be caused by any particular aspect of the research.

   2) Substantive actions are actions taken by an IRB that materially alters the substance and meaning of a protocol, informed consent form or process, or investigator status, including, but not limited to, restriction, suspension or termination of a study or investigator participation, and actions taken to prevent future occurrence(s) of the adverse event.

   3) An unexpected death refers to the death of a research subject in a trial in which a high risk of death is not projected, as indicated by the written protocol, informed consent form, and/or sponsor brochure. The death of a subject already at the end-of-life is *not* an unexpected death unless the research intervention clearly hastens the subject's death. A subject's death that is determined to be clearly not associated with the research is also not an "unexpected death" for purposes of the reporting requirements.

3. Suspension or termination of IRB approval. Report for cause suspensions and terminations (e.g., associated with unexpected harm, research not being conducted in accordance with the IRB's requirements, lack of continuing review) (38CFR16.113). Do not report routine study closures or study completions.

4. Any change in status of the Federal Wide Assurance or IRBs of record including notification of changes in institutional officials, IRB chair/membership, or contact staff. Changes in Memoranda of Understanding (MOU) about shared responsibilities in the human research protections program with other VA organizations or the academic affiliate must be reported. **Report information in item A.4 directly to ORO CO.**

B. Animal Welfare Issues:

1. Any changes in the Association for Assessment and Accreditation of Laboratory Animal Care International accreditation status of a facility used by the VA, whether internal or that of the affiliate institution.
2. Any change in the facility's Animal Welfare Assurance status as reported to OLAW.
3. Any citations listed on inspection reports of the Animal and Plant Health Inspection Service, United States Department of Agriculture (USDA).
4. Any significant changes in a MOU regarding animal care and use arrangements with affiliate institutions.
5. Any termination or suspension of an animal protocol by the VA Institutional Animal Care and Use Committee (IACUC).
6. Any serious or continuing noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals or VHA Handbook 1200.7.
7. Any serious deviation from the provisions of the Guide for the Care and Use of Laboratory Animals.
8. Any serious deviations from the provisions of Title 9 Parts 1, 2, and 3, USDA Animal Welfare Act Regulations and Standards.
9. Any work-related injuries to personnel working within an animal facility that require a hospital visit.
10. Any loss of animal life due to physical plant deficiencies and/or engineering failures/mishaps.

C. Research Safety and Security Issues:

1. Any suspension or termination of the Subcommittee on Research Safety approval.
2. Any serious or continuing non-compliance with Federal regulations and VHA policies, such as VHA Handbook 1200.8, VHA Directive 2002-075, 42 CFR 73, etc.
3. Any serious injury to personnel requiring hospitalization or leading to serious complications or death.
4. Any exposure, release, loss, or theft of select agents or toxins, or other serious incident requiring reporting and reevaluation of the facility's safety or emergency plan.
5. Any citation following an Office of Research and Development site visit or audit of the research safety program.
6. Any citation by National Institutes of Health on research involving recombinant DNA molecules.
7. Any citation by the Centers for Disease Control and Prevention or USDA on hazardous materials, including select agents and toxins.
8. Any citation by Occupational Safety and Health Administration on research safety.
9. Findings following an inspection by the Nuclear Regulatory Commission or VA National Health Physics Program Office.
10. Any Type 1 contingency following a Joint Commission on Accreditation of Healthcare Organizations site visit related to research safety.

D. Research Misconduct:

Report to ORO CO directly:

1. All initiations of inquiries and investigations of research misconduct as defined in 65 Federal Register 76260 (December 6, 2000), i.e., fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting results.
2. Copies of inquiry and investigation reports.
3. All adjudications (both finding of research misconduct and no findings of research misconduct).

OFFICE OF RESEARCH OVERSIGHT (ORO)

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VA Intranet Address: http://vaww.va.gov/oro/

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Note: Amended 10/25/04

OFFICE OF RESEARCH OVERSIGHT (ORO)

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ORO, WESTERN REGION

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Note: Amended 10/25/04