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Memorandum

Date: January 20, 2011

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

Subj: ORO Realignment – New Reporting Streams

1. ORO's recent realignment has resulted in several changes in the recipients for required reporting to ORO under VHA Handbook 1058.01. This memo clarifies the recipients for such reports (see attachment) pending revision of the Handbook.

2. ORO Regional Offices serve as the focal point for oversight of facility Human Research Protection Programs (HRPPs) and Research and Development (R&D) Committee Oversight Programs. Reports related to HRPP and R&D Committee matters should be sent to the ORO Regional Office responsible for the reporting Facility, as indicated on the ORO website at http://www1.va.gov/ORO/Docs/Memos/ORORealignmentAnnouncement.pdf.

3. Matters related to Federalwide Assurances (FWAs), other ORO-approved human research assurances, and Memoranda of Understanding (MOUs) related to human research protection arrangements should be sent simultaneously to the responsible ORO Regional Office and the ORO Central Office FWA/MOU Contact Person (priscilla.craig@va.gov).

4. The ORO Central Office Research Safety and Animal Welfare (RSAW) group serves as the focal point for oversight of facility research safety and animal welfare programs. Reports related to research safety, research laboratory security, Bio-Safety Level 3 (BSL-3) laboratories, and laboratory animal welfare should be sent to the ORO Central Office RSAW group.

5. The ORO Central Office Research Information Protection Program (RIPP) group serves as the focal point for oversight of facility research information protection programs. Reports related to research information protection should be sent to the ORO Central Office RIPP group.

6. Reports (signed by the Facility Director) may be attached to an encrypted e-mail message and forwarded to ORO electronically. Links to ORO Regional Office and Central Office mailboxes may be found on the ORO website at (http://www1.va.gov/ORO/eMail_ORO.asp).

7. ORO very much appreciates your continued commitment to excellence in the protection of human research subjects, laboratory animals, and research personnel and to the conduct of research benefiting Veterans.

8. Please do not hesitate to contact me should you have any questions.

J. Thomas Puglisi, PhD

Attachment: Summary of Requirements for Reporting to ORO – Effective January 1, 2011

SUMMARY OF REQUIREMENTS FOR REPORTING TO ORO – EFFECTIVE JANUARY 1, 2011

Human Research: Report to RO *	**Animal Welfare: Report to RSAW ***	**Research Safety: Report to RSAW ***	**Laboratory Security: Report to RSAW ***	**Information Protection: Report to RIPP ***
1. Problems involving risks to subjects or others that are unanticipated and serious and 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. 2. Local Serious AEs (SAEs) that are unanticipated and serious and related to the research. 3. Research Compliance Officer (RCO) audit findings of apparent serious or continuing noncompliance (also report to ORD). 4. Institutional Review Board (IRB) findings of serious or continuing noncompliance (also report to ORD). 5. Suspensions or terminations of study activities related to safety, rights, or welfare of subjects or others. 6. Any proposed change in facility's Federalwide Assurance (FWA) or other ORO-approved Assurance. 7. Any proposed change in facility's designated IRB(s). 8. Any change in a Memo of Understanding (MOU) for IRB or research protection arrangements (also notify ORO CO FWA contact). 9. Facility failure to gain full accreditation or change in facility accreditation or in affiliate accreditation affecting facility research protections.	1. Unanticipated loss of animal life. 2. Animal theft or potentially dangerous escape. 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. 4. Incidents reportable under applicable standards, including noncompliance or deficiency that substantively compromises the effectiveness of facility's animal research protection/oversight programs. 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. 6. Any change in facility's Public Health Service (PHS) Animal Welfare Assurance. 7. Any change PHS Animal Welfare Assurance of an affiliate or other entity on which the facility relies. 8. Any new MOU or substantive change in an MOU related to laboratory animal welfare or animal care and use arrangements 9. Facility failure to gain full accreditation or change in facility accreditation or in affiliate accreditation affecting facility research protections.	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. 2. Reportable incidents under applicable standards, including any deficiency that substantively compromises the effectiveness of facility research safety programs. 3. Suspensions or terminations of research activities related to the safety, rights, or welfare of research staff or others. 4. Unauthorized laboratory decommissions or reassignments requiring identification and disposal of hazardous materials, infectious agents, or equipment. 5. Any substantive change in an MOU related to research safety arrangements.	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. 2. Any break-in or security breach involving a VA Biosafety Level-3 (BSL-3) research laboratory. 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. 4. External findings of noncompliance. 5. Any noncompliance or other deficiency that substantively compromises the effectiveness of the facility's research laboratory security program. 6. Suspensions of terminations of research related to laboratory security concerns. 7. Any substantive change in an MOU related to research laboratory security arrangements.	1. **Report to ACOS for Research, Privacy Officer (PO), and Information Security Officer (ISO) Required Within 1 Hour:** a. Unauthorized access, use, disclosure, transmission, removal, theft, or loss related to research of VA sensitive information, including protected health information, individually identifiable private information, or confidential information, by the Privacy Act, HIPAA, or by Federal records requirements. b. Any research-related incidents reportable to NSOC. 2. **Report to ACOS for Research, PO, and ISO Required Within 5 Business days:** a. Findings of noncompliance. b. Any other deficiency that substantively compromises the effectiveness of the facility's research information protection program. c. Suspensions of terminations of research related to information protection concerns.

*** NOTE: RO = ORO Regional Office CO = ORO Central Office**
RSAW = ORO Research Safety and Animal Welfare Group (CO)
RIPP = ORO Research Information Protection Group (CO)

Except as noted under Information Protection Item 1, members of the VA research community, including RCOs, must ensure that the relevant research review committees are notified within 5 business days after becoming aware of these events. The facility Director must notify ORO in writing within 5 business days after being informed of these events. A copy should also be sent to the Network Director. Decision Charts for Human Research Reporting are provided on the ORO Website. Research Misconduct should be reported to the ORO Associate Director for Research Integrity and Assurance.