Handbook 1200.7 Pages 12 and 13 concerning HVAC Issues and Disaster Planning

information without requesting or receiving local permission to do so. ***NOTE:*** *Consistent with USDA AWAR (9 C.F.R. §2.32) and Title 5 (Pt. III, Subpt. A, Ch. 23, Sec. 2302), actions may not be taken against an employee for the act of contacting the CVMO.*

7. VMU OPERATIONS AT THE VA MEDICAL CENTER

VMUs must be operated as administratively-centralized facilities and services directed by a VMO or jointly by a VMC and a VMU supervisor. ***NOTE:*** *Under no circumstances may authority or responsibility for animal research conducted on VA property be ceded to non–VA entities, unless approved by CRADO.*

a. **Equipment and Physical Plant**

(1) **Request for VA Central Office or ORD Equipment Funds.** Funding for common use equipment needed in the animal research facility may be requested subject to the availability of funds and demonstrated need.

(2) **Animal Research Facility Heating, Ventilation, and Air Conditioning (HVAC) Equipment and Testing**

(a) All HVAC reheat boxes serving one or more rooms housing animals must be designed so that they fail in the "off" or "safe" position, to prevent the loss of animals due to excessive temperature. Laboratory animals can not be housed at any VA facility in rooms that are not so equipped.

(b) If an air handler serving one or more animal rooms contains a preheat coil or other equipment that could deliver excessive heat to animal rooms, engineering staff must determine if the equipment represents a potential threat to animals in case of a malfunction, and record findings in writing for IACUC review.

1. If such a threat is identified, preventative action such as installation of a preheat coil-fan interlock must be undertaken with due consideration of preventing damage to cooling coils or other air handler equipment.

2. Catastrophic air handler failures occur despite the presence of high-temperature alarms in animal rooms; thus the ability of facility personnel to detect high temperatures in animal rooms does not eliminate the need to comply with subparagraph 7a (2)(b).

(c) To test the ability of facilities management personnel to properly detect and respond to elevations in animal room temperatures, at least once every fiscal year research personnel must purposely overheat a temperature sensor (e.g., with a hair dryer, with input from facilities management personnel) in at least one animal room in each animal research facility without notifying engineering or facilities management personnel in advance. The response must be carefully noted, and reported to the IACUC by VMU staff at the next convened IACUC meeting.

1. The IACUC must decide if the response to the excessive temperature was timely and adequate. If the response is not deemed timely or adequate, corrective action must be taken

immediately by the medical center to ensure a proper emergency response.

2. Unannounced repeat tests must be conducted monthly until the IACUC approves the adequacy of the response. The IACUC minutes must reflect all reviews of testing. ***NOTE:*** *Repeated deficiencies may be considered reportable, as described in subparagraph 8g.*

(3) **Disaster Planning.** As required by the Guide, a disaster plan needs to be developed in order to protect the animals during a power loss. The plan needs to be in writing and approved by the IACUC. It is a "Best Practice" to connect the animal facility HVAC system to emergency power; however, alternate approaches to ensuring adequate temperature control after a power loss can be employed effectively. For instance, supplemental portable cooling and heating equipment can be available at the medical center, or from vendors on short notice.

(4) **Animal Facility Construction and Renovation.** To help ensure that costly mistakes are not made in the construction of new animal facility space, in the renovation of existing animal facility space, or in the renovation of non-animal facility space to animal facility space, the CVMO must approve the design plans for all animal facility construction or renovations costing more than $100,000 (equipment purchases count toward the $100,000 cut off). ***NOTE:*** *Construction and renovation activities must be conducted pursuant to existing VA policy when applicable (e.g. VHA Directive 1800.1, "Major Construction and Real Property Project Document Approval Level Procedures").*

b. **Animal Care, Husbandry, and Animal Research Practices.** All animal care, husbandry, and animal research practices at VA animal facilities must be in accordance with applicable laws, regulations, and policy. **Regarding animal procurement**:

(1) Any laboratory animal used in a VA research facility must be acquired in accordance with Federal laws, regulations, and policy. For procurement opportunities for aged and other special groups of animals see Appendix B.

(2) No request for animal procurement may be approved or initiated until the veterinarian or VMU Supervisor determines that the source of animals is appropriate, that adequate and appropriate housing is available upon arrival, and that the animals are going to be used in a protocol approved by the IACUC. Upon arrival, the delivered animals must be subtracted from the animal use ceiling approved by the IACUC.

(3) Delivery of live animals must be made directly to the animal research facility, unless special arrangements have been made between the VMU staff and receiving staff. To avoid delay, whenever possible, the procurement document should show the specific location in the animal research facility where delivery is to be made. Appropriately skilled personnel must be designated in order to represent the contracting officer at the time of delivery, in receiving and inspecting live animals.

(4) These procurement activities must be conducted pursuant to existing VA policy (e.g. VA Directive and Handbook 7126.2, "Procurement Sources and Programs") as is applicable.

Memo dated 10/27/03 from Deputy Undersecretary for Health for Ops and Management about HVAC Issues

Department of Veterans Affairs

Memorandum

Date: OCT 27 2003

From: Deputy Under Secretary for Health for Operations and Management (10N)

Subj: Animal Facility HVAC Equipment and Testing

To: Facility Directors (00)
Chief. Research Services
Thru: Network Directors (10N1-23)

1. Facilities must guard against the loss of laboratory animals due to excessive temperature fluctuations from the malfunction of reheat boxes and other equipment providing conditioned air to rooms housing research animals.

2. Heating industry standard for systems in large buildings is to "fail safe" in a manner that results in full heat in order to protect building piping systems from freezing. This normal industry practice can cause havoc in animal research facilities. Laboratory animals are very sensitive to excessive heat and can be killed by a single overheating event. It is also important to have in place a team that is familiar with the care of laboratory animals and current research to respond at any time (24/7) to emergencies since animals and research can be rescued even in the event of building mechanical system failure.

3. VHA requires that all laboratory animals be protected from excessive temperatures and procedures for their rescue be in place and regularly exercised.

4. Heating, Ventilating and Air Conditioning (HVAC) equipment must be designed, maintained and operated so as to "fail safe" within acceptable temperature conditions for laboratory animals. Facilities will conduct periodic HVAC system inspections to ensure that the "fail safe" mode is not reset to full heat. Animal facilities will include appropriate alarm systems to detect imminent danger and alert staff to respond. Research personnel will periodically conduct realistic drills to assess 24/7 response team training and effectiveness.

5. Facilities must accomplish the following actions and notify the Chief Veterinary Medical Officer (CVMO) of compliance by November 25, 2003:

   a. Conduct a detailed review of their HVAC systems for adequacy in keeping temperatures within acceptable limits, proper failure modes and for potential detrimental effects on laboratory animals in the event of failure. This review will include realistic testing of existing conditions under controlled conditions. No person or laboratory animals may be harmed in these tests.
   b. Determine whether the equipment represents a potential threat to animals in case of a malfunction.

c. Maintain a 24/7 capability to respond to HVAC emergencies involving laboratory animals.

d. Record and submit written findings to the facility Institutional Animal Care and Use Committee for review.

6. Facilities identifying a potential threat must complete necessary repairs to prevent catastrophic overheating (such as installation of a preheat coil-fan interlock) no later than February 1, 2004.

7. Refer to the attachment for the format and address for CVMO notification.

8. These requirements will be incorporated into VHA Handbook 1200.7, *Use of Animals in Research.*

Laura J. Miller

Attachment

Certification of VA Animal Facility HVAC System

1. VA Station (number and name):

2. Provide the location of each animal facility (building number or name):

3. For each animal facility, provide the make and model for every air handler supplying the facility:

4. For each air handler in item 3 above, indicate if a preheat coil or other equipment (besides room reheat boxes) is present that is capable of delivering heated air to animal facility rooms, and if that equipment could cause overheating of animal facility rooms if it malfunctioned with the air handler fan running.

5. For each air handler in item 3 above, indicate if all reheat boxes in animal facility housing rooms served by that air handler fail in the off position.

6. Provide a plan for correction and a timetable to meet the requirements in item 1 of the Deputy Under Secretary for Health for Operations and Management memo. If not applicable, so note.

7. I certify, to the best of my knowledge, that the information contained in this form is correct and reflects an accurate description of animal facility HVAC equipment:

_____

Director, Medical Center Date

8. Submit this certification by November 21, 2003:

Dr. Mike Fallon
Atlanta VA Medical Center - 151V
Room 4A-116
1670 Clairmont Road
Decatur, GA 30033
404-728-7644

Correct USDA Registration Numbers for VA Facilities

Cust No	Cert No	Name	Doing Business As	Address	City	Zip
		Alabama				
939	64-V-0002	Va Medical Center		Depart Of Veterans Affairs	Tuscaloosa	35404
941	64-V-0004	Va Medical Center		215 Perry Hill Road	Montgomery	36109
		Arizona				
1317	86-V-0002	Va Medical Center (678)		3601 S. 6th Avenue	Tucson	85723
		Arkansas				
1377	71-V-0001	Central Arkansas Veterans Healthcare Sys	J. L. Mcclellan Vamc(598)	4300 W. 7th St.	Little Rock	72205
1378	71-V-0003	Fayetteville Vamc #565		1100 N. College Ave.	Fayetteville	72701
		California				
1327	93-V-0008	J. L. Pettis Memorial Va Med Ctr (605)		11201 Benton Street	Loma Linda	92357
1323	93-V-0004	Va Animal Research Facility (664) - San D		3350 La Jolla Village Drive	San Diego	92161
1330	93-V-0012	Va Medical Center (570) - Fresno		2615 E. Clinton Avenue	Fresno	93703
1326	93-V-0007	Va Medical Center (600) - Long Beach		5901 E. 7th Street 09/151	Long Beach	90822
1322	93-V-0003	Va Medical Center (640) - Palo Alto		3801 Miranda Avenue	Palo Alto	94304
1324	93-V-0006	Va Medical Center (662) - San Francisco		4150 Clement Street	San Francisco	94121
1329	93-V-0010	Va Medical Center (665) - Los Angeles		16111 Plummer Street	Los Angeles	91343
1328	93-V-0009	Va Ncsc (612) - Pleasant Hill		2300 Contra Costa Blvd Ste 440	Pleasant Hill	94523
1325	93-V-0006	West La Va Medical Center (691)	(Wadsworth)	11301 Wilshire Blvd.	Los Angeles	90073
		Colorado				
1315	84-V-0002	Va Medical Center (554)		1055 Clermont	Denver	80220
		Connecticut				
453	16-V-0001	Va Medical Center (527)		555 Willard Avenue	Newington	06111
454	16-V-0002	Va Medical Center (689)		950 Campbell Avenue	West Haven	06516
		Delaware				
637	50-V-0001	Va Medical Center (460)		1601 Kirkwood Highway	Wilmington	19805
		Dist Of Columbia				
660	13-V-0001	Va Medical Center (405)		810 Vermont Avenue Nw	Washington	20420
649	10-V-0004	Va Medical Center (688)		50 Irving Street, N.W.	Washington	20422
		Florida				
931	58-V-0003	Fernandez	Va Medical Center	Dept Of Veterans Affairs	Bay Pines	33504
932	58-V-0004	James A. Haley Veterans Hospital		13000 N. Bruce B. Downs Blvd.	Tampa	33612
933	58-V-0005	Va Medical Center		1201 Nw 16th St.	Miami	33125
949	58-V-0007	Va Medical Center		Dept Of Veterans Affairs	Gainesville	32608
950	58-V-0010	Va Medical Center		801 S. Marion Street	Lake City	32055
		Georgia				
987	57-V-0001	Va Medical Center		1670 Clairmont Road	Decatur	30033
1007	57-V-0002	Va Medical Center		2460 Wrightsboro Road	Augusta	30904
		Idaho				
1314	82-V-0001	Va Medical Center (531)		500 West Fort Street	Boise	83702
		Illinois				
554	33-V-0004	Va Medical Center (151) Hines		Vmu (151)	Hines	60141
709	33-V-0002	Va Medical Center (535) Lakeside	Va Medical Center (535)	400 E. Ontario Street	Chicago	60611
564	33-V-0006	Va Medical Center (537) West Side	Va Medical Center (537)	820 S. Damen Avenue	Chicago	60612
555	33-V-0005	Va Medical Center (550)		1900 E. Main Street	Danville	61832
553	33-V-0003	Va Medical Center (556)		3001 Green Bay Road	North Chicago	60064
557	33-V-0009	Va Medical Center (609)		2401 W. Main Street	Marion	62959
		Indiana				
792	32-V-0002	Va Medical Center (568)		2121 Lake Avenue	Fort Wayne	46805

Cust No	Cert No	Name	Doing Business As	Address	City	Zip
		Indiana				
791	32-V-0001	Va Medical Center (583)		1481 West 10th Street	Indianapolis	46202
793	32-V-0003	Va Medical Center (610)		Va Medical Center	Marion	46953
		Iowa				
1585	42-V-0003	Des Moines Vamc (555)		3600 30th St.	Des Moines	50310
1584	42-V-0002	Iowa City Vamc (584)		Hwy 6 West	Iowa City	52246
1587	42-V-0005	Knoxville Vamc (582)		1515 W. Pleasant	Knoxville	50138
		Kansas				
1379	48-V-0003	Leavenworth Vamc (686)		4101 S. 4th St. Trafficway	Leavenworth	66048
1380	48-V-0002	Wichita Vam&Roc #452		5500 E. Kellogg	Wichita	67218
		Kentucky				
935	61-V-0002	Va Medical Center		800 Zorn Avenue	Louisville	40206
936	61-V-0003	Va Medical Center		Dept Of Veterans Affairs	Lexington	40511
		Louisiana				
1366	72-V-0005	Alexandria Vamc #502		Shreveport Hwy	Alexandria	71301
1365	72-V-0003	New Orleans Vamc (629)		1601 Perdido Street	New Orleans	70146
1364	72-V-0002	Overton Brooks Vamc (667)		510 E. Stoner Avenue	Shreveport	71101
		Maine				
456	11-V-0001	Va Medical Center (402)		Medical & Regional Office Ctr	Togus	04330
		Maryland				
742	51-V-0010	Va Medical Center (512)		10 N. Greene Street	Baltimore	21201
743	51-V-0009	Va Medical Center (568)		9600 N. Point Road	Fort Howard	21052
654	51-V-0013	Va Medical Center (641)			Perry Point	21902
		Massachusetts				
652	14-V-0001	Va Medical Center (518)		200 Springs Road	Bedford	01730
651	14-V-0004	Va Medical Center (523)		150 S. Huntington Avenue	Boston	02130
653	14-V-0003	Va Medical Center (526)		1400 Vfw Parkway	West Roxbury	02132
741	14-V-0006	Va Medical Center (750)		251 Causeway Street	Boston	02114
		Michigan				
739	34-V-0002	Va Medical Center (506)		2215 Fuller Road	Ann Arbor	48105
738	34-V-0005	Va Medical Center (515)		5500 Armstrong Road	Battle Creek	49016
724	34-V-0001	Va Medical Center (553)		Va Medical Center	Allen Park	48101
737	34-V-0004	Va Medical Center (585)		325 East H Street	Iron Mountain	49801
736	34-V-0003	Va Medical Center (655)		1500 Weiss Street	Saginaw	48602
		Minnesota				
556	41-V-0001	Va Medical Center (618)		One Veterans Drive	Minneapolis	55417
543	41-V-0002	Va Medical Center (656)		4801 8th Street North	St Cloud	56303
		Mississippi				
943	65-V-0003	Rieffel	Va Medical Center	Depart Of Veterans Affairs	Biloxi	39531
956	65-V-0002	Va Medical Center		1500 E. Woodrow Wilson Drive	Jackson	39216
		Missouri				
1373	43-V-0001	Harry S. Truman Vamc(543)		800 Hospital Drive	Columbia	65201
1376	43-V-0004	John J Pershing Vamc		1500 N. Westwood	Poplar Bluff	63901
1374	43-V-0002	Kansas City Vamc (589)		4801 E Linwood Blvd.	Kansas City	64128
1375	43-V-0003	St. Louis Vamc (657)		Va Medical Center	St Louis	63106
		Nebraska				
1556	47-V-0004	Lincoln Vamc (597)		600 South 70th Street	Lincoln	68510
1554	47-V-0001	Omaha Vamc (636)		4101 Woolworth Avenue	Omaha	68105

Cust No	Cert No	Name	Doing Business As	Address	City	Zip
			Nevada			
1319	88-V-0001	Va Medical Center (654)		1000 Locust Street	Reno	89520
			New Hampshire			
735	12-V-0001	Va Medical Center (608)		228 Maple Street	Manchester	03103
			New Jersey			
655	22-V-0001	Va Medical Center (561)		385 Tremont Avenue	East Orange	07018
656	22-V-0002	Va Medical Center (604)		151 Knollcroft Road	Lyons	07939
			New Mexico			
1316	85-V-0001	Va Medical Center (501)		2100 Ridgecrest Dr., Se	Albuquerque	87108
			New York			
663	21-V-0008	Va Medical Center (500)		113 Holland Avenue	Albany	12208
733	21-V-0013	Va Medical Center (513)		.	Batavia	14020
734	21-V-0012	Va Medical Center (514)		.	Bath	14810
604	21-V-0009	Va Medical Center (526)		130 W. Kingsbridge Road	Bronx	10468
10068	21-V-0014	Va Medical Center (526)		130 West Kingsbridge Rd	Bronx	10468
660	21-V-0004	Va Medical Center (527)		800 Poly Place	Brooklyn	11209
662	21-V-0002	Va Medical Center (528)		3495 Bailey Avenue	Buffalo	14215
659	21-V-0010	Va Medical Center (532)		400 Fort Hill Avenue	Canandaigua	14424
657	21-V-0011	Va Medical Center (620)		Va Medical Center	Montrose	10548
661	21-V-0003	Va Medical Center (630)		423 East 23rd Street	New York New York	10010
644	21-V-0006	Va Medical Center (632)		Middleville Road	Northport	11768
665	21-V-0007	Va Medical Center (670)		800 Irving Avenue	Syracuse	13210
			North Carolina			
982	56-V-0003	Va Medical Center		508 Fulton Street	Durham	27705
983	56-V-0004	Va Medical Center		Dept. Of Veterans Affairs	Fayetteville	28301
984	56-V-0005	Va Medical Center		1601 Brenner Avenue	Salisbury	28144
			North Dakota			
1568	45-V-0003	Fargo Vamc #437		2101 Elm St.	Fargo	58102
			Ohio			
669	31-V-0007	Va Medical Center (538)		17273 State Route 104	Chillicothe	45601
650	31-V-0005	Va Medical Center (539)		3200 Vine Street	Cincinnati	45220
668	31-V-0004	Va Medical Center (541)		10701 East Boulevard	Cleveland	44106
666	31-V-0006	Va Medical Center (552)		4100 West 3rd Street	Dayton	45428
670	31-V-0008	Va Medical Center (757)		2090 Kenny Road	Columbus	43221
			Oklahoma			
1368	73-V-0003	Muskogee Vamc (623)		Honor Heights Dr.	Muskogee	74401
1367	73-V-0001	Oklahoma City Vamc		921 N E 13th St	Oklahoma City	73104
			Oregon			
1321	92-V-0001	Va Medical Center (648)		3710 Sw Us Veteran Hospital	Portland	97201
			Pennsylvania			
676	23-V-0005	Va Medical Center (503)		2907 Pleasant Valley Blvd	Altoona	16602
675	23-V-0007	Va Medical Center (529)		325 New Castle Road	Butler	16001
671	23-V-0001	Va Medical Center (542)		1400 Black Horse Hill Road	Coatesville	19320
732	23-V-0010	Va Medical Center (562)		Va Medical Center (562)	Erie	16501
672	23-V-0006	Va Medical Center (595)		Va Medical Center	Lebanon	17042
658	23-V-0002	Va Medical Center (642)		University & Woodland Avenues	Philadelphia	19104
673	23-V-0008	Va Medical Center (645)		7180 Highland Drive	Pittsburgh	15206
678	23-V-0003	Va Medical Center (646)		University Drive C	Pittsburgh	15240
674	23-V-0009	Va Medical Center (693)		1111 East End Boulevard	Wilkes Barre	18711
			Puerto Rico			

Cust No	Cert No	Name	Doing Business As	Address	City	Zip
			Puerto Rico			
944	94-V-0001	Edward Valenzuela	Va Medical Center	One Veterans Plaza	San Juan	00927
			Rhode Island			
579	15-V-0001	Va Medical Center (650)		830 Chalkstone Avenue	Providence	02908
			South Carolina			
986	56-V-0003	Brown	Wjb Dorn Veterans Hospital	Garners Ferry Road	Columbia	29209
985	56-V-0002	Ogawa	Va Medical Center	Ralph H. Johnson Dept Of Vamc	Charleston	29401
			South Dakota			
1582	46-V-0001	V A Med Ctr - Sioux Falls #438		2501 W. 22nd St.	Sioux Falls	57105
1584	46-V-0003	Vamc - Ft. Meade #568		Medical Center	Fort Meade	57741
1583	46-V-0002	Vamc - Hot Springs #579		500 N. 5th St.	Hot Springs	57747
			Tennessee			
937	63-V-0002	Tennessee Valley Healthcare System		1310 24th Avenue, South	Nashville	37212
938	63-V-0003	Va Medical Center		1030 Jefferson Avenue	Memphis	38104
			Texas			
1370	74-V-0007	Amarillo Vamc		6010 Amarillo Blvd. West	Amarillo	79106
1372	74-V-0009	Audie L. Murphy Vamc (671)		7400 Merton Minter Blvd.	San Antonio	78284
1352	74-V-0015	Big Spring Vamc #519		C/O Chief Of Staff	Big Spring	79721
1371	74-V-0008	Dallas Vamc		4500 S. Lancaster Rd.	Dallas	75216
1350	74-V-0011	Houston V A M C (580/151)		2002 Holcomb Blvd.	Houston	77030
1535	74-V-0018	Kerrville Vamc (591)		3600 Memorial Blvd.	Kerrville	78028
1351	74-V-0012	Olin E. Teague V A M C (674)		1901 S 1st St	Temple	76504
1355	74-V-0020	Sam Rayburn Vamc (522)		1201 E.Ninth Street	Bonham	75418
1354	74-V-0016	Texas Tech V A M C #504		3601 4th Street	Lubbock	79430
1353	74-V-0017	Va Outpatient Clinic(756)		5919 Brook Hollow Drive	El Paso	79925
			Utah			
1318	87-V-0001	Va Medical Center (660)		500 Foothill Blvd.	Salt Lake City	84148
			Vermont			
30099	13-V-0002	Vamc Research & Development Services		215 North Main Street	White River Jctn	05009
			Virginia			
731	52-V-0002	Va Medical Center (590)		Med Research Service 151	Hampton	23667
681	52-V-0003	Va Medical Center (652)		1201 Broad Rock Boulevard	Richmond	23249
10070	52-V-0001	Va Medical Center (658)		1970 Roanoke Blvd	Salem	24153
			Washington			
1320	91-V-0001	Va Medical Center (663)		1660 South Columbia Way	Seattle	98108
			West Virginia			
685	54-V-0003	Va Medical Center		200 Veterans Avenue	Beckley	25801
684	54-V-0001	Va Medical Center (540)		Va Medical Center	Clarksburg	26301
682	54-V-0002	Va Medical Center (581)		1540 Spring Valley Drive	Huntington	25704
683	54-V-0004	Va Medical Center (613)			Martinsburg	25401
			Wisconsin			
631	35-V-0001	Va Medical Center (607)	Wm S. Middleton Memorial Hosp	2500 Overlook Terrace	Madison	53705
632	35-V-0003	Va Medical Center (676)		500 E. Veterans Street	Tomah	54660
633	35-V-0004	Va Medical Center (695)		Veterinary Medical Unit	Milwaukee	53295

"What to Report to ORO" Memo dated 9/8/2005 plus Handbook 1058.1, "Reporting Adverse Events In Research To The Office Of Research Oversight"

Department of Veterans Affairs

Memorandum

Date: September 8, 2005

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

Subj: What to Report to ORO: ACTION

To: Institutional Officials of VHA Facilities Conducting or Supporting Research
Thru: Principal Deputy Under Secretary for Health (10A)
Acting Deputy Under Secretary for Health for Operations and Management (10N)

1. The attached memorandum "What to Report to the Office of Research Oversight" (September 8, 2005) clarifies current requirements for reporting research-related issues to this office.

2. 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 subject protections, laboratory animal welfare, research safety and security, and research misconduct. ORO's mandate includes working prospectively with facilities to foster integrity and excellence in VHA research.

3. The September 8, 2005 memorandum supersedes all previous versions and identifies issues that VHA facilities must report to ORO as required by applicable Federal regulations and VHA policies.

4. Each VA facility must provide **written** information to ORO as indicated in the attached.

5. This memorandum addresses reporting requirements to ORO only. VHA facilities may also be required to report to other entities such as the VHA Office of Research and Development (ORD), the relevant VHA Network Director, the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), the Office of Research Integrity (ORI), Office of Laboratory Animal Welfare (OLAW), etc.

David A. Weber

David A. Weber, PhD, FACNP

Attachment: What to Report to the Office of Research Oversight

cc: Chief Research and Development Officer (12)
Network Directors
Facility Directors
ACOSs for Research and Development / Research Coordinators

Department of Veterans Affairs

Memorandum

Date: September 8, 2005

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

To: Institutional Officials of VHA Facilities Conducting or Supporting Research

What to Report to the Office of Research Oversight

This memorandum identifies issues that VHA facilities must report to ORO as required by applicable Federal regulations and VHA policies.

The memorandum addresses reporting requirements to ORO only. VHA facilities may also be required to report information to other entities such as the VHA Office of Research and Development (ORD), the relevant VHA Network Director, the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), the DHHS Office of Research Integrity (ORI), and/or the National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW).

Guiding Principles

1. **Report in Writing.** Although ORO staff are available for consultation regarding the content and scope of reports, each VA facility must provide the required information to ORO in a **written report from the facility Director. Reports should first be sent by FAX or e-mail <u>and</u> then promptly forwarded in hard copy.**

2. **Report Promptly.** Reports should be provided to ORO as soon as possible, but no later than 10 working days after the issue has come before the responsible facility official or oversight committee (e.g., Institutional Review Board, Institutional Animal Care and Use Committee), unless otherwise indicated in the following material. If the facility has not made a final determination as to disposition of the issue within this 10 day period, the facility Director should provide ORO with a preliminary report and with followup reports as needed until the issue is resolved.

3. **Report to ORO Regional Office.** Reports should be addressed to the ORO Regional Office Director for the region in which the facility is located, unless otherwise indicated (see contact information attached).

4. **Report Descriptive Information and Actions.** Reports should include:

    a. The name and any relevant Assurance number of the reporting VA facility.
    b. The title of the research project(s) involved.
    c. The name of the principal investigator(s) involved (except for animal research).
    d. The number(s) used by the facility's Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and/or Research Service to identify the project(s) involved.
    e. The name of any external sponsor(s) of the project(s) involved.
    f. The funding source(s) for the project(s) involved.
    g. A detailed description of the issue being reported.
    h. A detailed description of the actions the facility is taking, or plans to take, to address the issue.

What to Report to ORO: Protection of Human Subjects in VA Research

1. Any adverse event (i.e., an untoward physical, psychological, social, or economic occurrence) in a human subject, or an imminent threat of an adverse event, that results in a substantive action by the Institutional Review Board (IRB) under VHA Handbook 1058.1 on *Reporting Adverse Events in Research* (attached).
2. Any unexpected death of a human subject under VHA Handbook 1058.1 NOTE: Such deaths must be reported within 24 hours of the IRB's determination that the death was unexpected or within 10 working days if the IRB has not yet made a determination about whether the death was unexpected.
3. Any unanticipated problem involving risks to subjects or others that results in a substantive action by the IRB.
4. Any for-cause suspension or termination of VA human subject research by the IRB, the VA facility, or a VA affiliate institution. NOTE: This does NOT include suspensions or terminations resulting solely from the expiration of the IRB approval period.
5. Any serious or continuing noncompliance with federal regulations or VHA policies for the protection of human subjects (including 38 CFR Part 16; 45 CFR Part 46; 21 CFR Parts 50, 56, 312 or 812; and VHA Handbook 1200.5).
6. Any serious or continuing noncompliance with IRB requirements or determinations.
7. Any findings of noncompliance in human research protections from the VHA Office of Research and Development (ORD) or other VA office. NOTE: The report to ORO should include a copy of the official findings. The facility should promptly provide ORO with copies of all subsequent correspondence between the office and the facility until the issue is resolved.

8. Any findings of noncompliance in human subject protections from external oversight agencies such as the Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), etc. NOTE: The report to ORO should include a copy of the official findings (e.g., FDA Form 483, *Inspectional Observations)*. The facility should promptly provide ORO with copies of all subsequent correspondence between the agency and the facility until the issue is resolved.
9. Any change in the facility's accreditation status from a VA-recognized accreditation organization for human research protections, or in the accreditation status of an affiliate institution or other VA facility upon which the facility relies.
10. Any change in the facility's Federalwide Assurance (FWA) or designated IRB(s) as filed with OHRP. NOTE: Report such changes directly to ORO Central Office and simultaneously copy the ORO Regional Office.
11. Any significant change in the facility's Memorandum of Understanding (MOU) with an affiliate institution or other VA facility regarding the designation of IRB(s) or other human research protection function. NOTE: Report such changes directly to ORO Central Office and simultaneously copy the ORO Regional Office.

What to Report to ORO: Laboratory Animal Welfare in VA Research

NOTE: Reports regarding VA animal research should NOT include the name(s) of the investigator(s) unless this information has been specifically requested by ORO.

1. Any incident that seriously affects the health or safety of laboratory animals.
2. Any loss of animal life due to physical plant deficiencies and/or engineering failures or mishaps.
3. Any work related injury to personnel working within an animal facility that requires more than minor medical intervention or leads to serious complications or death.
4. Any for-cause suspension or termination of VA animal research by the Institutional Animal Care and Use Committee (IACUC).
5. Any serious or continuing noncompliance with the *Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals* or VHA Handbook 1200.7 on *Use of Animals in Research*.
6. Any serious deviation from the requirements of the Animal Welfare Act under 9 CFR Parts 1, 2, and 3.
7. Any serious deviation from the *Guide for the Care and Use of Laboratory Animals.*

8. Any findings of noncompliance in laboratory animal care from the VHA Office of Research and Development (ORD) or other VA office. NOTE: The report to ORO should include a copy of the official findings. The facility should promptly provide ORO with copies of all subsequent correspondence between the office and the facility until the issue is resolved.
9. Any findings of noncompliance in laboratory animal care from external oversight agencies such as the US Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), the National Institutes of Health (NIH) Office for Laboratory Animal Welfare (OLAW), etc. NOTE: The report to ORO should include a copy of the official findings. The facility should promptly provide ORO with copies of all subsequent correspondence between the agency and the facility until the issue is resolved.
10. Any change in the facility's accreditation status from a VA-recognized accreditation organization for laboratory animal welfare, such as the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), or in the accreditation status of an affiliate institution or other VA facility upon which the facility relies.
11. Any change in the facility's Animal Welfare Assurance status as filed with OLAW, or in the Animal Welfare Assurance status of an affiliate institution or other VA facility upon which the facility relies.
12. Any significant change in the facility's Memorandum of Understanding (MOU) with an affiliate institution or other VA facility regarding animal care and use arrangements. NOTE: Report such changes directly to ORO Central Office and simultaneously copy the ORO Regional Office.

What to Report to ORO: Safety and Security in VA Research

1. Any work-related occupational injury to personnel working within a research facility that requires more than minor medical intervention or leads to serious complications or death.
2. Any significant, work-related exposure to hazardous materials of personnel working within a research facility.
3. Any for-cause suspension or termination of VA research by the Subcommittee on Research Safety (SRS) or other institutional safety committee.
4. Any serious or continuing noncompliance with federal regulations or VHA policies governing research safety and security, including 7 CFR Part 331; 9 CFR Part 121; 29 CFR Part 1910, Sections 1910.1030, 1910.1200, 1910.1450; 29 CFR Part 1960; 42 CFR Part 73; VHA Handbook 1200.6; VHA Handbook 1200.8; VHA Directive 2003-030; and VHA Directive 2005-003.

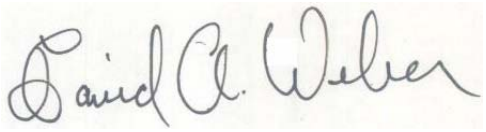
5. Any exposure, release, loss, or theft of hazardous materials, including select agents and toxins.
6. Any findings of noncompliance in research safety or security from the VHA Office of Research and Development (ORD), the VA National Health Physics Program Office, the VA Office of Inspector General (OIG), or other VA office. NOTE: The report to ORO should include a copy of the official findings. The facility should promptly provide ORO with copies of all subsequent correspondence between the office and the facility until the issue is resolved.
7. Any findings of noncompliance in research safety or security from external oversight agencies such as the National Institutes for Health (NIH) regarding the use of recombinant DNA; the Centers for Disease Control and Prevention (CDC) regarding hazardous materials, including select agents and toxins in research areas; the United States Department of Agriculture (USDA) regarding hazardous materials including select agents and toxins in research areas; the Occupational Health and Safety Administration (OSHA); the Nuclear Regulatory Commission (NRC); etc. NOTE: The report to ORO should include a copy of the official findings. The facility should promptly provide ORO with copies of all subsequent correspondence between the agency and the facility until the issue is resolved.

What to Report to ORO: Misconduct in VA Research

NOTE: Report the following DIRECTLY to the ORO CENTRAL OFFICE. ORO Central Office will notify the appropriate ORO Regional Office.

1. During the course of a research misconduct proceeding, ORO should be notified **immediately** of the following, and of any interim administrative actions taken to minimize resultant damage: any harm or threatened harm to research subjects; harm or threat of harm to those involved in an inquiry or investigation into research misconduct; serious violations of animal welfare requirements; research safety or security compromises; risks to public health or safety; loss or destruction of VA funds or property; possible violations of civil or criminal law associated with the alleged research misconduct. (VHA Handbook 1058.2 §12.e.1)
2. Any requests for pre-approval of significant changes or departures from the procedures outlined in VHA Research Misconduct Handbook. NOTE: Pre-approval of such changes by ORO is REQUIRED. (VHA Handbook 1058.2 §12.b & 12.d)
3. Any opening of a research misconduct <u>inquiry</u>. (VHA Handbook 1058.2 §14.c)
4. Any requests for approval of extensions of the normal 30-day period for the inquiry review. NOTE: Requests for extension of the inquiry review period must be timely. (VHA Handbook 1058.2 §14.e.1)

5. Any closure of a research misconduct inquiry without further investigation. NOTE: The report to ORO must include a copy of the Inquiry Report and the concurrence of the Facility Director. (VHA Handbook 1058.2 §14.g)
6. Any opening of a research misconduct investigation. (VHA Handbook 1058.2 §15.c)
7. Any requests for approval of extensions of the normal 90-day period for the investigation review. NOTE: Requests for extension of the investigation review period must be made at least 5 working days prior to the end of the initial investigation review period. (VHA Handbook 1058.2 §15.f.1)
8. Closure of a research misconduct investigation. NOTE: The report to ORO must include a copy of the final Investigation Report and the recommendations of the Facility Director. (VHA Handbook 1058.2 §15.h.3)
9. The final decision of the Director of the Veterans Integrated Services Network (VISN) on the merits of a research misconduct case. (VHA Handbook 1058.2 §16.f)



David A. Weber, PhD, FACNP

Attachments:

Office of Research Oversight (ORO). *Contacts for Reporting to ORO.*

VHA Handbook 1058.1, *Reporting Adverse Events in Research to the Office of Research Oversight.* (November 19, 2004).

Adverse Events (AEs) in VA Research AE – Report Format. VA Form 10-0420.

OFFICE OF RESEARCH OVERSIGHT (ORO)
CONTACTS FOR REPORTING TO ORO

Send written report to the appropriate ORO Office first by FAX or e-mail
and then forward promptly in hard copy.
For additional resources, reference ORO's website: http://www1.va.gov/oro/

CENTRAL OFFICE

811 Vermont Avenue, N.W., Suite 574 (10R)
Washington, D.C. 20420
PHONE: (202) 565-5184
FAX: (202) 565-9194

NORTHEASTERN REGIONAL OFFICE (VISNs 1, 2, 3)

Bedford VAMC – 200 Springs Road, Bldg 7, Room B-08 (10R)
Bedford, MA 01730
PHONE: (781) 687-3850
FAX: (781) 687-3858

MID-ATLANTIC REGIONAL OFFICE (VISNs 4, 5, 6, 9, 10)

50 Irving Street, N.W. (10R)
Washington, D.C. 20422
PHONE: (202) 745-8110
FAX: (202) 745-8538

SOUTHERN REGIONAL OFFICE (VISNs 7, 8, 16, 17)

1670 Clairmont Road (10R)
Decatur, GA 30033
PHONE: (404) 417-2929
FAX: (404) 417-2935

MIDWESTERN REGIONAL OFFICE (VISNs 11, 12, 15, 19, 23)

PO Box 5000, Building 1, Room B-103 (10R)
5th Avenue & Roosevelt Road
Hines, IL 60141
PHONE: (708) 202-7254
FAX: (708) 202-7250

WESTERN REGIONAL OFFICE (VISNs 18, 20, 21, 22)

P.O. Box 7360, Moreno Valley, CA 92552-7360
Express Delivery: ORO Western Regional Office (10R)
March Air Reserve Base – 5029 4th Street, Bldg. 2641
March Air Reserve Base, CA 92518
PHONE: (909) 801-5164
FAX: (909) 801-5176

Revised: September 8, 2005

REPORTING ADVERSE EVENTS IN RESEARCH TO THE OFFICE OF RESEARCH OVERSIGHT

1. PURPOSE

This Veterans Health Administration (VHA) Handbook sets forth the requirements for reporting certain adverse events (AEs) in research to the Office of Research Oversight (ORO) (10R) (formerly, ORCA). ***NOTE:*** *This Handbook does not preempt or otherwise alter any other applicable adverse event reporting requirements, whether within the Department of Veterans Affairs (VA) or to other Federal and state agencies or commercial sponsors.*

2. BACKGROUND

a. ORO serves as the primary VHA office for advising the Under Secretary for Health on all matters of compliance and assurance related to human subjects' protections. As part of its mission, ORO is responsible for overseeing compliance with the system-wide requirements for reporting AEs in research.

b. VA is committed to supporting high quality human research protection programs (HRPPs) in all its facilities involved in research. Reporting and management of AEs in research are important aspects of HRPPs. The Institutional Review Boards (IRBs) are integral parts of institutions' HRPPs and, as such, are responsible for reviewing and managing AEs in research (Title 38 Code of Federal Regulations [CFR] 16). Specifically, VA regulation requires prompt reporting of any unanticipated problems involving risks to subjects and others to the IRB, appropriate institutional officials, and the department or agency head (see 38 CFR 16.103(b)[5]). ***NOTE:*** *Likewise, Food and Drug Administration (FDA) regulations require investigators to report promptly to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, an investigational new drug (IND) (21 CFR 312.64(b)). Further investigators must submit to the sponsor and reviewing IRB a report of any unanticipated adverse investigational device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect (see 21 CFR 812.150[a][1]).*

c. Each IRB needs to develop Standard Operation Procedures (SOPs) that provide detailed instructions on how to report and manage AEs consistent with all relevant regulations and VHA policies, including the VHA Handbook 1050.1.

d. This VHA Handbook addresses only the reporting of certain AEs in research to ORO. Since ORO serves as the primary VHA office for advising the Under Secretary for Health on all matters of compliance and assurance related to human subjects' protections, ORO is responsible for overseeing compliance with the system-wide requirements for reporting AEs in research.

e. In the past, facilities were required to report all serious and unexpected AEs in research to ORO. This Handbook replaces that reporting requirement with a more narrowly defined reporting requirement. The new procedure set forth in this Handbook allows ORO to focus on

the most serious AEs in research and better assess how such incidents are being reported and managed by investigators and IRBs.

3. SCOPE

a. This Handbook:

(1) Identifies the AEs in research that must be reported to the relevant ORO Regional Office (ORO RO);

(2) Provides the timelines for reporting such AEs; and

(3) Indicates what information must be provided in such reports.

b. In addition to following this Handbook's reporting requirements, VA facilities must continue to follow all other relevant laws, regulations, and policies related to AE reporting (see par. 7). For example, VHA facilities must continue to report "unanticipated problems" and "adverse events" to their IRBs of record and to other oversight agencies such as the Office for Human Research Protections (OHRP), the FDA, and sponsors. It is essential that principal investigators report all research-related incidents to the IRB as required in the facility's IRB SOP, or any Office of Research and Development (ORD) policies on reporting of incidents. The definitions, procedures, and timelines contained in this Handbook pertain solely to the reporting requirements of this Handbook.

4. REPORTING REQUIREMENT GOALS

These reporting requirements are designed to:

a. Facilitate ORO's oversight of AEs in VA research;

b. Specify which AEs are to be reported to ORO, the details to be reported, and the timeline for reporting; and

c. Collect information to provide better oversight, guidance, and support for protecting research subjects and to assist IRBs in taking appropriate actions.

5. DEFINITIONS

a. **Adverse Event (AE) in Research.** An AE in research is defined for purposes of this Handbook as any untoward occurrence (physical, psychological, social, or economic) in a human subject participating in research. An AE in research 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 in research may occur even in the absence of any error or protocol deviation, and does not necessarily have to be caused by any identifiable aspect of the research.

b. **Imminent Threat of an AE in Research.** Any issue in which an AE in research has not yet occurred but is likely to occur, as determined by an IRB, research, or clinical team member, without preventative measures.

c. **Substantive Action.** An action 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 AE in research.

d. **Unexpected Death.** The death of a research subject in which a high risk of death is not projected, as indicated by the written protocol, informed consent form, or sponsor brochure. This definition does not include deaths associated with a terminal condition unless the research intervention clearly hastened 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 of this Handbook.

6. REPORTING REQUIREMENTS

a. Each VHA facility must report to the appropriate ORO RO (see sub. 6b) all AEs in research and imminent threats of AEs in research conducted on site that result in either:

(1) An IRB taking substantive action(s) as defined in subparagraph 5c. A written report of the AE in research (or an imminent threat thereof), and the IRB action(s) to be taken, must be submitted to the ORO RO within 10 working days of the IRB's determination to take such action(s).

Or

(2) An unexpected death of a research subject, regardless of IRB action. Such deaths must be reported to the ORO RO within 24 hours after the IRB determines that the death was unexpected, as defined in subparagraph 5d. If the IRB is unable to determine whether a research subject's death was unexpected after 10 working days of being informed of the death, the death must then be reported to the ORO RO. When a final determination is made as to whether or not the death was unexpected, a follow-up report must be made to the ORO RO.

b. **Written Report.** The institutional official (VHA facility Director), or designee, must:

(1) Prepare a separate report, for each AE in research (or imminent threat thereof) required to be reported by this Handbook, following the format indicated in Appendix A.

(2) Initial the completed report and facilitate its submission to the Director of the ORO RO that oversees the VHA facility, using express mail (e.g., Fed Ex) and either e-mail or fax. A copy of all IRB minutes from meetings in which the AE in research and subsequent actions were discussed, ratified, or summarized needs to accompany the report to the ORO RO, or be sent when the IRB minutes become available, but in no case no later than 4 weeks after the IRB meeting.

7. REFERENCES

a. Title 38 CFR 16.

b. Title 45 CFR 46.

c. Title 21 CFR 56.

d. Title 21 CFR 312.

e. Title 21 CFR 812.

f. VHA Handbook 1200.5.

g. VHA Handbook 1050.1.

Department of Veterans Affairs

ADVERSE EVENTS (AEs) IN VA RESEARCH - REPORT FORMAT

A. REPORTING INSTITUTION

INSTITUTION:	DATE OF THIS REPORT

B. STUDY IN WHICH THE AE OR IMMINENT THREAT OF AN AE IN RESEARCH OCCURRED:

1. STUDY TITLE

1A. STUDY NUMBER		1B. SPONSOR
1C. IND NUMBER		1D. IDE NUMBER
2. STUDY PRINCIPAL INVESTIGATOR (PI)	2A. TELEPHONE NUMBER	2B. E-MAIL ADDRESS

3. IS THIS A MULTI-SITE TRIAL? ☐ YES *(NOTE: Submit report only if AE occurred at your site)*

☐ NO

3A. IF YES, OVERALL PRINCIPAL INVESTIGATOR	3B. TELEPHONE NUMBER

C. INFORMATION ABOUT THE AE OR IMMINENT THREAT OF AN AE IN RESEARCH

1. DESCRIBE INCIDENT

2. CHECK ALL THAT APPLY

☐ AE IN RESEARCH RESULTED IN SUBSTANTIVE CORRECTIVE ACTION BY IRB

TYPE OF AE IN RESEARCH ☐ PHYSICAL ☐ PSYCHOLOGICAL ☐ SOCIAL ☐ ECONOMIC

☐ IMMINENT THREAT OF AE IN RESEARCH RESULTED IN SUBSTANTIVE CORRECTIVE ACTION BY IRB

TYPE OF AE IN RESEARCH ☐ PHYSICAL ☐ PSYCHOLOGICAL ☐ SOCIAL ☐ ECONOMIC

☐ UNEXPECTED DEATH OF A RESEARCH PARTICIPANT

3. DATE OF INCIDENT	3A. DATE PI BECAME AWARE OF INCIDENT
3B. DATE IRB INFORMED OF INCIDENT	3C. DATE OF IRB ACTION *(If any)*

4. PARTICIPANT STATUS

☐ RECOVERED/RESOLVED ☐ NOT RECOVERED/NOT RESOLVED ☐ DEATH

☐ RECOVERING/RESOLVING ☐ RECOVERED WITH SEQUELAE

5. HAVE OTHER AEs IN RESEARCH BEEN REPORTED IN THIS STUDY?

☐ YES ☐ NO

D. SUBSTANTIVE ACTION(S) TAKEN

1. CHECK ALL THAT APPLY

☐ MAJOR CHANGE IN PROTOCOL

☐ MAJOR CHANGE IN CONSENT FORM

☐ MAJOR CHANGE IN CONSENT PROCESS

☐ ADDITIONAL INFORMATION PROVIDED TO ENROLLED SUBJECTS

☐ ADDITIONAL MONITORING OF STUDY

☐ RESTRICTION OF STUDY

☐ SUSPENSION OF STUDY

☐ TERMINATION OF STUDY

☐ RESTRICTION OF INVESTIGATOR PARTICIPATION

☐ SUSPENSION OF INVESTIGATOR PARTICIPATION

☐ TERMINATION OF INVESTIGATOR PARTICIPATION

☐ ACTIONS TAKEN TO PREVENT FUTURE AE

☐ OTHER *(Describe below)*

D. SUBSTANTIVE ACTION(S) TAKEN(Continued)

2. DESCRIBE ACTION(S) TAKEN *(Append IRB minutes in which the substantive actions were discussed, ratified, and /or summarized.)*

3. ARE OTHER ENROLLED SUBJECTS POTENTIALLY EXPOSED TO THIS RISK?
☐ YES ☐ NO IF YES, HAVE THEY BEEN INFORMED ABOUT THIS RISK? ☐ YES ☐ NO

4. NAME OF IRB AND IRB CHAIR

4A. TELEPHONE NUMBER	4B. E-MAIL ADDRESS

E. REPORTING INFORMATION

1. REPORTER	1A. POSITION

1B. TELEPHONE NUMBER	1C. E-MAIL ADDRESS

1D. MAILING ADDRESS

2. OTHER REPORT(S) OF THIS INCIDENT

REPORTED TO	REPORTED BY			DATE
	IRB/INSTITUTION	PI	OTHER (Name/Title)	
☐ MANUFACTURER/SPONSOR	☐	☐	☐	
☐ FOOD AND DRUG ADMINISTRATION	☐	☐	☐	
☐ OFFICE FOR HUMAN RESEARCH PROTECTIONS	☐	☐	☐	
☐ OTHER (Identify)	☐	☐	☐	

COMMENTS

Handbook 1200.7 pages 28-31 concerning investigation and reporting of deficiencies

(f) For each project under consideration, list the first and last name of the principal investigator, and the complete name of the project.

(g) For each new project, the motion passed by the committee (approved, approved pending clarification, deferred, disapproved) must be recorded with the exact vote, which must include the number voting for the motion, the number voting against, and the number abstaining.

(h) Committee deliberations on each project must be reflected in the minutes so that an outside observer can understand the issues discussed, and recognize the specific revisions and clarifications requested for each protocol under consideration. Experience has shown that if IACUC members are asked to provide written or electronic copies of their reviews, their comments can be used to document deliberations and greatly streamline the process of writing the minutes as well as communicating IACUC decisions in writing to investigators.

(i) The minutes must note which members recused themselves for which project(s) to prevent conflicts of interest.

(j) If they are important to understanding the conduct of business, copies of any internal or external reports or correspondence with outside agencies referenced in the minutes need to be attached to the minutes.

(2) Once IACUC minutes are approved at the following meeting, the IACUC Chairperson needs to sign and date them at the bottom. No local official may alter the IACUC minutes once signed by the IACUC Chairperson, and no local official may exert pressure on any IACUC member to change the wording in the minutes to language more favorable to the institution. If requested by the CVMO or other VA Central Office official, complete copies of the signed minutes need to be sent through the ACOS for R&D and the medical center Director. The R&D Committee needs to review a copy of the signed minutes as an item of business, but R&D Committee approval is not necessary prior to sending minutes to ORD for review, i.e., if ORD requests a copy for review.

g. **Mandated Reporting of Deficiencies.** As a condition of extending the privilege of conducting animal research to individual medical centers, VA Central Office expects that the IACUC and institutional administrators will avoid any appearance of hiding or suppressing deficiencies. ***NOTE:*** *This goal is best achieved by prompt reporting of deficiencies before others outside of the program do so. Consistent with NIH Notice NOT-OD-05-034 dated 2/24/05, "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals," facilities should notify appropriate agencies by phone immediately that a full, written account of a reportable deficiency is forthcoming.*

(1) The main categories of deficiencies that must be reported to outside authorities and the elements needed in the report are as follows:

(a) Any serious or continuing non-compliance with PHS Policy (including any serious deviation or continuing non-compliance with the provisions of the Guide, as required by the PHS Policy) or USDA AWAR. The report needs to include:

1. When and how the IACUC became aware of the problem.

2. When the investigation was performed to determine facts and detail the circumstances that led to the non-compliance.

3. The results of that investigation, and

4. What corrective actions the IACUC approved to stop the noncompliant activity and prevent future recurrences.

(b) Suspensions of protocols previously approved or suspensions of procedures or studies never given approval (see subpar. 8h). The report needs to include:

1. When and how the IACUC became aware of the problem.

2. When the investigation was performed to determine facts and detail circumstances that lead to the non-compliance,.

3. The results of that investigation.

4. When the IACUC convened a quorum to suspend the activity.

5. What corrective actions the IACUC approved to prevent recurrences.

(c) Failure to correct a significant deficiency (identified during a semi-annual IACUC program or facility self-assessment review) according to the schedule approved by the IACUC.

(2) The report needs to include:

(a) The date when the IACUC identified the deficiency.

(b) The timetable and plan approved for correction.

(c) Why the correction(s) could not be completed according to the timetable,.

(d) The revised timetable.

(e) The plan to finish the correction(s).

(3) The USDA AWAR (see 9 C.F.R. §2.31[c][3]) states that the failure to correct a significant deficiency must be reported in writing within 15-business days of the self-imposed deadline by the IACUC, through the Institutional Official, to USDA and any Federal agency funding that activity. This required 15-business day reporting period is extended to cover all categories of reportable deficiencies. ***NOTE:*** *Consistent with NIH Notice NOT-OD-05-034 dated 2/24/05, "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals," facilities should notify appropriate agencies by phone immediately that a full, written account of a reportable deficiency is forthcoming.*

(4) Although an ORD veterinary hold (see subpar. 4d) is not considered an IACUC suspension, it must be reported to other Federal agencies if the IACUC and IO find that information in the ACORP represents a reportable deficiency as defined in subparagraph 8g(1).

(5) Deficiencies meeting any of the criteria in subparagraph 8g(1) must be reported in writing within 15 business days through the ACOS for R&D and the medical center Director to the following agencies and offices:

(a) ORD (by contacting the CVMO's office).

(b) OLAW, as required by PHS Policy.

(c) The Animal Care Section at USDA APHIS, as required by AWAR, if the deficiency involves a species meeting the definition of an animal in the AWAR, or if the deficiency impacts the care or use of such a species.

(d) AAALAC, as required by AAALAC rules of accreditation.

(e) The affiliate's IACUC, if a joint IACUC is not present and the project involves animals purchased with funds awarded to the affiliate, or if an agreement between the VA and affiliate requires such notification.

(f) The VA ORO, as required by ORO policy.

(g) Any Federal agency (other than the VA) funding an activity that has been suspended.

h. **Suspension of Projects.** The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the Principal Investigator (PI) and approved by the IACUC. It may also suspend any animal procedures not approved by the IACUC. Unless the IO has granted additional authority, the IACUC may suspend an activity only after review of the matter at a properly-convened IACUC meeting and with the suspension vote by a majority of a quorum.

i. **Investigation of Allegations of Improper Animal Care or Use.** All internal and external allegations of improper animal care and use at a medical center must be reviewed promptly by the IACUC, and investigated if warranted. A written report of the review or investigation needs to be approved by a majority of a convened IACUC quorum and sent to the medical center Director through the ACOS for R&D.

(1) If preliminary findings suggest that an allegation does indeed represent a reportable deficiency as defined in subparagraph 8g, the agencies and/or groups listed in subparagraph 8g(5) must be contacted as indicated in paragraph 8g(4).

(2) **Contact with CVMO**. If local efforts to correct deficiencies have proven inadequate, individuals may contact the CVMO directly to discuss concerns, solicit guidance, or seek information without requesting or receiving local permission to do so (see subpar. 6d).

j. **Reports.** The following reports and correspondence must be forwarded to the CVMO's office or ORD, as indicated:

(1) **USDA Annual Report of Research Facility.** This report (required by the USDA Animal Welfare Act Regulations and Standards, see Sec. 2.36) must be completed and submitted to ORD by November 15 each year as a component of Part II of the Research and Development Information System (RDIS). The forms are collected by ORD and sent to the appropriate USDA sector office. A copy of each form is also sent to the CVMO's office by ORD. Species not covered by the definition of an "animal" by USDA AWAR should not be included on this form. Instead, such animals should be reported on the VMU Annual Report (see subpar. 8j[4]).

(2) **AAALAC Reports.** Every third year a comprehensive AAALAC Program Description must be completed prior to the scheduled triennial AAALAC site visit (see Sec. 4, par. B), and annually, an abbreviated report also must be submitted to AAALAC (see Sec. 1, par. f).

(a) The triennial Program Description should not be submitted to ORD or the CVMO, unless a copy is requested.

(b) A copy of each annual report and all correspondence to and from AAALAC (minus the triennial Program Description) must be submitted to the CVMO and ORO no later than 30 days after submission to AAALAC, or receipt from AAALAC.

(3) **IACUC Semi-Annual Self-Assessment Reviews.** Semi-annual Self-assessment Reviews must be prepared by the IACUC as described in subparagraph 8d(1). No later than 60 days after the self-assessment review date, a copy of the approved report signed by a majority of IACUC members and the medical center Director must be forwarded to the CVMO's office through the ACOS for R&D and the medical center Director.

(4) **Annual VA VMU Report.** An annual VA VMU Report for the previous fiscal year must be completed using the website designed for that purpose by January 15. In contrast to the USDA Annual Report of Research Facility described in preceding subparagraph 8j(1), all animal species used must be included in the Annual VMU Report. Instructions for properly completing this report can be obtained from the CVMO.

(5) **PHS Assurances and Annual Assurance Updates**

(a) A PHS Assurance to conduct animal studies is required.

(b) New PHS Assurances and annual updates must be forwarded to the CVMO's office within 30 days of submission to PHS.

(6) **Correspondence.** A copy of all correspondence between OLAW, USDA, AAALAC and VA facilities must be forwarded to the CVMO and ORO within 15 business days of receipt or mailing.