Department of Veterans Affairs

Memorandum

Date: FEB 2 1 2007

From: Acting Under Secretary for Health (10)

Subj: Certification of Oversight of Veterans Health Administration (VHA) Research (WebCIMS 373445)

To: Medical Center Directors
VISN Directors

1. VHA policy requires that medical center Directors exercise a number of specific, substantive responsibilities related to the oversight of research at their facilities.

2. The Office of Research Oversight (10R) has developed the attached Certification of Research Oversight and Research Oversight Checklist to assist medical center Directors in verifying that these responsibilities have been satisfied.

3. I am directing that the Director of each VHA facility conducting research forward the attached Certification and Checklist, through the VISN Director, to the appropriate ORO Regional Office no later than July 1 annually.

4. ORO Regional Offices will be available to answer questions from, and provide assistance to, medical center Directors as they prepare their Certifications.

5. ORO Regional Offices will also conduct followup to ensure that any actions needed to ensure completion of these responsibilities are implemented in a timely fashion.

6. I appreciate your continued commitment to VHA research and to ensuring that your facility's research satisfies the highest ethical and regulatory standards.

Michael J. Kussman

Michael J. Kussman, MD, MS, MACP

Attachments:

Facility Director's Annual Certification of Research Oversight
Facility Director's Research Oversight Checklist

cc: Acting Principal Deputy Under Secretary for Health (10A)
Deputy Under Secretary for Health for Operations and Management (10N)
Chief Research Oversight Officer (10R)
Chief Research and Development Officer (12)

Veterans Health Administration (VHA)
Facility Director's Annual Certification of Research Oversight

1. ☐ As Director of this VHA Facility, I acknowledge my responsibility for oversight of the Facility's research program. I am the Institutional Official responsible for the Facility's compliance with all federal and VA research oversight requirements.

2. ☐ I certify that I have appointed the required research oversight personnel and committees in writing and in accordance with VHA requirements; **or**
   ☐ I have implemented the attached Action Plan, including timelines for completion.

3. ☐ I certify that the Facility maintains (a) all required programs, plans, and standard operating procedures (SOPs) for research compliance; and (b) documentation that these programs, plans, and procedures are current, accurate, and complete; **or**
   ☐ I have implemented the attached Action Plan, including timelines for completion.

4. ☐ I certify that the Facility's research oversight programs have sufficient resources and administrative support to maintain active fulfillment of their responsibilities; **or**
   ☐ I have implemented the attached Action Plan, including timelines for completion.

5. ☐ I certify that (a) Facility research personnel have received all required research compliance training, and (b) all training and credentialing requirements have been fulfilled and documented; **or**
   ☐ I have implemented the attached Action Plan, including timelines for completion.

6. ☐ I certify that all of the Facility's required research assurances, authorizations, accreditations, and memoranda of understanding (MOUs) are current, accurate, and complete; **or**
   ☐ I have implemented the attached Action Plan, including timelines for completion.

7. ☐ I certify that I have (a) performed the required reviews of annual and/or semi-annual program assessments and other research oversight reports; (b) submitted all required reports to oversight and accreditation agencies in a timely fashion; and (c)
   ☐ implemented the attached Action Plans, including timelines for completion; **or**
   ☐ identified no deficiencies warranting correction in these assessments and reports.

Signature of Facility Director: Date:

Name of Facility Director:

Name of Facility:

Station Number: VISN Number:

NOTE: This Certification and the attached ***VHA Facility Director's Research Oversight Checklist*** should be forwarded, through the VISN Director, to the appropriate ORO Regional Office no later than July 1 annually.

Veterans Health Administration (VHA)
Facility Director's Research Oversight Checklist
(Submit with Annual Director's Certification)

1. I am the Institutional Official responsible for the Facility's compliance with all federal and VA research oversight requirements. (NA = Not Applicable)

   ☐ I am responsible for ensuring compliance in research with all requirements for:
   - ☐ Security against terrorist events.
   - ☐ Inquiries and Investigations of alleged Research Misconduct.
   - ☐ Safety and control of infectious agents and radioactive materials. **NA** ☐
   - ☐ Protection of human research subjects. **NA** ☐
   - ☐ Care and use of laboratory animals. **NA** ☐
   - ☐ Control and security of hazardous agents (including select agents and toxins). **NA** ☐
   - ☐ Granting access to research areas in which hazardous agents are used or stored. **NA** ☐
   - ☐ Research involving recombinant DNA (rDNA). **NA** ☐

   ☐ I am responsible for all required reporting to and correspondence with:
   - ☐ Federal oversight offices and agencies.
   - ☐ Applicable accreditation organizations.

   ☐ I am responsible for reporting to the VHA Office of Research Oversight (ORO):
   - ☐ Serious or continuing noncompliance in research.
   - ☐ For-cause suspensions or terminations of research.
   - ☐ Initiation and closure of Research Misconduct Inquiries and Investigations.
   - ☐ Adverse events resulting in substantive Institutional Review Board (IRB) action. **NA** ☐
   - ☐ Adverse events resulting in the unexpected death of a human research subject. **NA** ☐
   - ☐ Unanticipated problems resulting in substantive IRB action. **NA** ☐
   - ☐ Any incident that seriously affects the health or safety of laboratory animals. **NA** ☐

   ☐ I am an *ex officio,* non-voting member of the R&D Committee and have attended R&D Committee meetings as appropriate. **NA** ☐

2. I certify that I have appointed, or ensured the appointment of, the required research oversight personnel and committees in writing and in accordance with VHA requirements.

   ☐ Associate Chief of Staff for Research (ACOS/R) or ☐ Facility Research Coordinator (FRC).
   ☐ Permanent Research Integrity Officer (RIO) for Research Misconduct.
   ☐ R&D Committee Chair (1-year renewable term) and members (staggered 3-year renewable terms) who reflect the Facility's research program. **NA** ☐
   ☐ IRB Chair (1-year renewable) and members (3-year renewable). **NA** ☐
   ☐ Institutional Animal Care and Use Committee (IACUC) Chair (1-year renewable) and members (3-year renewable). **NA** ☐
   ☐ Subcommittee on Research Safety (SRS) Chair (1-year renewable) and members (specified terms required). **NA** ☐
   ☐ Alternative Responsible Official (ARO) or AROs with specified duties related to control of hazardous agents in research laboratories. **NA** ☐
   ☐ Representatives to academic affiliate committees. **NA** ☐
   ☐ I have ensured the appointment of:
   - ☐ Research Misconduct Inquiry/Investigation Committee members. **NA** ☐
   - ☐ Radiation Safety Officer. **NA** ☐
   - ☐ Research Safety Coordinator. **NA** ☐
   - ☐ Biological Safety Officer (BSL-3 rDNA rsch; rDNA rsch with viable organisms). **NA** ☐

3. I certify that the Facility maintains (a) all required programs, plans, and standard operating procedures (SOPs) for research compliance; and (b) documentation that these programs, plans, and procedures are current, accurate, and complete.

   - ☐ Human Research Protection Program (HRPP). **NA** ☐
   - ☐ Animal Care and Use Program (ACUP). **NA** ☐
   - ☐ Research Safety and Security Program (RSSP). **NA** ☐
     - ☐ Research Safety Program. **NA** ☐
       - ☐ Chemical Hygiene Plan. **NA** ☐
     - ☐ Hazardous Agents / Select Agent Control Program. **NA** ☐
       - ☐ Safety (Biosafety) Plan (Research Service-Wide Safety Manual). **NA** ☐
       - ☐ Security Plan (Site-Specific). **NA** ☐
       - ☐ Emergency Preparedness and Incident Response Plan. **NA** ☐
       - ☐ Personnel access to select agents or toxins approval by the Animal and Plant Health Inspection Service (APHIS) or the Centers for Disease Control and Prevention (CDC) based on Security Risk Assessment. **NA** ☐
     - ☐ All Other Facility Safety Programs (cover all research personnel and space). **NA** ☐
   - ☐ Research Service Education Plan. **NA** ☐
   - ☐ Animal Facility Disaster Plan. **NA** ☐
   - ☐ Facility Self-Certification and Non-Profit Corporation (NPF) Accountability Plan
   - ☐ SOPs for Financial Conflicts of Interest in Research. **NA** ☐
   - ☐ SOPs for R&D Committee. **NA** ☐
   - ☐ SOPs for the IRB. **NA** ☐
   - ☐ SOPs for the IACUC. **NA** ☐
   - ☐ SOPs for the SRS. **NA** ☐
   - ☐ SOPs for other R&D Subcommittees. **NA** ☐
   - ☐ SOPs for Destruction of Select Agents and Toxins, including Exempt Quantities. **NA** ☐
   - ☐ BSL-3 Laboratory Safety Manual. **NA** ☐
   - ☐ SOPs for Research Misconduct (optional). **NA** ☐

4. I certify that the Facility's research oversight programs have sufficient resources and administrative support to maintain active fulfillment of their responsibilities, including sufficient personnel, space, equipment, engineering support, and technical assistance.

   - ☐ As applicable: HRPP, ACUP, RSSP, Hazardous Agents Control Program, Occupational Safety and Health Program, and Research Integrity Program.
   - ☐ As applicable: R&D Committee, IRB, IACUC, SRS, other R&D Subcommittees, Research Misconduct Inquiry/Investigation Committees, and other research oversight entities.

5. I certify that (a) all Facility research personnel have received required research compliance training, and (b) all training and credentialing requirements have been documented for:

   - ☐ All research investigators and study coordinators, laboratory animal personnel (where applicable), relevant administrative staff, and relevant support staff.
   - ☐ RIO (and Research Misconduct Inquiry/Investigation Committee members as needed).

- ☐ All relevant individuals to ensure knowledge of responsibilities for reporting:
  - ☐ Loss or compromise of keys, passports, combinations, etc.
  - ☐ Suspicious persons or activities.
  - ☐ Loss, release, or theft of select agents or toxins. **NA** ☐
  - ☐ Alteration or compromise of inventories or records for select agents or toxins. **NA** ☐
- ☐ Facility Director for Federalwide (Human Subject) Assurance (FWA). **NA** ☐
- ☐ ACOS/R (or FRC) and Administrative Officer for Research (AO/R). **NA** ☐
- ☐ R&D Committee and applicable Subcommittee members (e.g., IRB, IACUC, SRS). **NA** ☐
- ☐ All persons administering, working in, or (as warranted) visiting research laboratories to:
  - ☐ Ensure safety and security of select agents, toxins, and other hazardous agents. **NA** ☐
  - ☐ Convey the laboratory's Emergency Preparedness and Response Plan. **NA** ☐

6. I certify that all of the Facility's required research assurances, authorizations, accreditations, and memoranda of understanding (MOUs) are current, accurate, and complete.

   - ☐ FWA and IRB registration(s). **NA** ☐
   - ☐ Public Health Service (PHS) Animal Welfare Assurance. **NA** ☐
   - ☐ Accreditation by Association for the Accreditation of Human Research Protection Programs (AAHRPP) or the National Committee on Quality Assurance (NCQA). **NA** ☐
   - ☐ Accreditation by the Associate for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). **NA** ☐
   - ☐ Certificate(s) of Registration from APHIS or CDC for use or storage of select agents or toxins. **NA** ☐
   - ☐ Verification that other entities with which the Facility conducts human research hold appropriate human protection Assurances. **NA** ☐
   - ☐ Approval of the Chief Research and Development Officer (CRADO) for research involving:
     - ☐ Children. **NA** ☐
     - ☐ Prisoners. **NA** ☐
     - ☐ Access to VA records by non-VA employees. **NA** ☐
     - ☐ International research involving human subjects, human biological specimens, or human data. **NA** ☐
   - ☐ Authorization from the Under Secretary for Health (USH) for research invoking the Common Rule exemption for research involving public benefit or service programs. **NA** ☐
   - ☐ Approval of the Chief Veterinary Medical Officer in the VHA Office of R&D for any animal facility construction or renovation costing over $100,000. **NA** ☐
   - ☐ MOU(s) for the use of another entity's HRPP, ACUP, R&D Committee, IRB, IACUC, SRS, or other research oversight program or committee. **NA** ☐
   - ☐ Cooperative R&D Agreements (CRADAs) other written agreement(s) for collaborative research projects or research oversight arrangements. **NA** ☐

7. I certify that I have (a) performed the required review of annual and/or semi-annual program assessments and other research oversight reports; (b) submitted all required reports to oversight and accreditation agencies; and (c) implemented Action Plans to remedy any identified noncompliance by the Facility with federal or VA research oversight requirements.

   - ☐ Verification that all research involving sensitive or protected information has been reviewed by the IRB, Privacy Officer, and/or Information Security Officer (ISO).

Veterans Health Administration (VHA)
Facility Director's Research Oversight Checklist

- ☐ Verification that all research databases are compliant with Federal Information Processing Standards (FIPS) and VA Information Technology (IT) standards.
- ☐ Verification that all laptops used for research are encrypted and compliant with FIPS and VA IT standards.
- ☐ Annual Certification of Research Information Security Requirements.
- ☐ Submission in a timely fashion of all required reports to oversight and accreditation bodies.
- ☐ Review and Discussion by Director of:
  - ☐ Annual R&D Committee Program Review, including:
    - ☐ Review and recommendations regarding budgetary and resource needs.
    - ☐ As applicable: Review of the HRPP, ACUP, RSSP.
    - ☐ Review of all R&D Subcommittees (internal and external).
    - ☐ Review of compliance with relevant credentialing, training, and personnel requirements, including Without Compensation (WOC) requirements.
    - ☐ Quality Assurance (QA) review of publications listing VA support and affiliation.
    - ☐ QA review of CRADAs. **NA** ☐
  - ☐ Semi-Annual Inventory of Hazardous Agents. **NA** ☐
  - ☐ Semi-Annual IACUC Program and Facility Self-Assessment. **NA** ☐
  - ☐ IACUC reports on allegations of improper animal care and use. **NA** ☐
- ☐ Receipt and Review by Director of:
  - ☐ Meeting Minutes for R&D Committee and all R&D Subcommittees.
  - ☐ Research Misconduct Inquiry and Investigation Committee recommendations and reports. **NA** ☐
  - ☐ Annual audit of Non-Profit Research Corporation (NPC) financial practices. **NA** ☐
  - ☐ Annual Vulnerable Assessments of all research laboratories. **NA** ☐
  - ☐ Annual safety inspections and annual emergency preparedness and response drill to evaluate the Facility Safety Plan. **NA** ☐
  - ☐ Annual compliance inspection of each laboratory with select agents or toxins. **NA** ☐
  - ☐ Annual SRS review and R&D Committee Approval of Service-wide Safety Manual. **NA** ☐
  - ☐ Annual Occupational Safety and Health inspection of research space. **NA** ☐
  - ☐ USDA Annual Report of Research Facility. **NA** ☐
  - ☐ Annual VA Veterinary Medical Unit Report. **NA** ☐
  - ☐ Semi-Annual Review of status of persons authorized to enter areas where select agents or toxins are used or stored. **NA** ☐
  - ☐ Reports of monitoring programs to ensure the safety of research subjects. **NA** ☐
- ☐ Submission of Research Misconduct Inquiry and Investigation Reports and Director's recommendations to VISN Director. **NA** ☐
- ☐ Implementation of Action Plans to correct identified noncompliance with VHA or other federal research oversight requirements. **NA** ☐

Signature of Facility Director: Date:

Name of Facility Director:

Name of Facility:

Station Number: VISN Number: