Department of Veterans Affairs

Memorandum

Date: JAN 09 2009

From: Under Secretary for Health

Subj: Requirement for a Full-time Research Compliance Officer

To: VISN Director (10N1 – 23)
Medical Center Director (00)

1. On October 16, 2008, the Veterans Health Administration (VHA) published VHA Directive 2008-064, (Research Compliance Officers and the Auditing of VHA Human Subjects Research to Determine Compliance with Applicable Laws, Regulations, and Policies), which requires that the Director of each VHA facility conducting human subjects research appoint a full-time Research Compliance Officer (RCO). This is also included in the Fiscal Year 2009 Executive Career Field Performance Contract. The requirement to appoint a full-time RCO was established to ensure that each Department of Veterans Affairs (VA) approved research protocol involving human research subjects is completely audited at least once every 3 years for compliance with all applicable regulations and policies. It further requires that if the Institutional Review Board (IRB) of record has not waived the requirement to obtain an informed consent, this aspect of the protocol must be audited annually.

2. Implementing the requirement for a full-time RCO may place a burden on the facility's resources for VHA facilities conducting a small number of human subjects research protocols. Therefore, consideration will be given on a case-by-case basis to allow the position of RCO to be either part-time or combined with other related duties. If an individual case is approved, the VA facility must still meet all other requirements of VHA Directive 2008-064.

3. To request a waiver for the requirement for a VHA facility to have a full-time RCO, the facility Director must initiate the request and send it through the Veterans Integrated Service Network Director for concurrence prior to the request being sent to Central Office. Copies of the request must be sent to both the Chief Research and Development Officer (CRADO) and the Chief Officer, Office of Research Oversight (ORO). The CRADO and the Chief Officer ORO will review the request and make a recommendation for approval or disapproval. This recommendation will then be forwarded to the Deputy Under Secretary for Health for Operations and Management and then the Principal Deputy Under Secretary for Health for concurrence; prior to being sent to the Under Secretary for Health for approval or disapproval.

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Requesting a Waiver from the Requirements for a Full Time Research Compliance Officer

To obtain a waive from the requirements for a full-time Research Compliance Officer (RCO) at a facility conducting human subjects research, the facility Director through the VISN Director must submit a memo addressed to the Under Secretary for Health through the Principal Deputy Under Secretary for Health, and the Deputy Under Secretary for Health for Operations and Management. The memo and the applicable attachments must be sent to the Officer of Research and Development, Chief Research and Development Officer with a complete copy to the Office of Research Oversight (ORO), Chief Officer. The request must include the following:

1. Description of the research program at the facility.

    a. Total number of protocols and the number of protocols involving human subjects and , animals,
    b. Information on other types of research such as serving as a research coordinating center or reference laboratory conducted at the facility and the justification;
    c. Total number of investigators and list how many investigators are likely to be involved in each of the following areas: human subjects research, animal research and other types of research;
    d. What types of appointments (compensated and number of 8ths, work without compensation, or appointed or detailed under the Intergovernmental Personnel Act are held by the investigators and how many hold each of those appointments;
    e. Current arrangements for the facility's Institutional Review Board (IRB) of record and Research and Development (R&D) Committee,
    f. Size of the facility (number of hospital beds etc.);
    g. Discussion on the organization and structure of your Human Research Protection Program (HRPP) and the accreditation status of your HRPP; and
    h. Type of infrastructure (physical and personnel such as Research Office personnel, other compliance officers, IRB administrations, etc.) provided to support the research program.

2. Justification for such a request.

3. The proposed position description for the RCO including all the responsibilities of the proposed part-time RCO (both research compliance and non-research compliance).

4. Certification that the facility will comply with VHA Directive 2008-064 and all other applicable VHA research policies.

Please refer to either the ORD or ORO Web sites at http://vaww.research.va.gov or http://vaww1.va.gov/oro.