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Memorandum

Date: June 4, 2012
From: Chief Officer, Office of Research Oversight (ORO) (10R)
Subj: Annual Facility Director's Certification of Research Oversight for 2012
To: VHA Facility Directors and VHA Network Directors

Effective February 21, 2007, the Veterans Health Administration (VHA) requires that each Facility Director annually certify oversight of the facility's research program.

1. The 2012 Certification Checklist, which may be downloaded by your facility's staff, is available at: http://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/2012%20Facility%20Directors%20Certification%20of%20Research/Forms/AllItems.aspx.

2. ORO's Research Compliance Education Program (RCEP) staff will be available to answer questions and provide assistance related to this year's Certification Checklist. Please send questions to ORORCEP@VA.GOV.

3. Section I, "Awareness of Facility Director's Research Responsibility" and Section II, "Checklist of Research-Related Requirements" are provided for your review and facility use in assessing your research program. ORO encourages you to use these checklists to review your research-related responsibilities and as a tool for identifying any existing gaps and/or possible opportunities for improvement in your facility's research program. Any compliance deficiencies that are not corrected by July 31, 2012 should be reported along with your corrective action plan at the end of Section IV of the electronic Facility Director's Certification form. This is in addition to, but does not replace, the reporting requirements described in VHA Handbook 1058.01.

4. Submission of this year's certification must done electronically using the electronic reporting form found at the link above. The electronic reporting form must be completed, approved as desired by the Network Director, and electronically submitted to ORO by July 31, 2012. The required submission includes the following sections of this year's Facility Director's Certification:
   a. Section III: "Annual Summary of Informed Consent Audits"
   b. Section IV: "Annual Summary of Triennial Regulatory Audits"
   c. Section V: "Certification and Signature"
   d. Action Plans and Timelines to address any uncorrected deficiencies (include if needed in Section IV)

5. **For 2012, a copy of the most recent annual summary of reviews and evaluations of the research program received by the Facility Director from the Research and Development Committee must be submitted with the Certification as an attachment to the electronic reporting form. Documents may be submitted in whatever format is used locally.**

6. ORO will conduct follow up to approve remedial actions and timelines and ensure that remedial actions are completed in a timely fashion.

7. Thank you for your continued commitment to ensuring that your facility's research program satisfies the highest ethical and regulatory standards.

J. Thomas Puglisi, PhD

cc: Under Secretary for Health (10)
Principal Deputy Under Secretary for Health (10A)
Deputy Under Secretary for Health for Operations and Management (10N)