

Department of
Veterans Affairs

JAN 7 2005

Memorandum

Date:

From: Acting Chief Research and Development Officer (12)
Chief Officer, Office of Research Oversight (10R)

Subj: Checklist for Use in Developing a Memorandum of Understanding (MOU) between a VA Facility and an Affiliated Medical or Dental School for Use of the Institutional Review Board (IRB)

To: Directors of VA Facilities Holding Federalwide Assurances

1. The Office of Research and Development (ORD) and the Office of Research Oversight (ORO) have jointly developed a checklist for use in the development of a Memorandum of Understanding (MOU). The MOU is a required supplement to the VA Federalwide Assurance (FWA) that is issued by ORO and the Office for Human Research Protections (OHRP) for institutions that use the IRB of an affiliate university or another VA facility. The MOU formalizes the responsibilities of each signatory for the protection of human subjects at their institution. The MOU also is reviewed during the accreditation process as part of the Institutional Responsibilities (INR) accreditation standards.
2. The Checklist provides guidance on issues to be considered and documented by representatives of the VA facility and the affiliate when developing arrangements to share certain responsibilities for protection of human subjects in VA-conducted or supported research. Our hope is that this guidance will facilitate meaningful discussions between the two facilities. This document has two sections. The first section of the Checklist describes elements that should be discussed and included in the MOU. The second section is an addendum to the Checklist that provides elements for discussion specifically related to accreditation of the institutions signing the MOU. There are four separate checklists in the second section, one or more of which may apply to your VA facility.
3. ORO and ORD are interested in your comments on the Checklist and are prepared to make revisions to the document that will make it more useful. Please provide your comments on Section 1 of the Checklist to Priscilla Craig in ORO. Comments on the Addenda should be sent to Lynn Cates, MD, in ORD.



Stephan Fihn, MD, MPH



David A. Weber, PhD, FACNP

Attachments

cc: ACOS/R&D and Research Coordinators