

**Department of
Veterans Affairs**

Memorandum

Date: SEP 23 2004

From: Acting Chief Research and Development Officer (12)

Subj: Institutional Review Board (IRB) Arrangements: Serving as the IRB of Another Facility or Institution

To: Associate Chief of Staff for Research and Development, VA Medical Centers (151)
Thru: Medical Center Director (00)
Thru: Chief of Staff (11)

1. The purpose of this memorandum is to clarify VHA policy on appropriate IRB arrangements and to request that each VA facility conducting research involving human subjects review its IRB arrangements for compliance with current policy. Paragraph 4 describes actions that must be taken if your facility is not in compliance.
2. VHA Handbook 1200.5 "Requirements for the Protection of Human Subjects in Research," sets forth VHA policy on this issue. VHA policy requires that every VHA facility that conducts research involving human subjects have an established or designated IRB of record. The VHA facility may secure the services of an Office for Human Research Protections (OHRP) registered IRB(s) associated with another VA facility or a VA regional IRB. It may also secure the services of an IRB(s) that is established by its affiliated university with a medical or dental school. Under exceptional circumstances a VA facility may request a waiver from the Chief Research and Development Officer to utilize the services of an IRB within another Federal agency that is signatory to the Federal Policy for the Protection of Human Subjects (the Common Rule). All IRB arrangements must be formalized by a written agreement such as a memorandum of understanding (MOU) that outlines each institution's responsibility.
3. A VHA IRB may only serve as the IRB of record for another VA facility, or for a VA nonprofit research and education foundation. The VA IRB may not review research that is conducted at non-VA facilities by non-VA investigators.
4. It is the responsibility of the VHA IRB(s) of record to review all VHA human subject research prior to its initiation either through full or expedited review, unless the research has been exempted from IRB review in compliance with Handbook 1200.5. This responsibility cannot be fulfilled through the use of Cooperative agreements described in 38 CFR 116.114 or joint review arrangements.
4. If you find that your facility is not in compliance contact the Office of Research Oversight for assistance in developing appropriate arrangements and, if needed, in formalizing your

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current arrangements through a written agreement such as an MOU. Specifically, areas of non-compliance that must be addressed include:

- a) Your IRB's serving as the IRB of record for a non-VA institution,
- b) Your facility's utilizing an IRB as your IRB of record that is not allowed by VHA policy, or
- c) Your IRB arrangements have not been formalized by a written agreement such as an MOU. *Note: If they have not contact the Office of Research Oversight.*

5. If you have any questions concerning this issue please contact K. Lynn Cates, M.D. (phone: (202) 254-0282, e-mail: lynn.cates@hq.med.va.gov) or Brenda Cuccherini, Ph.D. (phone: (202) 254-0277, e-mail: Brenda.cuccherini@hq.med.va.gov) within the Office of Research and Development.



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