Department of Veterans Affairs

Memorandum

Date: JAN 7 2005

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.

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David A. Weber, PhD, FACNP

Attachments

cc: ACOS/R&D and Research Coordinators

Checklist for VAMC Memorandum of Understanding with Affiliated Medical or Dental School

VA Facility Agrees to:		University Affiliate Agrees to:
1a.	Adhere to the federal regulations as codified in 38 CFR 16 & 17; 45 CFR 46 Subpart A, 21 CFR 50 & 56; other pertinent federal regulations and guidance; and VA policies. All VA policies apply, i.e., VA cannot waive policy *requirements*.	1b. Adhere to the federal regulations as codified in 38 CFR 16 & 17; 45 CFR 46 Subpart A or Subparts A-D, 21 CFR 50 & 56; other pertinent federal regulations and guidance; and VA and university policies applicable to *human subjects research*.
2a.	Provide access to research subjects clinical records and/or case file to IRB as required for monitoring research activity. This includes any IRB member or designate.	2b. Provide access or provide requisite information from IRB database to approved representatives of the VA for the purposes of tracking ongoing VA research activity.
3a.	Assure that the R&D Committee considers the IRB review, and provides initial approval prior to the conduct of covered VA human subjects research. Work with the affiliate to develop mutually acceptable policies for monitoring human research, and for providing regular communication of results of this monitoring, and other documentation of human subjects research to the R&D Committee. Work with the affiliate to establish a description of the method and frequency of the affiliate's providing information including minutes, correspondence, and reports of quality improvement activities to the VA R&D Committee. Establish a definition of "timely" provision of such documentation. Provide information to the IRB about significant issues that come to light in the VA approval process that might affect the conduct of a protocol.	3b. Develop mutually acceptable policies for monitoring human subjects research, and for regular communication of results of this monitoring, and other documentation of human subjects research to the R&D Committee. Work with the VA to establish a description of the method and frequency of the affiliate's providing *information including minutes, correspondence, and* reports of quality improvement activities to the VA R&D Committee. Establish a definition of "timely" provision of such documentation.
4a.	Provide access and training to IRB re: VA policies and procedures that govern the VA Human Research Protection Program (HRPP) processes and determinations.	4b. Provide training to VA staff and investigators as appropriate for compliance with affiliate IRB policies and submission procedures as they apply to VA submissions.
5a.	Maintain current written Standard Operating Procedures that incorporate procedures for reviewing and approving VA human subjects research. These procedures can be separate in each institution or shared as one document.	5b. Maintain an IRB SOP that incorporates, either by inclusion or reference, VA policies and procedures applicable to reviewing VA human subjects research.
6a.	Promptly inform the IRB of any problems, including complaints, and serious/unanticipated events, encountered in VA human subjects research. *(Note: Specificity about this process is required.)*	6b. Promptly inform the VA of any issues or complaints associated with VA research. This includes serious/unanticipated adverse event reports observed in VA research.

	VA Facility Agrees to:		University Affiliate Agrees to:
7a.	Nominate representation on the IRB(s) that reviews VA research. At least two members (and alternates when possible) must be appointed to any IRB that is an IRB of record for VA research. VA representatives must be VA salaried for at least 5/8 FTEE. At least one member must have scientific expertise. They must be full voting members of the IRB (i.e., review all protocols, not just VA protocols). An R&D Committee representative is strongly encouraged. A VA voting member must be present during full board review of VA research.	7b.	Appoint VA representation to each IRB that is an IRB of record for VA research protocols. At least two members (and alternates when possible) must be appointed to each IRB that evaluates VA research. VA representatives must be VA salaried for at least 5/8 FTEE. At least one member must have scientific expertise. They must be full voting members of the IRB (i.e., review all protocols, not just VA protocols). An R&D Committee representative is strongly encouraged. A VA voting member must be present during full board review of VA research.
8a.	Promptly notify the IRB of any modifications to the VA FWA or changes to the status of the Assurance documents. (FWA in Appendix)	8b.	Promptly notify the VA of any changes to the Affiliate's Assurance status. (FWA in Appendix)
9a.	VA will not enter into collaboration with any Institution that does not have a Federalwide Assurance (FWA). VA will only use as its IRB(s) of record IRB(s) of entities that have FWAs.	9b.	Institution operating the IRB will maintain a current FWA. The affiliate agrees that it will not involve the VA in any activities with its collaborators that do not have FWAs.
10a.	Develop SOPs that detail how compliance monitoring, audits, and reporting to appropriate regulatory authorities will be handled by administrative officials, compliance officer(s), and the IRB and its administrators. Provide the results of any external monitoring or audits of research activity to the IRB. This includes visits by sponsors and regulatory/compliance bodies.	10 b.	Develop SOPs that detail how compliance monitoring, audits, and reporting to appropriate regulatory authorities will be handled by administrative officials, compliance officer(s), and the IRB and its administrators. Report the results of any external monitoring or audits of research activity at the university that impact upon VA research or the status of the VA HRPP. This includes visits by sponsors and regulatory/ compliance bodies.
11a.	Actively cooperate with the affiliate in both VA and affiliate HRPPs in resolving any problems encountered in either HRPP. Termination of this agreement with the university will be in an orderly manner so as not to harm subjects or put subjects at risk. (Note: Describe specific remedies available if the designated IRB does not fulfill its obligations.)	11b.	Actively cooperate with the VA in resolving any problems encountered in either HRPP, and, if this fails, terminate this agreement with the VA in an orderly manner so as not to harm subjects or put subjects at risk.
12a.	Assure that all key VA personnel engaged in research meet both VA and IRB training requirements and that there is a tracking system.	12b.	Ensure that all IRB members and Chairs have received the appropriate training as IRB members. Facilitate training that will ensure IRB members are knowledgeable about applicable VA policy.
13a.	Make available to the affiliate the required annual VA review and evaluation of the IRB structure, function, and performance as completed by the R&D Committee for the Institutional Official (VA facility's Chief Executive Officer).	13b.	Appoint a representative of the Dean's Committee (or its equivalent) to the VA R&D Committee.

VA Facility Agrees to:	University Affiliate Agrees to:
14a. Provide and facilitate the use of the VA Form 10-1086 by the affiliate.	14b. Require that the VA Form 10-1086, which includes specific indemnification and notification clauses, will be used as the informed consent form for all VA human subject research.
15a. Assure that no human research will be conducted without IRB approval or determination that the activity is exempt from review. Assure that R&D Committee approval is obtained after IRB approval and before human subjects research is initiated.	15b. Maintain VA human subjects research records at the affiliate for 5 years following project termination in accordance with VA Policy. Provide the VA ready access to these records for review and/or copying. Consult with the VA, and transfer such records to the VA if requested, before destruction of any records maintained by the IRB.
16a. Specify any financial arrangements or other resource arrangements provided to the Affiliate.	16b. Specify any financial arrangements made with VA.
17a. Assure that research is conducted in compliance with the Health Insurance Portability and Accountability Act (HIPAA).	17b. Assure that research is conducted in compliance with the Health Insurance Portability and Accountability Act (HIPAA).
18a. Accreditation See Addenda	18b. Accreditation See Addenda
19a. Adhere to requirements of affiliate regarding reporting of Conflict of Interest for IRB members.	19b. Advise VA of requirements for reporting Conflict of Interest for IRB members.

Checklist Addenda
Additional Points to Consider for Accreditation of HRPP

Select the following addendum (a) that applies to your HRPP arrangements.

1. **Affiliated With Institution Whose HRPP <u>Will</u> Be Accredited Separately**
2. **Affiliated With Institution Whose HRPP <u>Will</u> <u>Not</u> Be Accredited Separately**
3. **VA Facilities Sharing IRBs & R&D Committees**
4. **VA Facilities Sharing An IRB(s) But With Separate R&D Committees**

Checklist Addendum
Additional Points to Consider for Accreditation of HRPP

1. ***Affiliated With Institution Whose* HRPP <u>Will</u> *Be Accredited Separately***
2. **Affiliated With Institution Whose HRPP <u>Will</u> <u>Not</u> Be Accredited Separately**
3. **VA Facilities Sharing IRBs & R&D Committees**
4. **VA Facilities Sharing An IRB(s) But With Separate R&D Committees**

1. Affiliated With Institution Whose HRPP Will Be Accredited Separately

VA Facility Agrees to:	Academic Affiliate Agrees to:
1a. Develop a formal IRB agreement with the affiliate that includes, but is not limited to: Specific requirements for the membership and operation of the IRB to review VA research, in compliance with VA policy and guidance. The respective responsibilities for human subject protection of the VA facility and the designated IRB. The scope of VA activities to be reviewed by the IRB. The process by which the VA facility evaluates the IRB's performance. The remedies available to the VA facility, including revocation of the formal IRB agreement, if the designated IRB does not fulfill its obligations.	1b. Develop a formal IRB agreement with the VA facility that includes, but is not limited to: Specific requirements for the membership and operation of the IRB to review VA research, in compliance with VA policy and guidance. The respective responsibilities for human subject protection of the VA facility and the designated IRB. The scope of VA activities to be reviewed by the IRB. The process by which the VA facility evaluates the IRB's performance. The remedies available to the VA facility, including revocation of the formal IRB agreement, if the designated IRB does not fulfill its obligations.
2a. Oversee the affiliate IRB(s) and document consideration of the following: Assessment of the qualifications and experience of a new IRB Chair. Appropriateness of the IRB and IRB membership, given the research being reviewed. That the IRB includes representatives, either as members, alternates, or ad hoc consultants, interested in or who have experience with vulnerable populations involved in research and who will supplement the IRB's expertise in specific research areas. Adequacy of the IRB's policies and procedures.	2b. Allow the VA facility to oversee the IRB(s) and to document and consider the following: Assessment of the qualifications and experience of a new IRB Chair. Appropriateness of the IRB and IRB membership, given the research being reviewed. That the IRB includes representatives, either as members, alternates, or ad hoc consultants, interested in or who have experience with vulnerable populations involved in research and who will supplement the IRB's expertise in specific research areas. Adequacy of the IRB's policies and procedures.
3a. Assure that the documented processes of the affiliate IRB regarding managing conflicts of interest of IRB members are in accordance with VA policy.	3b. Assure that its documented processes regarding managing conflicts of interest of IRB members are in accordance with the Common Rule.
4a. Establish a documented process to identify and manage conflicts of interest for VA investigators.	4b. Adhere to the Common Rule to manage conflicts of interest for VA investigators.
5a. Cooperate with the Affiliate in scheduling accrediting body accreditation for the VA HRPP to allow time for the Affiliate to prepare for its own accreditation by an accrediting organization that is approved by the VA Office of Research and Development (ORD).	5b. Cooperate with the VA facility in scheduling accreditation by an accrediting organization that is approved by the VA within 365 days of the VA facility accreditation decision.
6a. Provide the affiliate with complete and timely notification of information needed to support its accreditation application submission and on-site survey. Specify the appropriate communication channels.	6b. Provide timely access to staff, IRB members, files and records needed by the accrediting body to support the VA facility's accreditation application submission and on-site survey. Specify appropriate communication channels.

VA Facility Agrees to:	Academic Affiliate Agrees to:
7a. Provide the VA accrediting body documentation of any change in the affiliate's accreditation status. The document must be on official letterhead of the accrediting organization and include the name of the accredited organization, the accreditation status, and the effective date and expiration date of the accreditation decision.	7b. Provide the VA with documentation of any change in affiliate's accreditation status as it occurs. The document must be on official letterhead of the accrediting organization and include the name of the accredited organization, the accreditation status and the effective date and expiration date of the accreditation decision.
8a. Notify the affiliate that it may not claim or imply that its HRPP has been accredited or evaluated by the VA facility's accrediting body	8b. Refrain from claiming or implying that its HRPP has been accredited or evaluated by the VA facility's accrediting body.

2. Affiliated With Institution Whose HRPP Will Not Be Accredited Separately

VA Facility Agrees to:	Academic Affiliate Agrees to:
1a. Develop a formal IRB agreement with the affiliate that includes, but is not limited to: Specific requirements for the membership and operation of the IRB to review VA research, in compliance with VA policy and guidance. The respective responsibilities for human subject protection of the VA facility and the designated IRB. The scope of VA activities to be reviewed by the IRB. The process by which the VA facility evaluates the IRB's performance. The remedies available to the VA facility, including revocation of the formal IRB agreement, if the designated IRB does not fulfill its obligations.	1b. Develop a formal IRB agreement with the VA facility that includes, but is not limited to: Specific requirements for the membership and operation of the IRB to review VA research, in compliance with VA policy and guidance. The respective responsibilities for human subject protection of the VA facility and the designated IRB The scope of VA activities to be reviewed by the IRB. The process by which the VA facility evaluates the IRB's performance. The remedies available to the VA facility, including revocation of the formal IRB agreement, if the designated IRB does not fulfill its obligations.
2a. Oversee the affiliate IRB(s) and document consideration of the following: Assessment of the qualifications and experience of a new IRB Chair. Appropriateness of the IRB and IRB membership, given the research being reviewed. That the IRB includes representatives, either as members or ad hoc consultants, interested in or who have experience with vulnerable populations involved in research and to supplement the IRB's expertise in specific research areas. Adequacy of the IRB's policies and procedures.	2b. Allow the VA facility to oversee the IRB(s) and to document and consider the following: Assessment of the qualifications and experience of a new IRB Chair. Appropriateness of the IRB and IRB membership, given the research being reviewed. That the IRB includes representatives, either as members or ad hoc consultants, interested in or who have experience with vulnerable populations involved in research and to supplement the IRB's expertise in specific research areas. Adequacy of the IRB's policies and procedures.
3a. Assure that the documented processes of the affiliate IRB regarding managing conflicts of interest of IRB members are in accordance with VA policy.	3b. Assure that its documented processes regarding managing conflicts of interest of IRB members are in accordance with the Common Rule.
4a. Establish a documented process to identify and manage conflicts of interest for investigators.	4b. Adhere to the Common Rule to manage conflicts of interest for VA investigators.
5a. Notify the accrediting body of the affiliate's accreditation plans prior to scheduling the VA facility's survey, and request its accreditation survey include the relevant review of the affiliate's HRPP.	5b. Notify the VA facility of plans not to seek separate accreditation. Notify the VA facility of any changes in this plan as soon as possible.
6a. Provide the affiliate with complete and timely notification of information needed to support its accreditation, including an agreement about scheduling the application submission and on-site survey, and specifying the appropriate communication channels.	6b. Provide timely access to staff, IRB members, files and records needed by the accrediting body to support the VA facility's accreditation application submission and on-site survey. Specify appropriate communication channels.

VA Facility Agrees to:
7a. Coordinate access by the designated HRPP accrediting organization to all the necessary personnel, documents and records of the IRB(s).

Academic Affiliate Agrees to:
7b. he accrediting organization under contract with VHA will include a review of the affiliate IRB(s) in its accreditation of the VHA HRPP. The VHA HRPP must coordinate access by the designated accrediting organization to all the necessary personnel, documents and records of the IRB(s) that reside at the affiliate location.

3. VA facilities Sharing IRBs and R&D Committees

Primary VA facility Agrees To:	Secondary VA facility Agrees To:
1a. Provide the IRB(s) and R&D Committee for the HRPPs of both sites; maintain responsibility for implementing the consolidated HRPP, and for its own human subjects research and HRPP.	1b. Utilize the primary VA facility's IRB(s) and R&D Committee for its HRPP program, but maintain overall responsibility for its own human subjects research and HRPP.
2a. Establish its IRB(s) as the IRB(s) of record for the secondary VA facility, and maintain responsibility for its operations.	2b. Recognize the primary VA facility's IRB(s) as its IRB(s) of record.
3a. Establish its R&D Committee as the R&D Committee of record for the secondary VA facility's HRPP.	3b. Recognize the primary VA facility's R&D Committee will oversee the IRB(s) and serve as the R&D Committee of record for its HRPP.
4a. Work with the secondary VA facility to develop one set of SOPs for the consolidated HRPP. Develop supplemental policies and procedures to address its own local HRPP issues.	4b. Work with the primary VA facility to develop one set of SOPs for the consolidated HRPP. Develop supplemental policies and procedures to address its own local HRPP issues.
5a. Develop a formal IRB and R&D Committee agreement with the secondary VA facility that includes, but is not limited to: Specific requirements for the membership and operation of the IRB(s) and R&D Committee, including appropriate representation from the secondary VA facility. The respective responsibilities for human subject protection of the primary and secondary VA facilities, and the designated IRB(s). The scope of activities to be reviewed by the IRB and R&D Committee. The process by which the IRB's and R&D Committee's performance is evaluated. The remedies available to the secondary VA facility, including revocation of the formal IRB agreement, if the designated IRB and or R&D Committee does not fulfill its obligations.	5b. Develop a formal IRB and R&D Committee agreement with the primary VA facility that includes, but is not limited to: Specific requirements for the membership and operation of the IRB(s) and R&D Committee, including appropriate representation from the secondary VA facility. The respective responsibilities for human subject protection of the primary and secondary VA facilities, and the designated IRB(s). The scope of activities to be reviewed by the IRB and R&D Committee. The process by which the IRB's and R&D Committee's performance is evaluated. The remedies available to the secondary VA facility, including revocation of the formal IRB agreement, if the designated IRB and/or R&D Committee does not fulfill its obligations.
6a. Oversee the consolidated IRB(s) and document consideration of the following: Assessment of the qualifications and experience of a new IRB Chair. Appropriateness of the IRB and IRB membership, given the research being reviewed. That the IRB includes representatives, either as members or ad hoc consultants, interested in or who have experience with vulnerable populations involved in research and to supplement the IRB's expertise in specific research areas. Adequacy of the IRB's policies and procedures.	6b. Allow the primary VA facility to oversee the IRB(s) and to document and consider the following: Assessment of the qualifications and experience of a new IRB Chair. Appropriateness of the IRB and IRB membership, given the research being reviewed. That the IRB includes representatives, either as members or ad hoc consultants, interested in or who have experience with vulnerable populations involved in research and to supplement the IRB's expertise in specific research areas. Adequacy of the IRB's policies and procedures.

Primary VA facility Agrees To:	Secondary VA facility Agrees To:
7a. Establish a documented process to identify and manage conflicts of interest for IRB members.	7b. Adhere to the documented processes regarding managing conflicts of interest of IRB members of the Primary VA facility, and establish and adhere to its own documented process regarding managing conflicts of interest for its representatives to the IRB(s).
8a. Establish and adhere to a documented process to identify and manage conflicts of interest for its investigators.	8b. Establish and adhere to a documented process to identify and manage conflicts of interest for its investigators.
9a. Primary VA will notify the accrediting body of the consolidated status of the VA facilities prior to scheduling the survey.	9b. Secondary VA will support Primary VA application as requested.
10a. Provide the secondary VA facility with complete and timely notification of information needed to support its accreditation, including an agreement about scheduling the application submission and on-site survey and specifying the appropriate communication channels.	10b. Provide timely access to staff, IRB members, files and records needed by the accrediting body to support the consolidated VA facility's accreditation application submission and on-site survey. Specify appropriate communication channels.
11a. Maintain its own FWA.	11b. Maintain its own FWA.

4. VA Facilities Sharing an IRB(s) But With Separate R&D Committees

Primary VA facility Agrees To:	Secondary VA facility Agrees To:
1a. Recognize that its R&D committee has responsibility for overall operations of its own HRPP program. Have a mechanism to ensure oversight of the IRB(s).	1b. Recognize that its R&D committee has responsibility for the overall operations of its own HRPP program. Have a mechanism to ensure oversight of the IRB(s).
2a. Establish its IRB(s) as the IRB(s) of record for the secondary VA facility, and maintain responsibility for its operations.	2b. Recognize the primary VA facility's IRB(s) as its IRB(s) of record.
3a. Work with the secondary VA facility to develop SOPs that will govern the role of the IRB(s) for the secondary site's HRPP.	3b. Work with the primary VA facility to develop SOPs that will govern the role of the IRB(s) for its HRPP. Provide information to the IRB about significant issues that come to light in the R&D approval process, which might impact the conduct of a protocol.
4a. Develop a formal IRB agreement with the secondary VA facility that includes, but is not limited to: Specific requirements for the membership and operation of the IRB including appropriate representation from the secondary VA facility. The respective responsibilities for human subject protection of the primary VA facility and the designated IRB(s). The scope of activities to be reviewed by the IRB(s). The process by which the IRB's performance is evaluated. The remedies available to the secondary VA facility, including revocation of the formal IRB agreement, if the designated IRB does not fulfill its obligations.	4b. Develop a formal IRB agreement with the primary VA facility that includes, but is not limited to: Specific requirements for the membership and operation of the IRB including appropriate representation from the secondary VA facility. The respective responsibilities for human subject protection of the secondary VA facility. The scope of activities to be reviewed by the IRB(s). The process by which the secondary VA facility evaluates the IRB's performance. The remedies available, including revocation of the formal IRB agreement, if the designated IRB does not fulfill its obligations.
5a. Oversee the IRB(s) and document consideration of the following: Assessment of the qualifications and experience of a new IRB Chair. Appropriateness of the IRB and IRB membership, given the research being reviewed. That the IRB includes representatives, either as members or ad hoc consultants, interested in or who have experience with vulnerable populations involved in research and to supplement the IRB's expertise in specific research areas. Adequacy of the IRB's policies and procedures.	5b. Oversee the IRB(s) and to document and consider the following: Assessment of the qualifications and experience of a new IRB Chair. Appropriateness of the IRB and IRB membership, given the research being reviewed. That the IRB includes representatives, either as members or ad hoc consultants, interested in or who have experience with vulnerable populations involved in research and to supplement the IRB's expertise in specific research areas. Adequacy of the IRB's policies and procedures.
6a. Establish a documented process to identify and manage conflicts of interest for IRB members.	6b. Adhere to the documented processes regarding managing conflicts of interest of IRB members of the primary VA facility.

Primary VA facility Agrees To:	Secondary VA facility Agrees To:
7a. Establish and adhere to a documented process to identify and manage conflicts of interest for its investigators.	7b. Establish and adhere to a documented process to identify and manage conflicts of interest for its investigators.
8a. Notify the accrediting body of the consolidated status of the VA facility's' IRB(s) prior to scheduling the survey.	8b. Notify the accrediting body of the consolidated status of the VA facility's' IRB(s) prior to scheduling the survey.
9a. Provide the secondary VA facility with complete and timely notification of information needed to support its accreditation, including an agreement about scheduling the application submission and on-site survey and specifying the appropriate communication channels.	9b. Provide timely access to staff, IRB members, files and records needed by the accrediting body to support the accreditation application submission and on-site survey. Specify appropriate communication channels.
10. Maintain own FWA.	10b. Maintain own FWA.