

Checklist for VAMC Memorandum of Understanding with Another Institution
For use of the Institutional Review Board (IRB) and Related Research Services
(May be VA or Non-VA Institution)

VA Facility Agrees to:	University Affiliate, VAMC or Other Institution Providing Services Agrees to:
<p>1a. Adhere to the federal regulations as codified in 38 CFR 16 & 17; 21 CFR 50 & 56; other pertinent federal regulations and guidance; VA requirements (including VHA Handbook 1200.05) and university policies applicable to human subjects research to the extent permissible under federal and VA requirements. All VA policies apply, i.e., VA facilities cannot waive policy requirements.</p> <p>It is recommended that the term "VA Research" be defined in the MOU.</p>	<p>1b. Adhere to the federal regulations as codified in 38 CFR 16 & 17; 45 CFR 46 Subparts B-E, 21 CFR 50 & 56; other pertinent federal regulations and guidance; VA requirements (including VHA Handbook 1200.05), and university policies applicable to VA human subject research.</p> <p>It is recommended that the term "University Research", if that term is applicable, be defined in the MOU.</p>
<p>2a. Provide the IRB access to all relevant investigator records (including data files, regulatory files/binders, case report forms, sponsor queries, internal and external monitoring reports, and audit reports); research subjects' clinical and research records or case files; and facility research records (including sponsor agreements), as required for oversight and monitoring of research activity. This access will be provided to any individual(s) designated by the IRB.</p>	<p>2b. Provide the VA facility and ORO with access for review and copying any IRB or other records, documents, or reports relevant to compliance reviews of research conducted or supported by VA, approved by the VA facility's R&D Committee, or involving individuals with VA appointments.</p> <p>Provide VA R&D Committee copies of unredacted IRB Meeting minutes.</p> <p>Provide access to, or information from, the IRB database (if any) to approved representatives of the VA for the purposes of tracking ongoing VA research activity.</p>
<p>3a. Work with the affiliate to develop and maintain mutually acceptable policies for monitoring human research and for providing regular communication of results of this monitoring, and other documentation of human subject 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 unredacted IRB 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.</p>	<p>3b. Develop and maintain mutually acceptable policies for monitoring human subject 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 unredacted IRB minutes, correspondence, and reports of quality improvement activities to the VA R&D Committee. Establish a definition of "timely" provision of such documentation.</p>
<p>4a. Provide access and training to IRB members regarding VA policies and procedures that govern the VA Human Research Protection Program (HRPP) processes and determinations.</p>	<p>4b. Provide training to VA staff and investigators as appropriate for them to comply with affiliate IRB policies and submission procedures as they apply to VA submissions.</p>

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5a.	<p>Cooperate with the affiliate in developing and maintaining current written IRB Standard Operating Procedures that incorporate procedures for reviewing, approving, and exercising oversight of VA human subject research.</p> <p>Specify whether each facility maintains separate or combined IRB SOPs.</p> <p>NOTE: Streamlining changes to VHA Handbook 1200.05 require specificity for certain SOPs no longer described in the Handbook. VAMCs must have SOPs describing certain operational procedures not described in the Handbook, but which are still required by other VA policies.</p>
6a.	<p>Promptly inform the IRB of any complaints from subjects or others; unanticipated problems involving risks to subjects or others; serious adverse events (whether anticipated or unanticipated; whether related or unrelated to the research); suspension or termination of activities; and serious or continuing noncompliance encountered in VA human subjects research. Report to ORO as required under VHA Handbook 1058.01 (Note: Specificity about this process is required.)</p>

University Affiliate, VAMC or Other Institution Providing Services Agrees to:	
5b.	<p>Develop and maintain an IRB SOP that incorporates, either by inclusion or reference all required procedures for reviewing, approving, and exercising oversight of VA human subject research.</p>
6b.	<p>Promptly inform the VA of any complaints from subjects or others; unanticipated problems involving risks to subjects or others; serious adverse events (whether anticipated or unanticipated; whether related or unrelated to the research); suspension or termination of activities; and serious or continuing noncompliance encountered in VA human subjects research. Provide the VA with information needed to fulfill the facility's reporting requirements under VHA Handbook 1058.01 (Note: Specificity about this process is required.)</p>

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<p>7a. VAMC Director appoints in writing VA member-representatives to each IRB that reviews VA research. (VHA Handbook 1200.05)</p> <p>Two or more VA member-representatives (and alternates when possible) must be appointed to any External IRB that is an IRB of record for VA research unless ORD has approved other arrangements (generally for Central IRBs.). VA representatives must be at least 1/8 VA-salaried (not IPA or WOC). VA member-representatives must be full voting members of the IRB (i.e., review all protocols, not just VA protocols). At least one VA voting member must be present during full board review of VA research.</p> <p>For VAMCs with 10 protocols or less, the Director may appoint 1 IRB member and 1 alternate. VA facilities may opt to retain the 5/8 salary requirement.</p> <p>Submit current IRB rosters to ORO within 30 days of a membership change in accordance with applicable VHA Handbooks.</p>	<p>7b. Appoint VA representation to each External 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 at least 1/8 VA salaried (not WOC or IPA). They must be full voting members of the IRB (i.e., review all protocols, not just VA protocols). At least one VA voting member must be present during full board review of VA research.</p> <p>Provide updated roster(s) to the VA facility within 30 days of IRB membership change.</p> <p>Comply with FDA requirements for mandatory reporting of information related to FDA-regulated research on the IRB Registration.</p> <p>Note: "IRB" means "IRB committee" or "IRB panel" VA representatives must be appointed to each panel that reviews VA research. It does not mean 2 VA IRB members per institution where the IRB has multiple panels or committees.</p>
<p>8a. Promptly notify the affiliate of any modifications to, or changes in the status of, the VA facility's Federalwide Assurance (FWA).</p>	<p>8b. Promptly notify the VA facility of any modifications to, or changes in the status of, the affiliate's Federalwide Assurance (FWA).</p>
<p>9a. Prohibit collaborative involvement in VA human subject research of any Institution that does not have a Federalwide Assurance (FWA) or other Assurance acceptable to the ORO Executive Director.</p>	<p>9b. Maintain a current Assurance. The affiliate agrees that it will not involve the VA in any human subject research with collaborators that do not have an FWA or other Assurance acceptable to the ORO Executive Director.</p>
<p>10a. Develop SOPs that detail how compliance monitoring, auditing, 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 internal or external monitoring or audits of human subject research, including inspections by sponsors and regulatory/compliance bodies, to the IRB.</p>	<p>10 b. Develop SOPs that detail how compliance monitoring, auditing, and reporting to appropriate regulatory authorities will be handled by administrative officials, compliance officer(s), and the IRB and its administrators. Report the results to the VA Institutional Official of any internal or external monitoring or audits of the affiliate's research, including inspections by sponsors and regulatory/compliance bodies, that impact VA research or the status of the VA HRPP.</p>

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VA Facility Agrees to:	University Affiliate, VAMC or Other Institution Providing Services Agrees to:
11a. Develop and maintain effective communication and cooperation mechanisms sufficient to ensure adequate protections for human research subjects. Actively cooperate with the affiliate in resolving any problems encountered in either the affiliate's or the VA facility's HRPP.	11b. Develop and maintain effective communication and cooperation mechanisms sufficient to ensure adequate protections for human research subjects. Actively cooperate with the VA facility in resolving any problems encountered in either the VA facility's HRPP or, to the extent that VA research is impacted, in the affiliate's HRPP.
12 a. Termination of this agreement by either the VA facility or the affiliate 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.) MOU <u>should not</u> state that the MOU can be terminated "Effective immediately". MOU must be renewed every 3 years and amended as conditions change. This includes changes of Signatory official. (VHA Handbook 1058.03)	12b. Termination of this agreement by either the VA facility or the affiliate will be in an orderly manner so as not to harm subjects or put subjects at risk. (Note: SOPS Describe specific remedies available if the designated IRB does not fulfill its obligations.) University agrees that IRB oversight of VA research will not be terminated until all the research is transferred to the oversight of another IRB or safely closed. The MOU may be modified to describe the process for termination and for transfer of VA research to another IRB. <i>Note: it is ok to specify a time period if desired by the university. ORO can help with estimating the time period.</i>
13a. Ensure that all key VA personnel engaged in human research meet both the affiliate's and the VA facility's training requirements and that there is a tracking system to document such training.	13b. Ensure that all IRB Chairs and members have received the appropriate training as IRB members, including training to ensure that they are knowledgeable about applicable VA requirements.
14a. Make available to the affiliate all VA requirements for informed consent.	14b. Require that all VA requirements for informed consent, including specific indemnification and notification language, will be used for all VA human subject research.
15a. Make available to the affiliate the annual VA review and evaluation of the IRB structure, function, and performance required under VHA Handbook 1200.01	15b. Allow necessary access for VA R&D Committee review. Reviews the annual evaluation of the IRB structure, function, and performance required under VHA Handbook 1200.01
16a. Ensure that no human research is conducted without IRB approval or determination that the activity is exempt from IRB review. Assure that R&D Committee approval is obtained as required under VHA Handbook 1200.01	16b. Understand that no VA human research can be conducted without both IRB approval (or determination that the activity is exempt from IRB review) and VA R&D Committee approval as required under VHA Handbook 1200.01.

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<p>17a. Where the affiliate maintains IRB and other research records for fewer than the required time frame (VA RCS 10-1), provide an acceptable mechanism to transfer records relating to VA research to the VA facility. Note: RCS 10-1 requirements have been released to the field.</p>	<p>17b. Maintain VA human subjects research records at the affiliate for the required time frame following project termination in accordance with VA Policy. Where the affiliate maintains IRB and other research records for a shorter period of time than required by VA RCS 10-1, provide an acceptable mechanism to transfer records relating to VA research to the VA facility OR</p> <p style="padding-left: 40px;">Provide the VA ready access to these records for review and/or copying.</p>
<p>18a. <u>If applicable</u>, specify any financial arrangements or other resource arrangements made between the VA facility and the affiliate related to IRB Review.</p>	<p>18b. <u>If applicable</u>, specify any financial arrangements or other resource arrangements made between the affiliate and the VA facility related to IRB review.</p>
<p>19a. Ensure that research is conducted in compliance with the Health Insurance Portability and Accountability Act (HIPAA). Describe how any privacy board functions will be handled and by which institution. Provides VA HIPAA Authorization form with required VA elements.</p> <p style="padding-left: 40px;">If there is no Academic Affiliation Agreement with the non-VA Institution, there must be a Business Associate Agreement (BAA) in place.</p>	<p>19b. Ensure that research is conducted in compliance with the Health Insurance Portability and Accountability Act (HIPAA) Describe how any privacy board functions will be handled and by which institution.</p> <p style="padding-left: 40px;">Agrees to use VA HIPAA Authorization form that contains the required elements for VA protocols, as appropriate.</p> <p style="padding-left: 40px;">If there is no Academic Affiliation Agreement with the non-VA Institution, there must be a Business Associate Agreement (BAA) in place.</p>
<p>20a. Designate and maintain specific mechanisms, consistent with VHA Handbook 1058.02 and other applicable VA and federal requirements, to address allegations of research misconduct involving VA human subject research or individuals acting as VA employees in VA human subject research. MOU should indicate that ORO will guide the research misconduct process for VA. Optional right now due to issues of confidentiality being unresolved</p>	<p>20b. Designate and maintain specific mechanisms, consistent with VHA Handbook 1058.02 and other applicable VA and federal requirements to address allegations of research misconduct involving VA human subject research or individuals acting as VA employees in VA human subject research. Affiliate acknowledges that the VA Office of Research Oversight will guide the research misconduct process at VA.</p> <p style="color: blue;">Optional right now.</p>

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VA Facility Agrees to:	University Affiliate, VAMC or Other Institution Providing Services Agrees to:
<p>21a. Adhere to the affiliate's requirements for reporting by investigators or IRB members of Conflicts of Interest in conducting or reviewing research. Advise the affiliate of any issues that occur.</p> <p>Advise the affiliate of VA requirements for reporting by investigators or IRB members of financial conflicts of interest. Advise affiliate of any issues that occur. Address how institutional COI will be handled</p>	<p>21b. Advise the VA facility of requirements for reporting by investigators or IRB members of Conflicts of Interest in conducting or reviewing research. Advise the VA facility of any issues that occur. Adhere to VA's requirements for investigator or IRB member reporting of financial conflict of interest. Advise VA facility of any issues that occur. Address how institutional COI will be handled</p>
<p>22a. Become accredited and/or maintain accreditation of the VAMC HRPP in good standing by the accrediting body designated by the Veterans Health Administration.</p> <p>Where VA accreditation has been voluntarily maintained, indicate in the MOU that the VAMC is maintaining accreditation.</p>	<p>22b. Either become accredited by an accrediting body, or participate in the HRPP accreditation process with the VA including allowing access to the necessary records, documents, reports, and personnel for the VA to become accredited.</p>
<p>23a. Address Information Security between the two institutions</p> <p>Stronger Language is desired here and in 23b</p>	<p>23b. Address Information Security between the two institutions</p>
<p>24a. Establish procedures for ISO and Privacy officer review of VA research as nonvoting members of or consultants to the IRB or R&D Committee</p>	<p>24b. Cooperate with VA in establishing procedures for ISO and Privacy Officer review of VA research as consultants to or nonvoting members of the IRB or R&D Committee.</p>
<p>25a. VA will comply with the provisions of, VHA Handbook 1605.1 §13, and VA Handbook 6500 with respect to reporting to the VAMC Privacy Officer of any unauthorized use, loss, or disclosure of individually-identifiable patient information of which it becomes aware. Collaborate with Affiliate IRB to establish written procedures.</p>	<p>25b. The affiliate IRB agrees to comply with the provisions of VHA Handbook 1605.1 §13, and VA Handbook 6500 with respect to reporting to the VAMC Privacy Officer of any unauthorized use, loss, or disclosure of individually-identifiable patient information of which it becomes aware. Affiliate further agrees to establish written procedures for such reporting.</p>
<p>26a. VA will comply with the provisions of VA Handbook 6500.2 with respect to reporting to the VAMC Information Security Officer of any violations of VA information security requirements of which it becomes aware. Collaborate with Affiliate IRB to establish written procedures.</p>	<p>26b. The University IRB agrees to comply with the provisions of VA Handbook 6500.2 with respect to reporting to the VAMC Information Security Officer of any violations of VA information security requirements of which it becomes aware. University further agrees to establish written procedures for such reporting.</p>

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VA Facility Agrees to:

27a Include a statement that The VA Facility Director (Institutional Official) is the individual legally authorized as Signatory Official to commit an institution to an Assurance. The IO serves as the official representative of the institution to external agencies and oversight bodies, and provides all written communication with external departments, agencies, and oversight bodies.

28a Indicate that where the VHA Central Office IRB, National Cancer Institute Central IRB, or other External IRB has jurisdiction of some VA Research at the facility, the local VA or Affiliate IRB does not have oversight of such research.

Where the NCI CIRB has oversight of VA research, indicate that the local affiliate or VAMC IRB has limited responsibility to assist the VAMC R&D Committee with oversight of the NCI research, to be described in local SOPs.

University Affiliate, VAMC or Other Institution Providing Services Agrees to:

27b The IRB agrees to establish effective communication methods to enable the VA Institutional Official to comply with requirements for reporting noncompliance to external oversight bodies such as OHRP, FDA, NIH, and other applicable Agencies.

28b Institution acknowledges that the Affiliate IRB does not have oversight of research overseen by the VHA Central Office IRB, National Cancer Institute Central IRB or other external IRB.

Where the NCI CIRB has oversight of VA research, indicate that the local affiliate IRB has limited responsibility to assist the VAMC R&D Committee with oversight of the NCI research, to be described in local SOPs.

