

**Checklist for Memorandum of Understanding (MOU) for Use of Another VA Medical Facility’s or Academic Affiliate’s Institutional Review Board (IRB) as Primary IRB and/or for Related Research Services**

VA Medical Facility Relying on Another VA medical facility or the Academic Affiliate for Primary IRB or other Committee Agrees to:	University/Academic Affiliate or VA Medical Facility Providing Committee Services Agrees to:
<p>1. <input type="checkbox"/> Adhere to the Code of Federal Regulations as codified in 38 CFR 16 &amp; 17; 21 CFR 50 &amp; 56; other pertinent federal regulations and guidance; VA requirements (including Veterans Health Administration (VHA) Directive 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 national policy requirements.</p> <p>For MOUs with the Academic Affiliate IRB it is recommended that the term “VA Research” be defined in the MOU.</p>	<p><input type="checkbox"/> Adhere to the Code of Federal Regulations as codified in 38 CFR 16 &amp; 17; 45 CFR 46 Subparts B-E, 21 CFR 50 &amp; 56; other pertinent federal regulations and guidance; VA requirements (including VHA Directive 1200.05), and university policies applicable to VA human subjects research.</p> <p>It is recommended that the term “University Research”, if that term is applicable, be defined in the MOU.</p>
<p>2. <input type="checkbox"/> 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><input type="checkbox"/> Provide the VA medical facility relying on the IRB and Office of Research Oversight (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 medical facility’s Research and Development Committee (R&amp;DC), or involving individuals with VA appointments.</p> <p>Describe how the Affiliate will provide VA R&amp;DC copies of IRB Meeting minutes or specify methods of access. Access must meet requirements of VHA Directive 1200.05 §8.c.(3)(a) or §8.c.(3)(b).</p> <p>Provide access to, or information from, the IRB database (if any) to approved representatives of the VA medical facility relying upon the IRB for the purposes of tracking ongoing VA research activity.</p>
<p>3. <input type="checkbox"/> Work with the IRB to develop and maintain mutually acceptable procedures for monitoring human research and for providing regular communication of results of this monitoring, and other</p>	<p><input type="checkbox"/> Develop and maintain mutually acceptable procedures for monitoring human subjects research and for regular communication of results of this monitoring, and other documentation of human subjects research,</p>

**Checklist for Memorandum of Understanding (MOU) for Use of Another VA Medical Facility’s or Academic Affiliate’s Institutional Review Board (IRB) as Primary IRB and/or for Related Research Services**

VA Medical Facility Relying on Another VA medical facility or the Academic Affiliate for Primary IRB or other Committee Agrees to:	University/Academic Affiliate or VA Medical Facility Providing Committee Services Agrees to:
<p>documentation of human subjects research, to the R&amp;DC. Work with the Affiliate to establish a description of the method and frequency of the Affiliate’s providing information including access to unredacted IRB minutes, correspondence, and reports of quality improvement activities to the VA R&amp;DC. 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>to the R&amp;DC. Work with the VA medical facility relying upon the IRB to establish a description of the method and frequency of the Affiliate’s providing information including access to unredacted IRB minutes, correspondence, and reports of quality improvement activities to the VA R&amp;DC. Establish a definition of “timely” provision of such documentation.</p>
<p>4. <input type="checkbox"/> 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><input type="checkbox"/> Provide training to VA staff and investigators at the facility relying upon the IRB as appropriate for them to comply with Affiliate or local VA IRB policies and submission procedures as they apply to VA submissions.</p>
<p>5. <input type="checkbox"/> Cooperate with the IRB in developing and maintaining current written IRB Standard Operating Procedures (SOPs) that incorporate procedures for reviewing, approving, and exercising oversight of VA human subjects research.</p> <p><b>Specify whether each facility maintains separate or combined IRB SOPs.</b></p> <p>NOTE: VA Medical Facilities must have local SOPs describing certain operational procedures not described in the Directive 1200.05, but which are still required by other VA policies, such as reporting requirements (VHA Directive 1200.05 §8.a).</p>	<p><input type="checkbox"/> Develop and maintain IRB SOPs that incorporate, either by inclusion or reference, all required procedures for reviewing, approving, and exercising oversight of VA human subjects research.</p>
<p>6. <input type="checkbox"/> Promptly inform the IRB of any complaints from subjects or others; unanticipated problems involving risks to subjects or others (UPIRTSOs); suspension or termination of activities; and serious or continuing noncompliance encountered in VA human subjects research. Report to ORO as required under VHA Directive</p>	<p><input type="checkbox"/> Promptly inform the VA medical facility relying upon the IRB of any complaints from subjects or others; UPIRTSOs; 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</p>

**Checklist for Memorandum of Understanding (MOU) for Use of Another VA Medical Facility’s or Academic Affiliate’s Institutional Review Board (IRB) as Primary IRB and/or for Related Research Services**

VA Medical Facility Relying on Another VA medical facility or the Academic Affiliate for Primary IRB or other Committee Agrees to:	University/Academic Affiliate or VA Medical Facility Providing Committee Services Agrees to:
<p>1058.01 (Note: Specificity about this process is required.) If the procedures for the review and reporting of events of the research review committee differ from, or the timeframes exceed those of, 1058.01, the Director must consult with the VHA Office of Research &amp; Development (ORD) and the appropriate ORO workgroup as to the adequacy of those procedures to protect the interests of VA and those involved in VA research.</p>	<p>Directive 1058.01 (Note: Specificity about this process is required.) Notify the VA medical facility if the procedures for the review and reporting of events of the research review committee differ from, or the timeframes exceed those of, VHA Directive 1058.01.</p>
<p>7. <input type="checkbox"/> If required by local medical facility policy, the medical facility Director appoints in writing VA member-representatives to each IRB that reviews VA research.</p> <p>VA member-representatives (and alternates when possible) will be appointed to the VA or Affiliate IRB that is a primary IRB of record for VA research if required by local policy.</p> <p>Regardless of whether VA members are appointed to the IRB, a membership roster must be submitted to ORO by the VA medical facility at the time of the IRB’s initial designation as the IRB of Record. VA medical facilities must maintain, or have readily available access to, accurate up-to-date rosters for all IRBs designated on the VA medical facility’s Federalwide Assurance (FWA.)</p>	<p><input checked="" type="checkbox"/> Per agreement with VA medical facility relying upon the IRB, appoint VA representation to each IRB that is an IRB of record for VA research protocols if required by local VA policy.</p> <p>Regardless of whether there is VA medical facility membership on the IRB, provide updated local roster(s), readily available access to local rosters, or Health and Human Services (HHS) Office for Human Research Protections (OHRP) IRB Registration to the VA medical facility promptly after any IRB membership change (VHA Directive 1200.05 §7.f).</p> <p>Comply with HHS-OHRP and Food and Drug Administration (FDA) requirements for mandatory reporting of information related to FDA-regulated research on the HHS-OHRP IRB Registration.</p>
<p>8. <input type="checkbox"/> Promptly notify the IRB of any modifications to, or changes in the status of, the VA medical facility’s FWA.</p>	<p><input type="checkbox"/> Promptly notify the VA facility relying upon the IRB of any modifications to, or changes in the status of, the VA/Affiliate’s FWA. Where the Academic Affiliate does not apply federal requirements to all other research overseen by the IRB, include a statement that the Affiliate acknowledges all VA research is federally- conducted and - supported and thus subject to federal requirements.</p>

**Checklist for Memorandum of Understanding (MOU) for Use of Another VA Medical Facility’s or Academic Affiliate’s Institutional Review Board (IRB) as Primary IRB and/or for Related Research Services**

VA Medical Facility Relying on Another VA medical facility or the Academic Affiliate for Primary IRB or other Committee Agrees to:	University/Academic Affiliate or VA Medical Facility Providing Committee Services Agrees to:
<p>9. <input type="checkbox"/> Prohibit collaborative involvement in VA human subjects research of any Institution that does not have an FWA or other Assurance acceptable to the ORO Executive Director.</p>	<p><input type="checkbox"/> Maintain a current FWA. The Affiliate/VA medical facility agrees that it will not involve the VA in any human subjects research with collaborators that do not have an FWA or other Assurance acceptable to the ORO Executive Director.</p>
<p>10. <input type="checkbox"/> 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 subjects research, including inspections by sponsors and regulatory/compliance bodies, to the IRB.</p>	<p><input type="checkbox"/> 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 the relying facility of any internal or external monitoring or audits of the Affiliate’s research that impact VA research or the status of the VA HRPP, including relevant inspections by sponsors and regulatory/compliance bodies.</p>
<p>11. <input type="checkbox"/> 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 medical facility’s HRPP.</p>	<p><input type="checkbox"/> Develop and maintain effective communication and cooperation mechanisms sufficient to ensure adequate protections for human research subjects. Actively cooperate with the VA medical facility relying upon the IRB in resolving any problems encountered in either the VA medical facility’s HRPP or, to the extent that VA research is impacted, in the Affiliate’s HRPP.</p>
<p>12. <input type="checkbox"/> Termination of this agreement by either the VA medical facility or the Affiliate will be in an orderly manner so as not to harm subjects or put subjects at risk. (Note: MOU may describe specific remedies available if the designated IRB does not fulfill its obligations.) MOU should not state that the MOU can be terminated “Effective immediately.”</p> <p>MOU must be amended as conditions change.</p>	<p><input type="checkbox"/> Termination of this agreement by either the VA medical facility relying upon the IRB or the Affiliate will be in an orderly manner so as not to harm subjects or put subjects at risk. (Note: MOU may describe specific remedies available if the designated IRB does not fulfill its obligations.) Affiliate/VA 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.</p>

**Checklist for Memorandum of Understanding (MOU) for Use of Another VA Medical Facility's or Academic Affiliate's Institutional Review Board (IRB) as Primary IRB and/or for Related Research Services**

VA Medical Facility Relying on Another VA medical facility or the Academic Affiliate for Primary IRB or other Committee Agrees to:	University/Academic Affiliate or VA Medical Facility Providing Committee Services Agrees to:
	<i>Note: it is ok to specify a time period if desired by the VA medical facility /Affiliate.</i>
<p>13. <input type="checkbox"/> Ensure that all key VA personnel engaged in human research meet both the Affiliate's and the VA medical facility's training requirements for VA researchers and that there is a tracking system to document such training.</p>	<p><input type="checkbox"/> 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.</p>
<p>14. <input type="checkbox"/> Make available to the IRB all VA requirements for informed consent.</p>	<p><input type="checkbox"/> Require that all VA requirements for informed consent, including specific indemnification and notification language will be used if applicable.</p>
<p>15. <input type="checkbox"/> Make available to the IRB the annual VA review and evaluation of the facility-specific aspects of the relationships between the IRB and the VA relying facility required under VHA Directive 1200.01. For example, review of an external committee would include evaluation of the number of projects handled by the committee, communication between entities, changes in MOUs or other agreements, change in processes, and challenges.</p>	<p><input type="checkbox"/> Allow necessary access for VA R&amp;DC review. Review the annual evaluation of the facility-specific aspects of the relationships between the IRB and the VA relying facility required under VHA Directive 1200.01</p>
<p>16. <input type="checkbox"/> Require that the VA medical facility's Research Compliance Officer (RCO) has access to the committee's records to the extent necessary for the RCO to fulfill research auditing requirements.</p>	<p><input type="checkbox"/> Make available to the facility's RCO access to the committee's records to the extent necessary for the RCO to fulfill research auditing requirements.</p>
<p>17. <input type="checkbox"/> Ensure that no human research is conducted without IRB approval unless there is a determination that the activity is exempt from IRB review. Ensure that R&amp;D Committee approval is obtained as required under VHA Directive 1200.01</p> <p>Describe which Institution makes the exempt determination if the IRB does not do it.</p>	<p><input type="checkbox"/> Ensure 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&amp;D Committee approval as required under VHA Directive 1200.01.</p>
<p>18. <input type="checkbox"/> Where the IRB maintains IRB and other research records for less than the required time frame (VA Records Control Schedule RCS 10-1), provide an acceptable</p>	<p><input type="checkbox"/> Maintain VA human subjects research records at the Affiliate for the required time frame following project termination in accordance with VA Policy. Where the</p>

**Checklist for Memorandum of Understanding (MOU) for Use of Another VA Medical Facility’s or Academic Affiliate’s Institutional Review Board (IRB) as Primary IRB and/or for Related Research Services**

VA Medical Facility Relying on Another VA medical facility or the Academic Affiliate for Primary IRB or other Committee Agrees to:	University/Academic Affiliate or VA Medical Facility Providing Committee Services Agrees to:
<p>mechanism to transfer records relating to VA research to the VA medical facility.</p>	<p>Affiliate maintains IRB and other research records for a shorter period than required by VA RCS 10-1, provide an acceptable mechanism to transfer records relating to VA research to the VA medical facility OR</p> <p>Provide the VA ready access to these records for review and/or copying.</p>
<p>19. <input type="checkbox"/> Ensure that research is conducted in compliance with the Health Insurance Portability and Accountability Act (HIPAA). Describe how any HIPAA review/oversight functions will be handled and by which Institution.</p> <p>Provide VA HIPAA Authorization form 10-0493 with required VA elements if using standalone HIPAA authorization.</p> <p>If combined informed consent / HIPAA authorization form is used, all required elements must be present.</p>	<p><input type="checkbox"/> Describe how any HIPAA review functions will be handled and by which Institution.</p> <p>If the Affiliate agrees to handle the HIPAA review functions for VA protocols, it agrees to ensure that research is in compliance with HIPAA privacy requirements and to ensure the use of VA HIPAA Authorization form 10-0493 that contains the required elements for VA protocols, when using a standalone HIPAA authorization.</p>
<p>20. <input type="checkbox"/> Remove any statement about financial arrangements that were in previous MOU versions.</p>	<p><input type="checkbox"/> Remove any statement about financial arrangements that were in previous MOU versions.</p>
<p>21. <input type="checkbox"/> Adhere to the IRB’s requirements for reporting by investigators or IRB members of Conflicts of Interest in conducting or reviewing research. Advise the Affiliate of any identified conflicts.</p> <p>Advise the Affiliate of VA requirements for reporting by investigators or IRB members of financial conflicts of interest. Advise Affiliate of any identified conflicts.</p>	<p><input type="checkbox"/> Advise the VA medical facility relying upon the IRB of requirements for reporting by investigators or IRB members of Conflicts of Interest in conducting or reviewing research. Advise the VA medical facility of any identified conflicts.</p> <p>Adhere to VA’s requirements for investigator or IRB member reporting of financial conflict of interest. Advise VA medical facility relying upon the IRB of any identified conflicts.</p>
<p>22. <input type="checkbox"/> Where accreditation of the research program has been voluntarily maintained by the VA medical facility, indicate in the MOU that the medical facility will maintain</p>	<p><input type="checkbox"/> If voluntary accreditation is in place for the IRB Institution, agree to maintain the accreditation in good standing. Agree to</p>

**Checklist for Memorandum of Understanding (MOU) for Use of Another VA Medical Facility's or Academic Affiliate's Institutional Review Board (IRB) as Primary IRB and/or for Related Research Services**

VA Medical Facility Relying on Another VA medical facility or the Academic Affiliate for Primary IRB or other Committee Agrees to:	University/Academic Affiliate or VA Medical Facility Providing Committee Services Agrees to:
<p>accreditation in good standing and that any loss in status will be reported to the Affiliate or VA IRB Institution.</p> <p>Agree to cooperate with IRB accreditation process at the IRB Institution, if any.</p>	<p>cooperate with the VA medical facility's accreditation process, if any.</p>
<p>23. <input type="checkbox"/> Address Information Security between the two Institutions related to transferring sensitive documents between VA and the Affiliate, or the Affiliate's storage of VA sensitive information if not addressed in other written agreements.</p>	<p><input type="checkbox"/> Address Information Security between the two Institutions related to transferring sensitive documents between the VA medical facility relying upon the IRB and the Affiliate, or the Affiliate's storage of VA sensitive information if not addressed in other written agreements.</p>
<p>24. <input type="checkbox"/> Establish procedures for Information System Security Officer (ISSO) and Privacy Officer (PO) review of VA research as nonvoting members of or consultants to the IRB or R&amp;D Committee.</p>	<p><input type="checkbox"/> Cooperate with the VA medical facility relying upon the IRB in establishing procedures for ISSO and PO review of VA research as consultants to or nonvoting members of the IRB or R&amp;DC.</p>
<p>25. <input type="checkbox"/> VA will comply with the provisions of VA Directive 6500 with respect to reporting to the VA medical facility PO 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><input type="checkbox"/> The Affiliate IRB agrees to comply with the provisions of VA Directive 6500 with respect to reporting to the relying medical facility PO 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>26. <input type="checkbox"/> VA will comply with the provisions of VA Handbook 6500.2 with respect to reporting to the VA medical facility ISSO of any violations of VA information security requirements of which it becomes aware. Collaborate with Affiliate IRB to establish written procedures.</p>	<p><input type="checkbox"/> The Affiliate IRB agrees to comply with the provisions of VA Handbook 6500.2 with respect to reporting to the VA medical facility ISSO of any violations of VA information security requirements related to VA research of which it becomes aware. Affiliate further agrees to establish written procedures for such reporting.</p>
<p>27. <input type="checkbox"/> Include a statement that the VA medical facility Director (Institutional Official) is the individual legally authorized as Signatory Official to commit an Institution to an Assurance. The Institutional Official serves</p>	<p><input type="checkbox"/> The IRB agrees to establish effective communication methods to enable the relying VA Institutional Official to comply with requirements for reporting noncompliance to external oversight bodies</p>

**Checklist for Memorandum of Understanding (MOU) for Use of Another VA Medical Facility’s or Academic Affiliate’s Institutional Review Board (IRB) as Primary IRB and/or for Related Research Services**

VA Medical Facility Relying on Another VA medical facility or the Academic Affiliate for Primary IRB or other Committee Agrees to:	University/Academic Affiliate or VA Medical Facility Providing Committee Services Agrees to:
<p>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.</p>	<p>such as HHS-OHRP, FDA, National Institutes of Health, and other applicable Agencies.</p>
<p>28. <input type="checkbox"/> Indicate that where the VHA Central Office IRB, National Cancer Institute (NCI) Central IRB, or other external IRB has jurisdiction of some VA Research at the VA medical facility, the local VA or Affiliate IRB does not have oversight of such research.</p> <p>Where the NCI CIRB or other External IRB has oversight of VA research but does not perform all necessary oversight functions such as HIPAA review, indicate that the local Affiliate or local VA medical facility IRB has agreed to limited responsibility to assist the VA medical facility R&amp;DC with oversight of the research, to be described in local SOPs.</p>	<p><input type="checkbox"/> VAMC/ Affiliate IRB Institution acknowledges that the local VAMC/Affiliate IRB does not have oversight of research overseen by the VHA Central Office IRB, NCI Central IRB or another external IRB.</p> <p>Where an external IRB does not provide certain review required by regulation, Local VA medical facility/Academic Affiliate IRB agrees to assist the medical facility R&amp;DC by providing HIPAA or other review to the R&amp;DC, to be described in local SOPs.</p>
<p>29. <input type="checkbox"/> Where the VA medical facility does not operate an internal R&amp;DC and/or other subcommittees such as the Subcommittee on Research Safety (SRS), VHA Directive 1200.01 par. 5.f(7) requires a VA medical facility to secure the services of an R&amp;DC and required subcommittee services from another VA medical facility (or Academic Affiliate), through a Memorandum of Understanding. Requirements for R&amp;DC oversight are stipulated in VHA Directive 1200.01 par 5.h.</p> <p>Describe the arrangement. Indicate whether there is VA medical facility membership on the R&amp;DC, SRS, or other subcommittee.</p> <p>Communications, reporting and accountability should be considered.</p>	<p><input type="checkbox"/> Concurs with or acknowledges the arrangement and agrees to provide the oversight required by Directive 1200.01.</p> <p>Indicate when/how minutes and notifications of R&amp;DC approvals are provided to the VA medical facility relying upon the IRB so the Associate Chief of Staff for Research notification letters can be issued.</p> <p>Appoints members to the R&amp;DC, IRB and other subcommittees as appropriate.</p>