



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Truman VA Hospital Human Subjects Research –
Special Considerations

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Approved By: Michele Kennett, JD, MSN, LLM
Associate Vice Chancellor for Research

A handwritten signature in cursive script that reads "Michele Kennett".

1. Purpose

To assure knowledge and compliance by documenting the policies and procedures to be followed when conducting human research at the Harry S. Truman Memorial Veterans' Hospital (Truman VA).

2. Scope

The policy applies to all Truman VA research falling under the purview of the University of Missouri Institutional Review Board (MU IRB) where research is occurring at the Truman VA.

3. Policy/Procedure

The MU IRB is the IRB of record for the Truman VA. A Memorandum of Understanding (MOU) was executed by both parties and outlines respective authorities, roles, and responsibilities.

Truman VA research is reviewed in the same manner as all other research under the purview of the MU IRB. Truman VA research is expected to comply with the federal regulations, VHA Directive 1200.05, other applicable VA Handbooks, and adhere to the MU IRB SOPs for all research. Post approval monitoring occurs in conjunction with the Truman VA research office.

Truman VA research cannot commence until Truman VA R&D Committee (RDC) approval is granted and the ACOS has provided written notification to begin in accordance with VHA Directive 1200.01. Therefore, research may not commence until RDC approval has been obtained. The ACOS will provide a written approval letter to the investigator with a copy sent to the MU IRB for inclusion in the study files.

The Truman VA does not conduct planned emergency research (see 21 CFR 50.24) or classified research involving human subjects.

There will be someone within the MU IRB designated as the primary VA contact; however, the MU IRB main resource account (muresearchirb@missouri.edu) will be used as an ongoing primary point of contact. This contact will be communicated, via a memo to the ACOS and updated memos will be sent for any changes.

1. IRB Membership

The MU IRB will comply with its policy on Board Structure and Responsibilities. The committee may include individuals associated with the Truman VA. If the MU IRB includes a VA representative on its roster, it will work directly with the Institutional Official at the Truman VA in accordance with the VA 1200.05 directive. If the MU IRB includes a VA representative on its roster, the representative or their alternate will be requested to review new VA full board applications. However, in the event the VA representative and their alternate are unable to attend a board meeting or participate in the review due to a conflict of interest, another board member will complete the review.

Both parties will provide appropriate training to the IRB members about applicable VA and other Federal requirements for the protection of human subjects. For members representing the Truman VA, the Truman VA research office will be responsible for providing additional training regarding specific VA policies. Training will occur on an as needed basis and utilizing various approaches.

2. VA Research

1200.05 defines VA Research as research that is conducted by investigators (serving on VA compensated, WOC (Without Compensation), or IPA (Intergovernmental Personnel Act) appointments) while on VA time or on VA property. 1200.05 also notes the research may be funded by the VA, by other sponsors, or be unfunded.

The MU IRB application collects information confirming the activity is VA research prior to applying this policy. The guidance set forth by the Office of Human Research Protections entitled “Engagement of Institutions in Human Subjects Research” is also taken into consideration when determining whether an activity is VA research.

When questions arise whether an activity falls under this definition, the local VA research office will be consulted.

The Truman VA Health System Specialist will have access to all Truman VA studies submitted to the MU IRB so the Truman VA can ensure all investigators have completed the required VA training modules. The MU IRB will not move forward with personnel additions to existing studies until the Truman VA Health System Specialist confirms completed VA training through a reviewer checklist in eCompliance.

3. VA Research Reviews, Reports, and Records

When reviewing VA research, the MU IRB ensures completion of the VA subform and VA reviewer checklist in eCompliance for review documentation and to ensure additional VA requirements are met.

The MU IRB informs all Truman VA investigators through direct communication of all research approvals, disapprovals, or modifications required to secure IRB approval. All communications with Truman VA investigators are documented in the eCompliance system (or other Truman VA/MU IRB approved systems). The Truman VA Health System Specialist uploads all RDC, RCO, and other research office approvals/reports/memos to the appropriate project in eCompliance. Any Truman VA approval/report/memo that requires IRB action will be sent directly to the IRB Director or designee for follow-up. Action items including ongoing monitoring will be addressed collaboratively with the Truman VA research office.

All Truman VA unanticipated problems and noncompliance issues will follow the MU IRB SOPs on unanticipated problems and/or noncompliance, and the VA Handbooks 1200.01, 1200.05, and 1058.01. Any suspensions or terminations for Truman VA research will follow the MU IRB SOP on suspensions and terminations, as well as the VA Handbook 1058.01. The Truman VA ACOS is responsible for ensuring reporting to VA's Office of Research Oversight (ORO) when applicable. The MU IRB will follow its Reporting SOP and report to other federal agencies, including OHRP, FDA, and/or federal sponsor, when applicable. Copies of the MU IRB reports are documented in the study's attached files section accessible to the Truman VA Health System Specialist and ACOS.

Appropriate individuals identified by the ACOS are provided access to reports including the monthly Truman VA approval report (including expedited and the expedited review category), pending report, and expired/expiring projects report within eCompliance.

All Truman VA IRB records will be accessible for inspection and copying (by authorized representatives of VA, ORO, OHRP, FDA and other authorized entities, accrediting bodies, or Federal department or agencies) at reasonable times in a reasonable manner.

IRB records and researcher records must be returned to the VA and then retained for a minimum of six years (or five years if the protocol is cancelled without participant enrollment). in accordance with privacy requirements, the Federal Records Act, and VHA RCS10-1. Codes or keys linking participant data to identifiers must be retained as part of the research record for at least six years. All disclosures and data transmission must meet VA privacy and security requirements per VA Directive 6500 and 1200.12.

4. VA Expired Projects

If a researcher does not provide continuing review information to the IRB or the IRB has not approved a protocol by the expiration date, the following must occur:

- a. The PI must stop all research activities as stated in the expiration notice, except where stopping such interventions or interactions could be harmful to participants;
- b. The PI must immediately submit to the IRB chair or designee a list of research participants who could be harmed by stopping the study procedures;
- c. The IRB chair, with appropriate consultation with the VA ACOS, determines within 2 business days whether participants on the list may continue participating in the research interventions or interactions.

5. VA Informed Consent Templates

The Truman VA research office will provide the VA Investigators with the appropriate VA research consent templates with required elements of consent, including the additional requirements set forth in the VA Directive 1200.05. The MU IRB will ensure the appropriate templates are used and will follow its SOP on informed consent. The “Informed Consent Requirements” SOP outlines the additional VA elements of consent.

6. IRB Meeting Procedures and Minutes

The MU IRB may invite appropriate Truman VA representative(s) to attend to offer information and/or to observe the review(s) of VA research agenda items.

The Truman VA Health System Specialist has access to a folder within eCompliance where the Truman VA agendas, minutes, and updated rosters are stored.

- a. The agenda will be placed in the folder approximately two weeks before the IRB meeting.
- b. A copy of redacted meeting minutes related to the MU IRB’s review of Truman VA protocols will be placed in the folder in a timely manner to allow the RDC an opportunity to review the IRB’s deliberations on VA protocols.
- c. The approved Truman VA minutes will be placed in the folder within a week of the meeting in which they were approved.
- d. The MU IRB will provide relevant Truman VA personnel with unredacted meeting minutes according to VHA Directive 1200.05.
- e. Updated rosters will be placed in the folder shortly after changes are made.

7. Exempt Research and Limited IRB Review

On March 1, 2020, existing Truman VA exempt studies were transferred to the oversight of the Truman VA research office and will no longer fall under the purview of the MU IRB.

Truman VA exempt studies proposed on or after March 1, 2020 will be under the purview of the Truman VA RDC (or an IRB designated by the Truman VA), not the MU IRB.

8. HIPAA, Information System Security Officer, and Privacy Officer Reviews

The MU IRB will review requests for HIPAA waivers/alterations associated with Truman VA expedited and full board studies within the purview of the MU IRB.

The Truman VA reviews HIPAA authorizations when not embedded in the consent document for all Truman VA studies and activities preparatory to research. The MU IRB will review HIPAA authorizations when they are embedded in the consent document.

The Truman VA RDC is also responsible for overseeing any Information System Security Officer and/or Privacy Officer reviews. If issues arise during the review processes that may affect MU IRB determinations, the Truman VA Health System Specialist will inform the IRB to determine if changes to IRB actions are necessary. The MU IRB will follow its SOP on the amendment review process, if necessary.

9. Collaborative Research between VA and non-VA Investigators

Collaboration is encouraged when Truman VA investigators have a substantive role in the design, conduct, and/or analysis of the research at the University of Missouri (affiliate) and will be conducted in accordance with VA handbook 1200.05Sec15. The Truman VA may also serve as a Coordinating Center for collaborative studies between the Truman VA and the University of Missouri.

- A. Research studies meeting the definition of multi-site studies with more than one site “engaged” in research will follow the MU IRB SOP regarding multi-site research and IRB reliance process. The MU IRB will serve as the reviewing IRB with either the Truman VA or the University of Missouri (affiliate) serving as the lead site and the other serving as an external site.
- B. The collaborative section of the Truman VA subform located within the MU IRB application must be completed for collaborative studies not meeting the multi-site definition. For multi-site studies, additional information will be requested within the Truman VA subform of the MU IRB application.
- C. When a study involves populations at both the Truman VA and affiliate, each institution engaged in the multi-site research must use the informed consent document and HIPAA authorization required by their respective institutional policies for subjects recruited from that institution, or procedures requiring participation of the subject at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed at the Truman VA and which will be performed at other institutions.
 - (a) The Truman VA informed consent document must clearly state when procedures mentioned at other institutions are part of the VA’s portion of the study.

- (b) The informed consent document and HIPAA authorization must be consistent and include information describing the following:
 - i. PHI to be collected and/or used by the VA research team;
 - ii. PHI to be disclosed to the other institutions; and
 - iii. Purpose for which the PHI may be used.
- D. Projects including a VA population with (1) research activity occurring at the affiliate location, and/or (2) sharing subject identifiable private information between sites will require certain agreements to be in place before the research can begin. The PI will need to work with the Truman VA to ensure necessary agreements have been finalized between institutions prior to study activities commencing. The Truman VA Health System Specialist uploads all pertinent agreements upon execution.

10. Quality Improvement (QI) Activities

The Truman VA will be responsible to review all VA Quality Improvement activities. The VA research office has a review system through a VA Electronic Determination Aid (VAEDA) and a VA LEAF application on the Truman VA Sharepoint Site for QI submissions. The VA research office does not utilize eCompliance to document their QI activities. Any new or ongoing QI activities should receive VA review.

If the Truman VA Health System Specialist determines a project does not meet the criteria for Quality Improvement but does meet the definition of non-exempt research as defined under 38 CFR 16.102 (e), the VA Health System Specialist will notify the MU IRB if the study appears not to meet exempt criteria as defined in 38 CFR 16.104. The MU IRB will confirm the study meets criteria requiring IRB review and perform the review if required, and the MU IRB will follow its local policy reviews. After verification, the VA Health System Specialist will notify the investigator to submit appropriate documents to the IRB in eCompliance.

11. Emergency Use of a Test Article

According to VHA Directive 1200.05(3), emergency use of a test article does not require R&D Committee approval or oversight but is VA research. The Truman VA ACOS will be notified when the MU IRB is notified by investigators. MU IRB will review according to the MU HRPP/IRB “Investigational, Compassionate, Emergency, and Humanitarian Uses” SOP.