



**Institutional Review Board**

University of Missouri-Columbia

Standard Operating Procedure

Truman VA Hospital Human Subjects Research –  
Special Considerations

## Truman VA Hospital Human Subjects Research – Special Considerations

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

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

### 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/R&D has provided written notification to begin in accordance with VHA Directive 1200.01. Therefore, research may not commence until R&D approval has been

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obtained. The ACOS/R&D 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](mailto:muresearchirb@missouri.edu)) will be used as an ongoing primary point of contact. This contact will be communicated, via a memo to the ACOS/R&D 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 must be present at the board meeting during the review of a new full board VA application.

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 HRPP/RISP Program Specialist will be notified of all personnel changes submitted to the MU IRB so the Truman VA can ensure all investigators have completed the required VA training modules prior to any personnel changes being accepted by the MU IRB.

### **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 HRPP/RISP Program Specialist uploads all R&D, RCO, and other research office approvals/reports/memos to the appropriate project in eCompliance. The documents uploaded will also be forwarded to the MU IRB primary resource account for confirmation purposes. The MU IRB office will confirm receipt of all forwarded items. 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, terminations, or reporting requirement applicable for Truman VA research will also follow the MU IRB SOP on suspensions and terminations, as well as the VA Handbook 1058.01.

Appropriate individuals identified by the ACOS/R&D 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 retained for a minimum of six years (or five years if the protocol is cancelled without participant enrollment) according to VA records retention requirements. Codes or keys linking participant data to identifiers must be retained as part of the research record for at least six years. Records must be retained at the VA.

### **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;

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- c. The IRB chair, with appropriate consultation with the VA Associate Chief of Staff, 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 MU IRB 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 templates will be made available to all Truman VA investigators on the MU IRB website. 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 HRPP/RISP Program 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 R&D committee 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**

On March 1, 2020, existing Truman VA exempt studies will be transferred to the oversight of the Truman VA research office and will no longer fall under the purview of the MU IRB. New Truman VA exempt studies proposed on or after March 1, 2020 will be reviewed by the Truman VA research office, not the MU IRB.

The Truman VA HRPP/RISP Specialist will be responsible in making exempt determinations and RDC will be responsible for oversight of all proposed exempt research conducted by Truman VA investigators. If the Truman VA research office determines a project is exempt under 45 CFR 46.104(d)(2)(iii) or 104(d)(3)(C) requiring a limited IRB review, the Truman VA HRPP/RISP Program Specialist will notify the MU IRB. The MU IRB does not review research that falls under 46.104(d)(7) or 46.104(d)(8). The MU IRB will confirm an exempt determination requiring limited IRB review and perform the review if required, and the MU

IRB will follow its local policy for exempt reviews. The limited IRB review will be completed prior to approval by the R&D committee.

For a period of time, the MU IRB will allow access to eCompliance to authorized Truman VA personnel to perform and document these exempt determinations. When the VA research office develops and releases its own review system for exempt submissions, the VA research office will no longer utilize eCompliance to document exempt activities. If limited IRB review is required, the VA research office will direct investigators to submit in eCompliance.

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

The Truman VA reviews HIPAA authorizations, approval of HIPAA waivers/alterations, and activities preparatory to research.

The Truman VA 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 HRPP/RISP Program 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. The Truman VA may also serve as a Coordinating Center for collaborative studies between the Truman VA and the University of Missouri.

- A. Each institution engaged in the collaborative 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.
- B. Collaborative research studies include activities and populations at both the Truman VA and the affiliate institution MU that will require separate project submissions to the IRB for each location of research. The research occurring at the VA will receive a designation at the end of the project number of “-VA”. Each project will be reviewed by the MU IRB as a separate project for approval.

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- C. Projects of a VA only population with data analysis occurring at the affiliate location will require a signed Data Use Agreement (DUA) but will not require two separate project submissions for review and approval.
- D. Projects of a VA only population with data analysis occurring only at the VA will not require a Data Use Agreement and will not require two separate project submissions for review and approval. However, individuals will need to meet VA policy requirements and follow procedures related to appointments and data security and privacy.

### **10. Investigational Drug Information Record**

The Truman VA Research Office forwards the Investigational Drug Information Records (VA Form 10-9012) (signed by the PI) for signature approval by the IRB Chair. The Truman VA staff add the signed document to the project documents in eCompliance. The IRB takes no further action.

### **11. Quality Improvement (QI) Activities**

The Truman VA will be responsible to review all VA Quality Improvement activities. For a period of time, the MU IRB will allow access to eCompliance to authorized VA personnel to perform and document these reviews. When the VA research office develops and releases their own review system for QI submissions, the VA research office will no longer utilize eCompliance to document their QI activities.

If the Truman VA HRPP/RISP Specialist determines a project does not meet the criteria for Quality Improvement but does meet the definition of non-exempt research as defined under 46.102 (1), the VA HRPP/RISP Program Specialist will notify the MU IRB if the study appears not to meet exempt criteria as defined in 46.104. 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 HRPP/RISP Specialist will notify the investigator to submit appropriate documents to the IRB in eCompliance.