

Department of Veterans Affairs
Harry S. Truman Memorial Veterans' Hospital
800 Hospital Drive
Columbia, MO 65201

HPM 589A4-321
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Issued by: Research

HUMAN RESEARCH PROTECTION PROGRAM

1. **PURPOSE:** To delineate policy and procedures relating to the Human Research Protection Program (HRPP) at the Harry S. Truman Memorial Veterans' Hospital (Truman VA) and the affiliated Missouri Foundation for Medical Research (MFMR). This program will ensure the protection of human research subjects who participate in research programs at the Truman VA, including patients, volunteers, and employees.

2. **POLICY:** The activities related to human subject research will be carried out in accordance with all applicable federal laws and regulations including the Belmont Report.

3. **BACKGROUND:**

a. The Truman VA will conduct the HRPP in conjunction with the University of Missouri-Columbia Health Sciences-Institutional Review Board (HS-IRB) and the Department of Veterans Affairs (VA) Central Institutional Review Board (IRB) through an approved Federal Wide Assurance (FWA) #00002426. Memoranda of Understanding (MOU) delineating details of these arrangements are on file in the Research Office.

b. The HRPP will be conducted in accordance with Federal Law 38 CFR 16 & 17 (Common Law), Veterans Health Administration (VHA) Handbook 1200.05, applicable Department of Health & Human Services (DHHS) regulations, and Food & Drug Administration (FDA) regulations.

4. **DEFINITIONS:**

a. Health Sciences Institutional Review Board (HS-IRB): One of two IRBs of record for the Truman VA located at the University of Missouri-Columbia.

b. VA Central IRB: One of two IRBs of record for the Truman VA located in Washington, D.C.

c. Principal Investigator (PI): Is a qualified person or persons designated by an applicant institution to direct a research project or program. The PI oversees scientific, technical, and day-to-day management of the research .

d. Research and Development (R&D) Committee: The organization that will provide oversight of the HS-IRB, VA Central IRB, Subcommittee for Research Safety (SRS), and Subcommittee for Animal Studies (SAS) to assure compliance with applicable regulations.

e. Belmont Report: The summary of the basic ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This report puts forth a statement of basic ethical principles and guidelines to

assist in resolving the ethical problems confronted when conducting research with human subjects.

f. Good Clinical Practices (GCP): The international ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing and reporting studies. Adhering to the GCP will ensure that the research data reported will be collected using credible and accurate methods to protect research participants' rights and confidentiality.

g. Food and Drug Administration (FDA): The federal agency that promotes public health by promptly and efficiently reviewing clinical research and taking appropriate actions with regard to marketing of the regulated process.

h. Health Insurance Portability and Accountability Act (HIPAA): The regulation that includes under Title II an Administrative Simplification Compliance Act that applies to the following four areas:

- (1) Patient privacy;
- (2) Security of protected patient information;
- (3) Standardization of transactions and code sets;
- (4) Standard Identifiers for such entities as employers and healthcare providers.

i. Office for Human Research Protection (OHRP): The Federal government office that issues assurances and oversees compliance with regulations concerning human research.

j. Office of Research Oversight (ORO): The Veterans Health Administration (VHA) office that will advise the Under Secretary for Health on matters related to the protection of human research subjects, animal welfare, research safety, and research misconduct. ORO supports and promotes the responsible conduct of research through periodic inspections and evaluations of research integrity, and through investigations of allegations of non-compliance with policies and regulations at VA research facilities.

5. RESEARCH INVOLVING CERTAIN CATEGORIES OF PARTICIPANTS NOT CONDUCTED:

- a. Research involving fetuses is not approved.
- b. Research involving *in vitro* fertilization is not approved.
- c. Research involving prisoners or children as participants is not approved unless a waiver is granted by the Chief Research and Development Officer.

6. RESPONSIBILITIES:

a. The Medical Center Director of the Truman VA will be the signatory official for the FWA of the institution and will maintain ultimate responsibility for the oversight of the HRPP. The Medical Center Director delegates the day to day monitoring of compliance of the HRPP to the Research Compliance Officer (RCO). The Director will ensure that the RCO has adequate resources allocated for the HRPP, adequate RCO support systems, adequate space and equipment for the RCO, adequate HRPP-related educational funding, and support for VA representation to the HS-IRB. In the case of the VA Central IRB, the Director will appoint a liaison.

b. The Associate Chief of Staff for Research and Development (ACOS/R&D) will maintain overall responsibility for the entire research program including the implementation of the HRPP. The Medical Center Director and Chief of Staff delegate authority to the ACOS/R&D in order for a strong, compliant HRPP to be maintained.

c. The Department of Veterans Affairs (VA) Research and Development (R&D) Committee will review and approve all research conducted at the Truman VA. The R&D Committee will provide oversight of HS-IRB and VA Central IRB activities to assure compliance with applicable regulations. Specific responsibilities of VA R&D Committee will include the following:

(1) To ensure the scientific quality and appropriateness of all research involving human subjects;

(2) To annually evaluate all research studies involving human subjects to assure regulatory compliance and protection of human subjects;

(3) To review the membership and performance of the HS-IRB to ensure compliance with all applicable regulations.

d. VA Principal Investigators (PI's) will be responsible for the following:

(1) Adhering to the policies and requirements of the HS-IRB or VA Central IRB and the VA Research Service, including VHA Handbook 1200.05, Paragraphs 9 and 10; specifically, PIs are required to comply with HS-IRB and VA Central IRB policies regarding adverse event reporting, continuing review reports, filing amendments, informed consent, recruitment of subjects, vulnerable populations, protocol approval, and other policies as may be applicable for specific projects.

(2) Securing signatures from human research participants or participants' legally authorized representative on all HS-IRB and VA Central IRB approved informed consent documentation and the legally effective authorization for the use and disclosure of the subject's protected health information (PHI);

(3) Implementing human research studies to include, but not limited to, the following:

(a) Protocol design and methods that minimize risks to subjects while maximizing research benefits;

(b) Ensuring that all members of the research team involved in human research have successfully completed the required trainings available at www.va.gov/columbia-mo.

(c) Ensuring that all members of the research team comply with the directives of the HS-IRB, VA Central IRB, and the VA R&D Committee;

(d) Ensuring that the informed consent documentation, processes, and compliance standards are met;

(e) Notifying the HS-IRB, VA Central IRB, VA R&D Committee and the study sponsor of any problems, including side effects, encountered when conducting human research, as well as the timely submission of all required reporting and documentation (e.g. adverse events, unanticipated problems involving risk to subjects and others, data and safety monitoring board reports, and continuing review);

(f) Obtaining the HS-IRB or VA Central IRB and the VA R&D Committee review and approval prior to initiating a research project by completing the following steps:

1. Completing and submitting the appropriate HS-IRB or VA Central IRB application (e.g., exempt, expedited, full board) to request the HS-IRB or VA Central IRB review the plan for research and all supporting documentation to include the full research protocol, risk/benefit analysis, recruiting plan and any recruitment materials, data collection tools, surveys and/or questionnaires, and

2. Submitting to the VA Research Office the "Request to Conduct Research" application (human and/or animal, as applicable); Conflict of Interest forms; and other information as requested;

(g) Following study approval, at intervals specified by the IRB of record completion of the IRB of record continuation review to update the HS-IRB or VA Central IRB and VA R&D Committee regarding study progress;

(h) Informing the HS-IRB or VA Central IRB of any financial conflicts of interests pursuant to the Conflict of Interest (COI) policies as described in VHA Directive 1200;

(i) Documentation in progress notes in VA Computerized Patient Record System (CPRS) is required when study participants are inpatients, being treated as outpatients, or when the research procedures or interventions are used in the medical care of the VA research subject at a VA facility or contracted facility. The minimum information that must be included in CPRS can be found in the HRPP Handbook and/or VHA Handbook 1200.05, Paragraph 43.b.

(j) Ensuring appropriate initial telephone contact with subjects by preceding telephone contact with personal contact or a letter unless there is written documentation that the subject is willing to be contacted by telephone.

(k) Ensuring appropriate later telephone contact by referencing the preceding contacts.

(l) Maintain a master list of all enrolled subjects whether or not the IRB of record granted a waiver of documentation of consent. The IRB of record may waive the requirement for the investigator to maintain a master list if (1) there is a waiver of documented consent and (2) the IRB of record determines that a master list may pose a potential risk to the subject.

e. The Research Compliance Officer (RCO) and/or the ACOS/R&D will be responsible for the following:

(1) Evaluating the institution's adherence to applicable federal and state regulations and accreditation standards governing human subject research;

(2) Evaluating the investigator's compliance of human research protections and adherence to applicable regulations and procedures;

(3) Evaluating the institution's quality improvement and quality assurance programs to establish systematic monitoring procedures for the human subject research programs;

(4) Communicating between the HS-IRB, VA Central IRB (via the liaison), and the VA R&D Committee.

(5) Communication to the Director, ACOS R&D, COS, HS-IRB Chair, VA Central IRB (via the liaison) and R&D Chair any suspicion of serious or continuing non-compliance.

7. PROCEDURES:

a. All investigators, research coordinators, and other research personnel that have access to personally identifiable information will be required to meet the educational requirements for human subject's protection (www.va.gov/columbia-mo/). Education will be updated on an biennial basis.

b. The HSTMVH will maintain a RCO position to oversee the Human Research Protection Program.

c. HRPP support will be provided by the HSTMVH and the Missouri Foundation for Medical Research. Industry-sponsored studies involving human subjects will have an established fee imposed to support the HRPP.

d. All "Requests to Conduct Research" applications must be submitted to the VA Research Office for administrative review prior to review by the VA R&D committee.

e. Submission of applications for HS-IRB approval must be submitted electronically at <https://irb.missouri.edu/eirb>. Submissions to the VA Central IRB must follow the application directions found at <http://www.research.va.gov/programs/pride/cirb/default.cfm>.

f. Submissions of continuing research reviews, amendments, adverse event reports, serious adverse events, unanticipated problems, and consent forms will be reviewed and approved by the HS-IRB or VA Central IRB. All IRB actions will be communicated in a timely fashion to the RCO and the R&D Committee.

g. An HRPP Handbook will be made available to human researchers on the VA research website to serve as a practical guide to assist human research teams to follow policies, regulations, and laws and to protect the rights and welfare of human participants. The HRPP Handbook will provide information regarding where investigators can go to find more information or to have questions addressed. In addition, human researchers and their team members will be encouraged to express any concerns they may have about the HRPP process or to offer suggestions for improvement.

8. REFERENCES: VHA Handbook 1200.05, dated October 15, 2010
VHA Directive 1200, dated July 9, 2009

9. RESCISSION: HPM 589A4-321, dated February 25, 2011.

10. FOLLOW-UP RESPONSIBILITY: Research Service (RES)

APPROVED:

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