

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

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## RESEARCH INFORMED CONSENT

1. **PURPOSE:** To describe the policies and procedures for obtaining informed consent from research participants.
2. **POLICY:** The Veterans' Health Administration (VHA) national regulations concerning the use of human subjects in research are found in VHA Handbook 1200.05 "Requirements for the Protection of Human Subjects in Research." The provisions of this VHA Handbook apply to all research involving human subjects conducted completely or partially within the Department of Veterans Affairs (VA) facilities, including research funded from extra-VA sources and research conducted without direct funding. The Handbook outlines the purpose, authorities, and responsibilities of VHA staff in the conduct of human research. The policy of this facility is that all requirements and responsibilities described in VHA Handbook 1200.05 and at IRBs of record. IRBs of record include the University of Missouri Health Sciences Institutional Review Board (HS-IRB) where policies are available at <http://www.research.missouri.edu/hsirb/index.htm>, and the VA Central Institutional Review Board (IRB) where policies are available at <http://www.research.va.gov/vacentralirb/sop/default.cfm>. The policies of each IRB of record will be strictly followed, as applicable.
3. **DEFINITIONS:**
  - a. Child is any individual under eighteen years of age. However, the mission of the VA does not include research on children, so the Harry S. Truman Memorial Veterans' Hospital (Truman VA) does not approve use of children as research participants unless a waiver has been approved by the Chief Research and Development Officer.
  - b. Legally Authorized Representative is an individual or body authorized under applicable law to consent on behalf of a prospective participant to the participant's involvement in research. In the State of Missouri, persons authorized to consent when a patient is incapable of consenting to an experimental treatment, test, or drug are as follows (in order of priority): (a) legal guardian, (b) attorney-in-fact (persons appointed by durable power of attorney), and (c) family members in sequence as follows: spouse (unless the patient has no spouse, is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas); adult child; parent; brother or sister; other relative by blood or marriage. However, legal guardians, attorneys-in-fact, or family members are not authorized to consent to treatment in contravention to an incapacitated person's expression of assent regarding such treatment. If the patient is competent to consent, but cannot read and/or write, the HS-IRB or VA Central IRB must be contacted for guidance and direction.
  - c. Guardian is an individual who is authorized under applicable state or local law to consent on behalf of a child to medical care.

d. Research Team Members: Staff involved in VA-approved human research will include the principal investigator (hereafter referred to as the investigator), co-principal investigator, co-investigators, study coordinator(s), and other team members who are credentialed for work on the protocol through the VA Research Office.

#### 4. **PROCEDURES FOR OBTAINING INFORMED CONSENT:**

a. A prospective subject is presumed to have decision-making capacity unless one or more of the following applies: (a) a qualified practitioner (who may be a member of the research team) has documented in the prospective subject's medical record that the individual lacks capacity to make the decision to participate in the proposed study; (b) the individual has been ruled incompetent by a court of law; or (c) if there is any question as to whether or not a potential adult subject has decision-making capacity, and there is no documentation in the medical record that the individual lacks decision-making capacity, and the individual has not been ruled incompetent by a court of law, the investigator must consult with a qualified practitioner (who may be a member of the research team) about the individual's decision-making capacity before proceeding with the informed consent process. If the individual is deemed to lack decision-making capacity at the time of their participation in the study, a legally authorized representative (LAR) must provide informed consent. However, should the subject regain decision-making capacity, the investigator or other IRB-approved research staff member designated to consent must repeat the informed consent process with the subject, and obtain the subject's permission to continue with the study.

b. The LAR (as defined in this Medical Center Policy Memorandum) may serve as the representative for subjects determined to be incapable of making an autonomous decision.

c. In order to be eligible to inform prospective subjects regarding all aspects of the research, members of the research team must be approved by their Functional Statement of Research Duties and Responsibilities through the Research Office, be authorized/approved by the IRB of record, and demonstrate evidence of all mandated training.

d. In order to be eligible to conduct the informed consent process, members of the research team must be approved by their Functional Statement of Research Duties and Responsibilities through the Research Office, be authorized/approved by the IRB of record, and demonstrate evidence of all mandated training.

e. Prior to entering subjects into a study and/or conducting protocol procedures, investigators involved in human subject research will obtain informed consent from the subject or the subject's legally authorized representative, unless consent is waived by the IRB or record.

f. All information provided to the subject or their legally authorized representative must be in language that can be understood by the subject or their representative.

g. The research informed consent procedures must include the active participation of

the prospective participants or their legally authorized representative. The consent process must allow an ample opportunity for consideration of whether or not to participate, including sufficient time for discussion with family members and other interested parties.

h. The prerogative of persons to decline participation in research studies will be respected, and consent will be given without undue influence or coercion.

i. Informed consent must be obtained from human participants under conditions that eliminate or properly manage conflicts of interest, including financial, personal, professional, dual relationships, publication, and/or promotion/tenure.

j. In emergency situations in which a study drug or procedure is expected to benefit the subject and no equal alternatives are available, consent may be given by the Chief of Staff if the patient has been adjudged to be incompetent, or is unable to provide legally authorized representation, unable to comprehend significance of consent actions, unable to exercise judgment, is unconscious, or is otherwise unable to give consent.

#### **5. PROCEDURES FOR CONSENT DOCUMENTATION:**

a. The Research Compliance Officer (RCO) and HS-IRB or VA Central IRB representatives will have the authority to observe the informed consent process and to monitor compliance with human subjects protections in all VA-approved research.

b. The Research Compliance Officer (RCO) will perform an annual review of all consents obtained on all research subjects.

c. The RCO will perform a triennial review of all research protocols that enroll human subjects.

d. The informed consent process will be documented by the use of an HS-IRB- or VA Central IRB-approved written consent form (including use of VA Form 10-1086) and must be signed by the subject or the subject's legally authorized representative, and signed by an authorized study representative obtaining consent unless an HS-IRB or VA Central IRB waiver is approved. A witness signature is required only if specifically required by the IRB of record.

e. Research informed consent documentation must be developed in accordance with VHA Handbook 1200.05 "Requirements for the Protection of Human Subjects in Research" and be consistent with state laws. The research informed consent documentation approved by the HS-IRB or VA Central IRB must include all of the basic elements of information as described in the VHA Handbook 1200.05. If the investigator delegates authority to consent to someone other than his or her self, then that request must be made in writing via the IRB of record's application or in the protocol.

f. The research consent documentation approved by the HS-IRB or VA Central IRB also must include all applicable additional elements of information as set forth in VA and other Federal regulations as described in VHA Handbook 1200.05.

g. The consent must include full disclosure of the amount and payment schedule for

research participation, including a statement regarding anticipated consequences of such payment.

h. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the legally authorized representative is made to waive, or appear to waive, any of the subject's legal rights or to release, or appear to release, the investigator, the sponsor, the institution, or its agents from liability or negligence.

i. The content of the HS-IRB or VA Central IRB consent forms will be consistent with the laws of the State of Missouri.

j. The research consent form must follow the VA Central IRB or HS-IRB template and be written in lay language at approximately the sixth grade level. The HS-IRB template is available at <http://www.research.missouri.edu/hsirb/>. The VA Central IRB template is located at <http://www.research.va.gov/vacentralirb/forms/investigator-forms.cfm>.

k. The consent documentation must bear the stamp of the HS-IRB or VA Central IRB dated at the time of approval; the most recently approved consent documentation must be used.

l. An HS-IRB- or VA Central IRB- acknowledged Health Insurance Portability and Accountability Act (HIPAA) authorization must be obtained from each human participant.

m. Participants will be given a signed and dated copy of the consent documentation. Original copies of the documentation will be retained by the investigator.

n. For clinical purposes, a copy of the research informed consent will be scanned into the participant's electronic medical record, and a chart note must document the consent process in the participant's medical record for all research participants who are required to have a VA Health Record as outlined in VHA Handbook 1200.05.

6. **REFERENCES:** VHA Handbook 1200.05, dated October 15, 2010.

7. **FOLLOW-UP RESPONSIBILITY:** ACOS, R&D

8. **RECISSION:** HPM 589A4-342 dated November 12 12, 2010

APPROVED:



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