

HUMAN SUBJECT RESEARCH

1. PURPOSE. To establish policy and procedure for human subject research.
2. POLICY. Rights of human subjects will be protected when participating in research. The overriding principle governing approval of all clinical studies involving humans is that the welfare of each subject who participates in the study supersedes all other considerations.
3. PROCEDURE.
 - a. Request for approval. Any clinical professional within the System who plans to conduct investigational studies involving VA patients, staff, facilities or medical records must submit, in writing, one complete hard copy with signatures and one complete electronic version of the investigational protocols to the Research Service Human Subjects Coordinator. These protocols will be reviewed. No VA research may begin prior to Research & Development (R&D) Committee approval.
 - (1) Submission of protocols. Before a project may be initiated, protocols for human subject research must be submitted to and approved by the University of Florida Institutional Review Board (IRB-01). The IRB approved protocols must be submitted to the Research Compliance Core at NF/SGVHS. Once the Research Compliance Core approves the protocol, it will be forwarded to the R&D Committee for final approval. Submission must include one complete hard copy with signatures and one complete electronic version. Protocols must contain an informed consent form that has been approved and stamped by the IRB with lay-language description of the planned procedures for participants to sign as their official VA Informed Consent Form (VA Form 10-1086). The VA Central IRB may be utilized for VA-funded multi-site human subject research that is limited to VA personnel, patients, facilities, and/or resources. All local requirements as outlined above must also be followed for VA Central IRB protocols conducted at NF/SGVHS.
 - (2) Eligibility. The investigator responsible for the conduct of an investigational or experimental study in humans must be a member of the NF/SGVHS professional staff. Individuals may assist the principal investigator in various stages of the research, but the supervision and conduct of the project may not be delegated.
 - (3) Members. Current membership lists of the R&D Committee and all subcommittees are available from Research Service.
 - b. Action upon approval. The Associate Chief of Staff/Research (ACOS/R) will notify the investigator when a research project can be initiated and provide VA Form 10-1223, "Report of Subcommittee on Human Studies" and the R&D Committee approval letter. The principal investigator or designee (per the delegation log) will then obtain the consent of the patient by signature on the Informed Consent. A copy of the consent form must be scanned into the patient's medical record and a research consent process progress note must be completed.

3. PROCEDURE. (Continued)

c. Storage and issue of drugs. Only those prescriptions signed by a physician specifically authorized to prescribe the drug will be honored. The drugs will be separated from other drug stocks and kept in a secured location.

d. Storage and issue of devices. Devices used in experimental studies involving VA patients will be stored in an approved secure location under lock and key. Records of receipt, use or disposition of device will be documented as stipulated in 21CFR812.140. Compliance is subject to random monitoring.

4. RESPONSIBILITY.

a. The ACOS for Research and Development is responsible for ensuring adherence to the procedures outlined in this policy.

b. Investigators are responsible for adhering to this policy and for protecting rights of human subjects.

5. REFERENCES: M-3, Parts I, II, III, and IV.
M-2, Part XIV, Chapter 8.
21 CFR Ch. 1, Section 812.140

6. RESCISSION. Memorandum No. 151-1, Change 4, dated July 17, 2006.

7. EXPIRATION DATE. February 23, 2012.

8. FOLLOW-UP RESPONSIBILITY. ACOS for Research and Development.



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Director