

## **PROTECTION OF HUMAN SUBJECTS IN RESEARCH ESTABLISHING AN INSTITUTIONAL REVIEW BOARD**

1. **PURPOSE:** To outline the duties, responsibilities and membership of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) Institutional Review Board (IRB), a Subcommittee of the Research and Development (R&D) Committee, according to "The Common Rule" (38 CFR 16).

### **2. POLICY**

a. The IRB prospectively reviews and makes decisions concerning all research involving human subjects that is conducted completely or partially in LSCDVAMC facilities, conducted in approved off-site locations, facilities, and/or conducted by LSCDVAMC researchers, employees, or agents, while on official VA duty time. It includes research conducted using non-public patient data from VA records, using VA resources, publishing or presenting results with the VA cited as supporting or conducting the research, or recruiting VA patients at VA facilities. The research may be VA funded, funded from non-VA sources, or conducted without direct funding.

b. The IRB is an autonomous administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the LSCDVAMC.

c. The IRB has the following authority to:

- (1) Approve, require modifications to secure approval, or disapprove human subject research activities overseen and conducted under the auspices of the LSCDVAMC.
- (2) Suspend or terminate research for continued noncompliance with the Common Rule, VA, Department of Health and Human Services (DHHS), and Food and Drug Administration (FDA) regulations, or its own findings, determinations, and requirements (38 CFR 16.113).
- (3) Suspend or terminate research that has been associated with unexpected serious harm to participants.
- (4) Observe and/or monitor LSCDVAMC research (including the consent process) to whatever extent it considers necessary to protect human subjects.
- (5) Review copies of reports, audit findings, or correspondence to or from any regulatory agency (such as the VA Office of Research Oversight (ORO),

Office of Human Research Protections (OHRP), or the FDA) that bear upon the protection of human subjects in research in which they are involved.

- (6) Bring any matter directly to the attention of the LSCDVAMC IO, the ACOS/R, RCO, or Regional Counsel when warranted.

- d. All IRB approved research studies are subject to ongoing review, which must be conducted at least once annually by the IRB. If approval by the IRB lapses, all research activity must stop unless the IRB finds that there is an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating in the research interventions or interactions.

### 3. RESPONSIBILITIES

- a. The Medical Center Director is responsible for overseeing the development, management, and implementation of LSCDVAMC policies governing the R&D Committee, IRB, all LSCDVAMC human subject research, and all LSCDVAMC investigators and study staff. This includes monitoring changes in regulations and policies that relate to human research protection and overseeing all aspects of the HRPP program.

- b. The Associate Chief of Staff for Research and Development (ACOS/R) is delegated responsibility for the daily management of the LSCDVAMC R&D program, including the operations of the IRB.

- c. The Administrative Officer for Research and Development (AO/R) supervises the day-to-day operations of the Research Office and provides staff support to the R&D Committee and IRB.

- d. The R&D Committee provides overall direction and oversight of the LSCDVAMC R&D Program and is responsible for maintaining high scientific standards throughout the program. These include ensuring the scientific and ethical quality of VA research projects, the protection of human subjects in research, the safety of personnel engaged in research, the welfare of laboratory animals, security of VA data, and the security of VHA research laboratories. The R&D Committee plays a crucial role in the establishment and development of the HRPP.

- e. The IRB is responsible for the protection of rights and welfare of human research subjects at the LSCDVAMC. It discharges this duty by complying with the requirements of the Common Rule; FDA regulations; the FWA; and the VHA Handbook 1200 series.

- f. The IRB Administrator is responsible for ensuring that all IRB functions are accomplished in a professional fashion that complies with all relevant regulatory requirements.

- g. The Medical Center Director, R&D Committee, and the IRB shall adopt operating procedures to implement this policy. These procedures shall be reviewed and approved by the LSCDVAMC Research & Development Committee and will serve as the

governing procedures for the conduct and review of all human research conducted under the auspices of the LSCDVAMC.

#### 4. DEFINITIONS

a. **Human Research Protection Program (HRPP).** The HRPP is a comprehensive system to ensure the protection of human subjects participating in research. The HRPP is a multi-tiered program involving the Medical Center Director, Chief(s) of Staff, Associate Medical Center Director, Associate Chief of Staff for Research and Development (ACOS/R), Administrative Officer for Research and Development, Research and Development Committee, Institutional Review Board (IRB), IRB Administrator and Staff, Subcommittee on Research Safety, Research Safety Coordinator/Chemical Hygiene Officer, Research Quality Improvement Program and the Research Oversight Committee, Conflict of Interest Committee, Research Compliance Officer (RCO), Conflict of Interest Administrator, Research Credentialing Coordinator, Research Service Program Analyst, Research Information Resource Manager, Executive Director, Staff, and Board of Trustees of the Cleveland VA Medical Research and Education Foundation, Investigators, Study Staff, Research Subjects/Participants, Medical Executive Committee, Pharmacy Service, Pharmacy & Therapeutics Committee, Environment of Care Committee, Radiation Safety Committee, Radiation Safety Officer, Information Security Officer, Risk Management and the Patient Advocates, Patient Care Administrative Staff, Privacy Officer, Regional Counsel's Office, Case Western Reserve University, Case IRB Advisory Committee, Case Conflict of Interest Advisory Committee, and the Case Institutional Biosafety Committee.

b. **Research.** Research is defined as the testing of concepts by the scientific method or formulating a hypothesis or research question, systematically collecting and recording relevant data, and interpreting the results in terms of the hypothesis and/or research question. The Common Rule (38 CFR 16) defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

Under FDA regulations, the terms *research* and *clinical investigation* are deemed to be synonymous.

c. **Human Subject.** A human subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information (38 CFR 16.102(f)). The definition provided in the Common Rule includes investigators, technicians, and others assisting investigators, when they serve in a "subject" role by being observed, manipulated, or sampled. As required by 38 CFR 16.102(f) an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes.

For research covered by Food and Drug Administration (FDA) regulations (21 CFR 50 and 56), human subject means an individual who is or becomes a participant in a clinical investigation (as defined below), either as a recipient of the test article or as a control. A subject may be in normal health or may have a medical condition or disease. In research involving devices, a human subject means a human who participates in an

investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control (21 CFR 812).

d. **Research under the Auspices of the LSCDVAMC.** Research considered under the auspices of the LSCDVAMC includes all research involving human subjects that is conducted completely or partially in LSCDVAMC facilities, conducted in approved off-site locations, facilities, and/or conducted by LSCDVAMC researchers, employees, or agents, while on official VA duty time. It includes research conducted using non-public patient data from VA records, using VA resources, recruiting VA patients at VA facilities, publishing or presenting results with the VA cited as supporting or conducting the research, or recruiting VA patients at VA facilities. The research may be VA funded, funded from non-VA sources, or conducted without direct funding.

5. **REFERENCES:** 38 CFR Parts 16 and 17; 45 CFR 46, Subparts A-D; 21 CFR 50, 56, 312, 361 and 812; VHA Handbook 1200.1 "Research and Development Committee"; VHA Handbook 1200.5 "Requirements for the Protection of Human Subjects in Research"; Human Research Protection Standard Operating Procedures; Medical Center Policy 151-001 "Research and Development Committee"; Medical Center Policy 151-012 "Policies and Procedures for Conducting Research"

6. **RESCISSION:** Medical Center Policy 151-002 dated September 1, 2004 has been rescinded. The review date of this policy is September 10, 2010.

7. **FOLLOW UP RESPONSIBILITIES:** Associate Chief of Staff for Research.

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