LOUIS STOKES CLEVELAND
DVA MEDICAL CENTER
10701 East Boulevard
Cleveland, OH 44106

MEDICAL CENTER POLICY 151-001
September 1, 2007

RESEARCH AND DEVELOPMENT COMMITTEE

1. **PURPOSE.** To establish and outline the duties, responsibilities and membership of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) Research and Development (R&D) Committee which has the following Subcommittees: the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), and the Subcommittee on Research Safety (SRS).

2. **POLICY.** The R&D Committee serves in an advisory capacity to the medical center Director, through the Chiefs of Staff, on the professional and administrative aspects of the Biomedical Laboratory R&D, Clinical Science R&D, Rehabilitation R&D Programs, Health Services R&D, and Cooperative Studies Program. The R&D Committee is responsible for maintaining high standards throughout the R&D Program. These include ensuring the scientific and ethical quality of VA research projects, the protection of human subjects in research, the welfare of laboratory animals, the safety of personnel engaged in research, the security of VA data, and the security of VHA research laboratories.

All research activities, regardless of funding source, that: 1) are conducted by VA staff (including full-time, part-time employees, or who have without compensation [WOC], or Intergovernmental Personnel Agreement [IPA] appointments), 2) are conducted completely or partially in VA facilities, 3) are conducted in approved off-site locations by VA staff while on official duty time, or 4) utilize VA resources are under the purview of the R&D Committee. Research may not be undertaken without review and approval of the R&D Committee and its appropriate subcommittees.

3. **RESPONSIBILITY**

a. **Medical Center Director**: The medical center Director is responsible for the R&D program, advised and assisted by the R&D Committee. He/she is responsible for: 1) ensuring that research in which the facility is engaged is approved by the R&D Committee; 2) assuring that adequate resources, including funds, space, and personnel, are provided for research and its administrative functions, including those of the R&D Committee and its Subcommittees; and 3) providing appropriate educational and training opportunities for members of the R&D Committee, the research administrative staff, and other staff involved in research.

On the recommendation of the R&D Committee and the Associate Chief of Staff for Research (ACOS/R), the medical center Director appoints in writing the Chairpersons and members of the R&D Committee and its Subcommittees. The R&D Committee Chairperson must not simultaneously chair a subcommittee of the R&D Committee

b. **Investigators** are responsible for: 1) holding specific credentials and privileges awarded by the VA facility and VHA (where applicable) to conduct research in VA; 2) complying with all applicable personnel and other VHA policies, whether compensated,

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WOC, or IPA; 3) obtaining the R&D Committee and its appropriate subcommittee approvals prior to initiating research; 4) developing a research plan that is scientifically valid; minimizes risk to human subjects, to animals used in research, and to personnel; and contains a sufficient description of the research including all procedures and the plan for statistical analysis; 5) developing and implementing plans for data use, storage, and security that are consistent with VA, VHA, and other Federal statues, regulations, and policies; 6) preparing and submitting information annually on their research program(s) and on each project.

c. **Associate Chief of Staff for Research.** The ACOS/R is responsible for the management of the R&D program, including the operations of the R&D Committee and its Subcommittees. He/she also serves as Executive Secretary of the R&D Committee.

d. **Administrative Officer for Research.** The Administrative Officer (AO/R) for Research provides staff support to the R&D Committee and its Subcommittees by assuring that meetings are held as scheduled, minutes are recorded accurately and promptly, correspondence relating to committee actions is processed, required records and reports are maintained, and actions mandated by the committees are executed.

e. **The R&D Committee**

1) The Committee is responsible for ensuring the effective operation of the research program and making appropriate recommendations to the medical center Director based on the Committee's oversight and evaluation of the research program. The R&D Committee:

a) Plans and develops broad objectives for the R&D Program so that it supports VA's mission.

b) Determines the extent to which the R&D Program has met its objectives.

c) Reviews the budgetary and other resource needs (personnel, materials and supplies, space, capital equipment, training, and education) of the R&D Program, at least annually, and makes appropriate recommendations regarding these needs.

d) Reviews and evaluates all subcommittees or committees both within the VA facility and at external entities that function in lieu of subcommittees, such as the Institutional Biosafety Committee at Case Western Reserve University (Case).

e) In fulfilling its responsibilities the Committee relies on information sources including activities of the R&D Committee, quality assurance activities, reports to the committee by the ACOS/R, AO/R, or other research staff members, subcommittee reports, facility reports or activities, and other appropriate sources.

2) The Committee reviews all research for scientific quality and appropriateness in which the facility is to be engaged, to promote the:

a) Maintenance of high scientific standards,

b) Protection of human subjects (including privacy and confidentiality) for study volunteers as well as research personnel.

c) Welfare and appropriate use of animals in research.

d) Safety of volunteer subjects and personnel engaged in research.

e) Security of research laboratories where hazardous agents are stored or utilized.

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f) Security of VA data, VA protected information (VAPI), and VA sensitive information.

g) Availability of adequate resources (financial and other) to conduct and complete the research.

h) Relevance of research to, and in support of, VHA's mission.

3) Each research project must be reviewed and approved initially and at least annually thereafter. An initial review of projects requires review at a convened meeting where there is a quorum consisting of a majority of voting members of the Committee.

f. **Conflict of Interest**

1) VA investigators and R&D Committee members must comply with the Standards of Ethical Conduct for Executive Branch Employees and the Federal criminal code. The obligation to follow applicable ethics laws and regulations also applies to WOC employees and IPAs conducting VA research or participating on a R&D Subcommittee.

2) R&D Committee members with outside consulting, employment, or royalty payment opportunities must ensure that these activities do not present any actual or perceived financial conflict of interest, and must recuse themselves from the review of proposals for which any conflict of interest may exist.

3) When conducting the initial or subsequent review of research programs or projects, R&D Committee members must be cognizant of any financial conflicts of interest related to the Principal Investigator, others working on the research project, or others that may influence the conduct of, and the reporting on, the research (such as a sponsor)

4. **PROCEDURES:**

a. **Research and Development Committee**

1) The medical center Director, Chiefs of Staff, ACOS/R, AO/R and Research Compliance Officer (RCO) will be ex-officio members without a vote. Chairpersons of the Subcommittees (IRB, IACUC, and SRS) will be ex-officio members with a vote.

2) All voting members must be compensated full-time or permanent part-time Federal government employees.

3) The R&D Committee consists of at least five voting members. Members have diverse backgrounds with consideration as to race, gender, ethnicity, and expertise. The voting membership will be comprised of at least: two members from the VA staff who have major patient care or management responsibilities; two members who are VA investigators actively engaged in major R&D programs or who can provide R&D expertise; one member must hold an academic appointment.

4) Committee members, exclusive of ex-officio members, must elect a Chairperson on an annual basis. The Chairperson must be approved and officially appointed, in writing, by the medical center Director for a term of one year. The Chairperson may be reappointed without any lapse in time.

5) Voting members will be appointed by the medical center Director in writing for a term of three years. Members may be reappointed without any lapse in time, if it is

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deemed in the Committee's best interest. Terms of membership will be staggered to provide partial change in membership annually. Ex-officio members will serve without time limit.

6) Other ex-officio, non-voting members (i.e. Information Safety Officer, Supervisor of the Animal Research Facility, Research Safety / Chemical Hygiene Officer) may be nominated to serve on the R&D Committee in order to fulfill its review obligations. The R&D Committee also may appoint non-voting, ad hoc members to provide expertise beyond, or in addition to, that available on the committee.

7) Members of the IACUC, IRB and SRS, in consultation with the R&D Committee, nominate new subcommittee members for appointment by the medical center Director.

8) IACUC, IRB and SRS Chairpersons are appointed by the medical center Director annually and may be reappointed indefinitely. Ex-officio members (non-voting) may not serve as Chairperson on any committee. The R&D and Subcommittee Chairpersons may not simultaneously serve as Chairperson of any other Research committee.

9) All members of the R&D Committee must fulfill the educational requirements specified by VHA's ORD and other applicable Federal regulations found on ORD's web site at: www.research.va.gov. This includes annual combined VA human subjects protection and Good Clinical Practices (CITI), as well as VA Research Data Security and Privacy.

10) The R&D Committee meets monthly and records minutes for the purpose of advising the medical center Director on all issues relating to the execution of the R&D Program. A quorum will be established by the attendance of a majority of the voting members. Approvals will require a majority of the voting members in attendance at the convened meeting. Proxy material will be considered but will not be counted in the voting.

b. **R&D Committee Actions**

1) An initial review of projects requires a review at a convened meeting at which there is a quorum consisting of a majority of voting members of the R&D Committee and requires a majority vote. The R&D Committee must evaluate scientific quality, the relevance to both VA's mission and the facility's research program, and the ability of the investigator to perform and complete the research. In addition, the review must include information on the use, storage, and security of VA data and VA sensitive information including VA Protected Information; the budget; the requirements for space, personnel, equipment and supplies; the role of the investigator at the facility; the investigator's qualifications and other information deemed relevant by the R&D Committee. If this project involves the use of veterans' data or another person's data (identified or de-identified), the review must include an assessment of the mechanisms in place to ensure: Security of data and all files; confidentiality of data, including data derived from research subjects; release of data in accordance with VHA regulations and policies and control of the data so that reuse of the data is within an approved research protocol and

in compliance with VHA procedures.

2) The R&D Committee may approve, approve with conditions, or disapprove a research project, program, or center. The final approval of the R&D Committee may only occur after all applicable subcommittees have granted final approval. The R&D Committee cannot approve a project if it has been disapproved by a subcommittee. The R&D Committee must consider the findings of its Subcommittees. The approval of research must include a specific approval period, not to exceed 1 year.

3) If after the initial R&D Committee review, the subcommittees do not require any significant changes to the protocol, the Chairperson of the R&D Committee, or his/her designee who is a voting member of the committee, may grant final approval for the R&D Committee. The R&D Committee must be notified of this action at the next convened meeting.

4) If any subcommittee required significant changes to the protocol, the protocol including the changes, must be reviewed by the R&D Committee at a convened meeting.

5) Once approved by the R&D Committee, the research becomes VA-approved research.

6) Just-In-Time Procedures. “Just-In-Time” procedures allow research projects to be submitted for funding consideration prior to receiving final R&D Committee approval to conduct the research. Research projects that are to be submitted to VA, other Federal agencies, or other entities for funding consideration must undergo a pre-submission review and receive concurrence from the R&D Committee or Scientific Review Subcommittee prior to submission of the project. Subcommittee approvals are not necessary at the time the project is submitted to the funding agency.

For VA Merit Review or VA Investigator Initiated Research proposals, this just-in time review requires a review by a convened meeting at which there is a quorum consisting of a majority of voting members of the R&D Committee. For projects funded by other entities, this review may be conducted by a Scientific Review Subcommittee that presents its findings to the R&D Committee for consideration and approval.

Concurrence of the R&D committee during the just-in-time process does not represent approval to conduct the research. The investigator must submit the protocol to the appropriate subcommittees for approval prior to receiving final R&D approval.

7) Continuing Review of research may occur during a convened meeting or through other mechanisms described in the R&D Committee’s written operating procedures, i.e. Continuing Review Subcommittee. A continuing review must assess the research activities that have occurred, the progress of the research, and any issues that may impact on the progress of the research including compliance issues.

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The Continuing Review of research projects that involves the use of veterans' data or another person's data (identified or de-identified) must include an assessment of the mechanisms in place to ensure: 1) security of data and all files; 2) confidentiality of data, including data derived from research subjects; 3) release of data in accordance with VHA regulations and policies; and 4) control of the data so that reuse of the data is within an approved research protocol and in compliance with VHA procedures.

c. **Institutional Review Board**

1) The membership and operation of the IRB will conform to the requirements of the Federal Policy for the Protection of Human Subjects known as "The Common Rule" (38 CFR 16) and VA Handbook 1200.5.

2) The IRB will have at least five members from varying backgrounds. The ACOS/R and the AO/R will be ex-officio members without a vote. Remaining members will include those who will enable the IRB to consider the medical, scientific, legal, and ethical issues involved in the participation of human subjects in research. At least one member must not otherwise be affiliated with the VA medical center or be a part of the immediate family of a person who is affiliated with the medical center. The non-affiliated member may appropriately include a member of the clergy, an attorney, a community lay member, or a practicing physician from the community. The IRB shall include at least one member whose primary expertise is in scientific areas and at least one member whose primary expertise is in nonscientific areas. The membership shall include at least two members who are knowledgeable about potential research participants who are mentally ill or who have impaired decision-making capacity. Members will have diverse backgrounds with consideration given to gender, ethnicity and profession. Alternate members may be appointed to substitute for specified regular voting members. When attending the meeting as the designated alternate of the regular voting member, alternate members will have the vote. Otherwise, they will be non-voting.

3) The Chairperson will be appointed in writing by the medical center Director for a term of one year; and may be reappointed indefinitely. Ex-officio members may not serve as Chairperson. Members appointed by the medical center Director will serve terms of three years and may be reappointed indefinitely.

4) A quorum will be established by the attendance of a majority of the voting members of which at least one must be a non-scientist. Meetings may be conducted or individual members may participate by video or teleconferencing. Approvals will require a majority of the voting members in attendance, including those attending by video or teleconferencing.

d. **Institutional Animal Care and Use Committee (IACUC)**

1) The IACUC will have at least five voting members. The ACOS/R and the AO/R will be ex-officio members without a vote. The consulting Veterinarian is an ex-officio member with a vote. The membership will include at least one practicing biomedical scientist experienced in research involving animals, one non-scientist and one member who is not affiliated with the VA Medical Center other than as a member of

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the IACUC and will represent the general community interests in the care and treatment of animals. A quorum will be established by the presence of a majority of the voting members. Approvals will require a majority of the voting members in attendance. Proxy material will be considered but will not be counted in the voting.

2) The Chairperson will be nominated by the members of the IACUC and appointed in writing by the medical center Director for a term of one year; consecutive appointments of the Chairperson are permitted. Ex-officio members may not serve as Chairperson. Members appointed by the medical center Director will serve terms of three years and may be reappointed indefinitely.

e. **Subcommittee on Research Safety (SRS)**

1) The SRS will have at least five members in addition to the ex-officio members. Ex-officio members without vote will be the ACOS/R and the AO/R, or another non-voting member from the R&D Office. The Research Safety/Chemical Hygiene Officer is an ex-officio member with a vote. Other ex-officio members with vote will include a representative of the Medical Center's recognized union (AFGE). The union representative will be nominated by the Union President and appointed by the medical center Director with concurrence of the R&D Committee. Additional membership, with vote, will include a representative of the Infection Control staff; the facility Radiation Safety Officer; and at least three members who possess expertise in chemical hazards, carcinogens, physical hazards, etiologic agents, blood-borne and airborne pathogens, and/or recombinant DNA (r-DNA). A representative of the medical center Safety staff may be an ex officio non-voting member of the committee. One voting member of the SRS must also be a member, with vote, of the R&D Committee

2) When research involves nonexempt r-DNA, the committee will defer to the Institutional Biosafety Committee at Case.

3) A quorum will be established by the presence of a majority of the voting members. Approvals will require a majority of the voting members in attendance. Only members in attendance may vote. Proxy or in absentia votes will not be permitted.

4) The Chairperson will be appointed in writing by the medical center Director for a term of one year; and may be reappointed indefinitely. Ex-officio members may not serve as Chairperson. Members appointed by the medical center Director will serve terms of three years and may be reappointed indefinitely.

f. **Subcommittee for Quality Improvement Program Oversight (QIP)**

1) The QIP advises the R&D Committee and subcommittees on the compliance and assurance activities of the research program. The QIP strives to maintain the high standards of the LSCDVAMC research program with emphasis on the HRPP. The QIP will be comprised of the Chief of Staff – Wade Park, ACOS/R, R&D Chairperson, Administrative Officer for Research and Development (AO/R), a representative from Quality Management, and the RCO, who serves as committee chair. Ad hoc members include the subcommittee chairs (IRB Chairperson, IACUC Chairperson, and the SRS Chairperson), IRB Administrator, IRB Coordinator, Research Safety Officer, IACUC Coordinator/Animal Research Facility (ARF) Manager and/or Executive Director of VA

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Medical Research and Education Foundation. The committee meets at least 4 times a year and is tasked with proactively assessing and improving the quality of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center's (LSCDVAMC) human research protection program (HRPP), animal care and use program (ACUP), safety program and basic science program.

g. The ACOS/R may convene ad hoc Subcommittees for Research Service that may include Subcommittees for Research Budget (local allocation of research funds), Research Space (allocation of existing research space within the facility), and Research Equipment (acquisition of equipment, supplies and services purchased from pooled funds not spent by investigators), or others that are deemed necessary to carry on business.

1) Subcommittees for Research Budget

The Subcommittee is comprised of three rotating members who have VA-funded research programs; one of these members will serve as Chairperson. Permanent members of the Subcommittee are the ACOS/R and the AO/R (ex-officio / non-voting), who serves as secretary.

2) Subcommittee for Research Space

The Subcommittee is comprised of three rotating members, who have VA-funded research programs. Permanent members of the Committee are the ACOS/R, who serves as Chairperson and Secretary, and the AO/R (ex-officio / non-voting)

3) Subcommittee for Research Equipment

The Subcommittee is comprised of four rotating members, who have VA-funded research programs; one member shall be a Biomedical Engineer. One of the rotating members will serve as Chairperson of the Committee. Permanent members of the Committee are the Assistant Chief of Engineering (Wade Park Unit), the ACOS/R and the AO/R (ex-officio / non-voting), who serves as secretary.

5. **REPORTING REQUIREMENTS.** Minutes will be recorded for all Subcommittees and submitted to the parent R&D Committee for approval. Minutes will be recorded for the R&D Committee, including consideration and approval of all Subcommittee minutes. Minutes of the R&D Committee will be approved by the Chairperson, and submitted to the medical center Director through the ACOS/R and the Chief of Staff for review and appropriate action. Minutes are forwarded to VACO upon request.

6. **REFERENCE:** VHA Handbooks 1200.1, 1200.5, 1200.7, 1200.8; Medical Center Policy 151-002, "Protection of Human Subjects in Research Establishing An Institutional Review Board"; Medical Center Policy 151-003, "Protection of Animal Subjects in Research Establishing An Institutional Animal Care And Use Committee "; Medical Center Policy 151-007," Subcommittee On Research Safety"; Medical Research Service Standard Operating Policy and Procedure, 151-012 "Policies and Procedures for Conducting Research Studies".

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7. **RESCISSION:** Medical Center Policy 151-001 dated September 1, 2004 has been rescinded. The review date of this policy is September 1, 2010.

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

WILLIAM D. MONTAGUE
Medical Center Director

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