

TABLE OF CONTENTS

(All VA policies and forms can be found at www.va.gov/detroitresearch)

Human Research Protection Plan (MCNM IIR-1)

CHAPTER I INVESTIGATORS

Institutional Conflict of Interest in Research (MCNM IIR-4)

Guidance on QI/QA vs. Research

Guidelines for Submission of a Research Proposal

Investigator Responsibilities (Research Policy #3)

Publication of Professional Papers (Research Policy #13)

Report of Monitor

Research Security (MCNM IIR-5)

Research Space (Research Policy #9)

CHAPTER 2 PROTECTION OF HUMAN SUBJECTS

(Wayne State University Human Investigation Committee provides IRB review for the John D. Dingell VA Medical Center. Their policies & forms can be found at <http://www.hic.wayne.edu/>)

Informed Consent (Research Policy #4)

Checklist on Informed Consent

Human Studies Education Requirements (Research Policy #11)

Identifying Research Patients in CPRS (Research Policy #10)

Investigational Drugs (MCNM IIR-303)

VAF 10-9012, Investigational Drug Information Record

Investigational Devices (Research Policy #7)

Privacy & Data Security (Research Policy #12)

Participant Outreach (Research Policy #15)

Posting Recruitment Flyers for Non-VA Research (Research Policy #14)

Research Compliance/Performance Improvement Plan (Research Policy #6)

Subject Recruitment (Research Information Bulletin)

VA Tissue Banking

CHAPTER 3 COMMITTEES

Clinical Investigation Committee (CIC) (Research Safety Policy #2)

Research & Development Committee (Research Policy #1)

Research & Development Committee (Medical Center Bulletin #10)

Subcommittee on Research Safety (Biosafety) (SRS) (Research Policy #5)

CHAPTER 4 ANIMAL RESEARCH

(VA forms and policies can be found at www.va.gov/detroitresearch. Wayne State University Animal Investigation Committee policies & forms can be found at <http://www.aic.wayne.edu/>)

Controlled Substances in Animal Research (MCNM IIR-3)

Procedure to Request Controlled Substances for Animal Research (SOP #2)

Occupational Health & Safety Plan for Research Personnel with Animal Contact
(MCNM IIR-2)

CHAPTER 5 EMPLOYEES

Hiring Procedures and Salary Guidelines

Without Compensation (WOC) Employees Information

(All employee application forms can be found at www.va.gov/detroitresearch)

NOTE: Investigators located in VA Labs should also have copies of the RESEARCH LABORATORY SAFETY MANUAL AND CHEMICAL HYGIENE PLAN and the Radiation Safety Manual in the labs.

Policies and procedures cannot possibly address all situations. Please make sure that you exercise good judgment and common sense. Remember that patient needs always come first.

HUMAN RESEARCH PROTECTION PROGRAM
(HRPP)

1. PURPOSE

The policy describes the overall mission, values, responsibilities, and requirements of the Human Research Participant Protection (HRPP) Program.

2. SCOPE

This policy applies to all research involving humans as subjects conducted at this VA Medical Center. VA research is considered all research involving human subjects that is conducted completely or partially at the John D. Dingell VA Medical Center, conducted in approved off-site locations, facilities, and/or conducted by VA researchers while on official VA duty time. This research may be VA funded, funded from extra-VA sources, or conducted without direct funding. All human subjects research conducted at this institution must be approved, or granted an exemption, by the IRB and approved by the Research and Development Committee. Decisions about whether a study meets the criteria for “human studies research” are made by the Wayne State University Human Investigation Committee. (See Wayne State University Human Investigation Committee “Human Participant Research – How is it Defined?”) Research that has been reviewed and approved by the IRB may be subject to further review and disapproval by other review bodies or officials, including, but not limited to, the Research and Development Committee, the Director, or the national Office of Research and Development.

3. POLICY

a. The mission of the HRPP Program is to assure that all VA research associated with the John D. Dingell VA Medical Center (JDDVAMC) is conducted ethically and in accordance with federal regulations for the protection of human subjects. The HRPP Program promotes a culture of shared responsibility and accountability in order to protect the rights and interests of human subjects who participate in research, to minimize the risks and maximize the benefits of participation, and to treat fairly the groups and individuals involved. It is imperative that human research subjects receive the highest level of protection possible and that any questions or any legal or ethical ambiguities always be resolved in favor of the human research participant.

b. The basic ethical principles governing human subject research in the VA can be found in the Belmont Report. These three principles are briefly described as:

- (1) **Respect for persons** - which is applied by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations;
- (2) **Beneficence** - which is applied by weighing risks and benefits; and
- (3) **Justice** - which is applied by the equitable selection of subjects.

c. The VA is one of the seventeen Federal departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects (Common Rule). This is incorporated in

2.

Medical Center Numbered Memorandum 11R-1

Title 38 Code of Federal Regulations (CFR) Part 16. The procedures for implementing 38 CFR Part 16 are defined in VHA Handbook 1200.5, effective July 15, 2003. In addition, the VA follows applicable regulations in 38 CFR Part 17 such as patient rights (38 CFR 17.33), treatment of research-related injuries (38 CFR 17.85), hospital care for research purposes (38 CFR 17.45), and outpatient care for research purposes (38 CFR 17.92). The VA also adheres to the HIPAA Privacy Rule (Standards for Privacy of Individually Identifiable Health Information in 45 CFR Parts 160 and 164), and VHA Handbooks 1605.1 and 1605.2 Privacy Policy.

d. For all clinical research regulated by the FDA, FDA regulations apply (21 CFR 50 and 56). The following additional regulations are used for specific test articles:

- (1) Investigational New Drug Applications (IND) (21 CFR 312)
- (2) Radioactive Drugs (21 CFR 361)
- (3) Biological Products (21 CFR 600)
- (4) Investigational Device Exemptions (IDE) (21 CFR 812)

e. Research in the VA supported by the Department of Health and Human Services (DHHS) must also follow regulations at 45 CFR 46. VA has not adopted regulations similar to 45 CFR 46 Subparts B through D that include additional protections for fetuses, pregnant women, and human in vitro fertilization (Subpart B), prisoners (Subpart C), and children (Subpart D). Research in which the subject is a fetus, in-utero, or ex-utero (including human fetal tissue) must not be conducted in the VA. Research in prisoners and children can be conducted with a waiver from the Office of Research and Development and be conducted in accordance with the appropriate subpart protections.

f. **International Research.** All human subject research in which JDDVAMC investigators are involved must comply with all applicable federal regulations for the protection of human subjects in all material respects. This includes research conducted by JDDVAMC investigators in foreign countries.

VA regulations at 38 CFR 16.101(h) and DHHS regulations at 45 CFR 46.101(h) recognize that "the procedures normally followed in the foreign countries may differ from those set forth in this policy." Research may be approved, therefore, if "the procedures prescribed by the [foreign] institution afford protections that are at least equivalent to those provided in this policy." The foreign country's procedures may then be substituted for the procedures required by the federal regulations. Approval of the substitution is to be given by the relevant federal department or agency head after review of the foreign procedures; notice of actions taken on such reviews is to be published in the Federal Register (or elsewhere, as provided for in department or agency procedures). *Note: FDA has not adopted this provision for research that it regulates. All FDA funded research, however, must comply with both DHHS and FDA regulations.*

g. **Sponsored Research at the JDD VAMC.** All sponsored research at the John D. Dingell VA Medical Center must involve a contractual arrangement through the Metropolitan Detroit Research & Education Foundation (MDREF), be approved by the JDDVAMC R&D Committee and abide by ethical principles. MDREF is the congressionally authorized non-profit corporation that has the ability to contract with third parties to facilitate and support research activities at the JDDVAMC.

3.

Medical Center Numbered Memorandum 11R-1

As a general rule, Cooperative Research and Development Agreements (CRADAs), a mechanism well known to other federal agencies and private sector organizations that participate in federal/private research partnerships, will be used. On occasion, a clinical research agreement (CRA) can be approved for use. If so, clauses addressing the following areas must be included:

1. Procedures that protect human participants.
2. Medical care for research participants with a research-related injury.
3. Reporting of findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB's approval to continue the study.
4. Plans for disseminating findings from the research and the roles that investigators and sponsors will play in publication or disclosure of results.
5. How results will be communicated to study participants when participant safety or medical care could be directly affected by study results.

Acceptable samples of the necessary clauses will be provided to the sponsor. As part of the process, all contracts with MDREF must be reviewed for required CRADA language (clauses) and approved by the VA Office of General Counsel.

h. Undue Influence

Undue influence exerted on any committee member is reported to the Associate Chief of Staff for Research and Development when it occurs. The ACOS investigates the allegations and takes corrective action if necessary. This report may take the form of an e-mail, telephone call, or memo and is attended to within seven working days. Undue influence may be construed as research misconduct and functioning as the Research Integrity Officer for the institution, the ACOS/R&D processes the incident dependent upon its nature. Reporting to the IRB may also be necessary.

i. Legal Counsel

Research is governed by federal laws, regulations and standards [45 CFR 46.101(e), 38 CFR 16.102(c), 21 CFR 50, 56, 312, 812; 38 CFR 46]. Federal regulations also require that human participant research conducted, wholly or in part, within the state must comply with pertinent state and local laws and regulations [38 CFR 16.101(e)-(f), 38 CFR 15.102(c); 45 CFR 46.101(e)-(f), 45 CFR 46.102(c), 45 CFR 46.402(d)-(e)]. State law must take precedence when it provides a higher level of protection than federal regulations. Michigan has no specific statute concerning human participant research. However, both the Michigan Mental Health Code and the Michigan Public Health Code require the protection of human participants in research. In addition, various other local and state laws and regulations may apply. All policies and procedures are forwarded to the VA Office of General Counsel for review. If no revisions are necessary, the OGC certifies that the policy meets legal and regulatory requirements. Existing policies are reviewed by the OGC on an ongoing basis, but not less than annually. Relevant changes in state and local laws are reviewed on a regular basis by the OGC. Laws that require the immediate attention of the research administration are promptly reported to the ACOS/Research. For studies not conducted in the JDDVA Medical Center or with non-veterans, Michigan law regarding surrogate informed consent is applied in accordance with the policies of WSU HIC.

4.

Medical Center Numbered Memorandum 11R-1

4. RESPONSIBILITIES

a. **Institutional Official (IO)** - The Medical Center Director, as the IO, is responsible for the HRPP Program advised and assisted by the Chief of Staff, the Associate Chief of Staff for Research, and the Research & Development (R&D) Committee. The IO is responsible for:

- (1) maintaining a current Federal-Wide Assurance (FWA).
- (2) implementing the R&D program, policies and procedures, including establishing and appointing members to the R&D Committee and any appropriate subcommittees.
- (3) assuring that the IRB complies with the terms of the assurance and the MOU and possesses appropriate knowledge of the local context in which this institution's research will be conducted.
- (4) ensuring that R&D funds are used appropriately and that adequate resources, including funds, space and personnel, are provided for research and its administrative functions as outlined in VHA Directive 1200.
- (5) Ensuring that all relevant personnel will receive appropriate initial and continuing education about human subject protection.

b. **The Associate Chief of Staff/Research & Development (ACOS/R&D)** - The ACOS/R&D is delegated by the Medical Center Director with overall responsibility for the R&D Program, including the HRPP Program, at the facility.

c. **The R&D Committee** - The R&D Committee is responsible, through the Chief of Staff to the Director, for maintaining high standards throughout the R&D program. These standards include those assuring the scientific quality of research projects, adequate resource allocations, protection of human subjects in research, and safety of personnel engaged in research. Required annual reviews of all research protocols (including exempt projects) ensures continuing fulfillment of the organization's ethical standards. The R&D Committee advises the Director on professional and administrative aspects of the R&D Program. All R&D activities within the facility, whether funded or unfunded, are within its purview. No research may be undertaken without R&D Committee and appropriate subcommittee(s) review and approval. Neither the R&D Committee nor any organizational official, including the Medical Center Director, can overturn a disapproval of a research project by the IRB. The R&D Committee, Medical Center Director, or ORD can overturn a research project approval by the IRB.

d. **The Institutional Review Board (IRB)** - A Memorandum of Understanding (MOU) dated May 26, 2006 establishes Wayne State University Human Investigation Committee (HIC) as the IRB of record for the John D. Dingell VA Medical Center and empowers the IRB to act on behalf of the JDDVAMC in all issues pursuant to human subjects research and protection. The IRB is responsible for the evaluation and oversight of all research involving humans as subjects. The IRB has the authority given to it by the Medical Center Director to review and approve, require modifications (to secure approval), or disapprove all human research activities in order to assure that the rights and welfare of individuals involved as subjects of research are being protected in accordance with federal regulations. WSU IRBs evaluate whether exempt research (See Wayne State University Human Investigation Committee policy "Exempt Review") fulfills the organization's ethical standards and, when appropriate, also ensures that participants involved in exempt research are provided necessary protections. The IRBs also have the authority to suspend or terminate approval of human research activities and observe or have an observer present during the consent process of human subject research. In accordance with VA Handbook 1200.5, two or

5.

Medical Center Numbered Memorandum 11R-1

more VA employees will be included as voting members of the IRB on each IRB that reviews VA research.

The WSU HIC:

- (1) Serves as the Privacy Board for research related issues. Functions include review and determinations of requests for Waiver or Alteration of Authorization to use or disclose Protected Health Information in Research.
- (2) Investigates and addresses all incidents of non-compliance, unanticipated problems, terminations, suspensions, and serious adverse events in accordance with established WSU HIC policies and procedures. (See WSU HIC Policy “Reporting of Unanticipated Problems, Terminations, Suspensions, and Serious & Continuing Non-Compliance”)
- (3) Complies with the requirements of all relevant regulatory and compliance enforcement agencies or offices, including ORO, OHRP, and FDA. The IRB will additionally speak for the VA in reports relevant to the VA. Copies of any reports or correspondence (e.g., notices of non-compliance, on-site serious adverse events, research misconduct, etc.) to or from such agencies concerning JDDVAMC research must be provided by the WSU IRB to the R&D Committee, which shall determine whether any additional notifications are necessary.
- (4) Evaluates and manages investigator conflict of interest in accordance with established policies. (See WSU HIC Policy “Conflict of Interest: Principal Investigator/Key Personnel”)

e. **Investigators** - The Principal Investigator, as the individual responsible for the implementation of research, is directly responsible for all aspects of the research project, ensuring the protection of every human subject in the research project. When appropriate, the investigator must also ensure that participants involved in exempt research are provided additional protections. This responsibility starts with protocol design, ensuring all members of the research team always comply with the findings, determinations and requirements of the HIC and R&D Committees. Investigators must maintain appropriate oversight of project(s) and staff in order to conduct research effectively and to ensure the rights and welfare of human participants are protected. At all times, research must be conducted in compliance with all applicable regulatory requirements and the determinations of the HIC and R&D Committees.

f. **The Research Compliance Officer (RCO)** responds to questions, concerns or complaints regarding an individual’s rights as a research subject. Any issue that cannot be resolved will be addressed by the ACOS/R&D or the HIC, as appropriate. He/she conducts procedures and recordkeeping audits to detect, correct and report, as necessary, administrative and/or material breaches in protecting the rights and welfare of human participants, as required by federal regulations and/or institutional policy. He/she reviews all unexpected and/or adverse events. He/she conducts an initial review of reports of noncompliance or research impropriety. The Research Compliance Officer conducts annual reviews of the IRB membership composition and the IRB policies and procedures to ensure they meet all applicable VA and Federal regulations and guidance. RCO also evaluates and reports on participant outreach activities.

6.

Medical Center Numbered Memorandum 11R-1

5. REPORTING REQUIREMENTS

a. **Adverse Reactions and Unexpected Events.** Wayne State University Human Investigation Committee Policy entitled “Adverse Reactions and Unexpected Events” establishes the policies and procedures for reporting and review of serious adverse events and unexpected events. If an adverse event (or imminent threat of an adverse event) results in a **substantive IRB action**, then the IRBs determination to take such action must be reported to the ORO Regional Office within **10 working days**. **Substantive IRB actions** materially alter the substance and meaning of a protocol, informed consent process or document, investigator status, including but not limited to restriction, suspension or termination of a study or investigator participation, and actions taken to prevent future occurrence(s) of the adverse event.

Regardless of IRB action, all **unexpected deaths** of research subjects must be reported to the ORO Regional Office no later than **2 working days** after the IRB is informed of the death. See **Notification to Relevant Agencies** (paragraph g) below.

b. **Suspension or Termination of IRB Approval.** VA policy requires that for cause suspensions and terminations be reported to ORO within 10 working days. Wayne State University Human Investigation Committee Policy entitled “Suspension and Termination of Research Protocols” establishes additional reporting requirements. See **Notification to Relevant Agencies** (paragraph g) below.

c. **Research Subject Complaints/Inquiries:** The primary mechanism for research subjects to address their complaints or inquiries about a research project is by telephone. Each IRB-approved VA Informed Consent Document includes the following: “If you have any questions, concerns or complaints about this study now or in the future, you may contact [*insert name of PI*] or one of [*his/her*] research team members at the following phone number [*insert telephone number*]. If you have questions or concerns about your rights as a research participant, the Chair of the Human Investigation Committee can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call (313) 576-1000, ext. 61046 to ask questions or voice concerns or complaints or you may call the Patient Advocate at (313) 576-1000, ext. 65158.”

d. **Non-compliance:** When non-compliance issues (See Wayne State University Human Investigation Committee Policy entitled Reporting of Unanticipated Problems, Terminations, Suspensions, and Serious & Continuing Non-Compliance”) are identified, every effort is taken to correct these issues at the administrative level. WSU HIC is involved immediately. Initiation of an inquiry process can begin at the direction of, and through, the Associate Chief of Staff for Research and Development (ACOS/R&D), the Administrative Officer for Research and Development (AO/R&D) or the Research Compliance Officer (RCO). If an issue involves human subject protection and safety, immediate action may be taken to minimize potential harm to subjects or staff pending the outcome of formal inquiry.

e. **Regulatory Improprieties in Research:** All instances of improprieties in research will be reported to the RCO, the AO/R&D, the ACOS/R&D, and the HIC administrator, if human subjects are involved. Each instance of alleged impropriety will be evaluated on a case-by-case basis. All efforts will be made to correct the impropriety at the administrative level. If the impropriety

7.

Medical Center Numbered Memorandum 11R-1

involves potential harm to others or significant property damage, the appropriate institution officials will be notified for immediate action pending formal inquiry.

f. Actions on Research Subject Complaints, Noncompliance and Regulatory

Improprieties in Research: The RCO conducts an initial review, as appropriate to the nature of the complaint, noncompliance issue, or impropriety. During this review, every effort is exercised to maintain the confidentiality of all parties involved. The ACOS/R&D is notified of the incident and that an inquiry has begun. Findings and recommendations from this review are forwarded to the ACOS/R&D and the AO/R&D.

The final course of action is entirely dependant upon the nature, severity, and degree of seriousness of the findings. All actions taken are at the institutional level most appropriate for the circumstances.

g. Notification to Relevant Agencies: The HIC, in accordance with their written policies and procedures, complies with the requirements of all relevant regulatory and compliance enforcement agencies or offices, including ORO, OHRP, and FDA. The HIC will additionally speak for the VA in reports relevant to the VA. Copies of any reports or correspondence (e.g., notices of non-compliance, on-site serious adverse events, research misconduct, etc.) to or from such agencies concerning JDDVAMC research must be provided by the WSU HIC to the R&D Committee, which shall work with the IRB to determine whether any additional notifications are necessary.

5. REFERENCES

Title 38 Code of Federal Regulations (CFR) Part 16 and Part 17

Title 21 CFR 50, 56, 312

Title 45 CFR 46, Subparts B through D

VHA Directive 1200

VHA Handbook 1200.5

Wayne State University Human Investigation Committee Policies & Procedures

6. RECISSIONS

Medical Center Numbered Memorandum 11R-1 dated 11/24/06

7. EXPIRATION DATE

May 22, 2010

Michael K. Wheeler
Director

Distribution: E, H

Policies and procedures cannot possibly address all situations. Please make sure that you exercise good judgment and common sense. Remember that patient needs always come first.

INSTITUTIONAL CONFLICT OF INTEREST (COI) IN RESEARCH

1. PURPOSE

This policy describes the relationships that may produce a real or perceived conflict of interest (COI) for the research being conducted at the John D. Dingell VA Medical Center.

2. POLICY

The policy of the VA is to ensure that the welfare of human subjects and the integrity of research will not be compromised, or appear to be compromised, by competing institutional interests or obligations. Although the Department of Veterans Affairs (VA) has separated technology transfer functions (see VHA Handbook 1200.18) from research administration, circumstances may exist in which separation of function is not sufficient to avoid the appearance of institutional conflict of interest.

3. SCOPE

This policy applies to all human subjects research conducted in a VA facility. This policy applies to investigators, research coordinators, IRB members and staff, R&D members and staff, and institutional officials.

4. DEFINITIONS

- a. **Disclosure** - Disclosure is the formal written process of documenting all aspects relating to the development of potential intellectual property for the purpose of determining and assigning ownership.
- b. **Equity** - The money value of a property or of an interest in a property in excess of claims or liens against it.
- c. **Institutional conflict of interest** - An institutional conflict of interest may occur when the institution, or any of its senior management or an affiliate foundation or organization, has an external relationship or financial interest in a company or organization that itself has a financial interest in a VA investigator's research project.
- d. **Institutional officials** - Individuals in a position to make decisions with institution-wide implications. These include the Medical Center Director, Chief of Staff, Associate Chief of Staff for Research & Development, and other senior officers.
- e. **Intellectual Property (Invention)** - Intellectual property is any art, machine, manufacture, design, or composition of matter, or any variety of plant, which is or may be patentable under the patent laws of the United States.
- f. **Inventor** - The inventor is the individual responsible for the conception or reduction to practice of a device or process.
- g. **Patent** - A patent is an official written document securing to an inventor for a term of years the exclusive right to make, use, or sell an invention.

2.

Medical Center Numbered Memorandum 11R-4

h. **Re-disclosure** - Re-disclosure is the formal written process of documenting all aspects relating to any improvement of a previously disclosed invention for the purpose of issuing a new determination on the improved invention.

i. **Royalty** - A royalty is compensation for an invention.

j. **Significant financial interest** - Any equity interest, royalties, compensation valued (when valued in reference to current public prices, or where applicable, using accepted valuation methods) at equal or greater than \$10,000.

5. **RESPONSIBILITIES**

The R&D Committee will be responsible for evaluating potential institutional conflict of interest and will take actions as required to avoid, or to appropriately manage, apparent institutional COI. These actions may involve referral to appropriate advisors outside the facility or obtaining advisement from the Office of Regional Counsel. If used, outside advisors will be individuals who have sufficient seniority, expertise, and independence to evaluate the competing interests at stake and to make credible and effective recommendations. All outside advisors will be independent of the management of oversight for the Human Research Protection Program (HRPP) within the institution. The utilization of outside advisors will increase the transparency of the deliberations and enhance the credibility of determinations. After reviewing a significant financial interest in research, the R&D Committee will communicate its conclusions, along with any management arrangements to be imposed, to the IRB. All relevant conflicts will be disclosed to research participants in a form to be determined by the IRB. The R&D Committee also will communicate conclusions and COI management strategies to the Institutional Official and the Principal Investigator.

6. **PROCEDURES**

a. Assessment of Potential Conflict of Interest (COI)

(1) **Invention/Intellectual Property Disclosure**. In the case of an invention (to include improvement of an invention) or believed invention, the inventor must complete a VA certification page and prepare a statement for submission to the inventor's supervisor. These documents are available at the Technology Transfer Program (TTP) website www.vard.org.

The inventor's supervisor must review the employee inventor's statement. The file is then submitted via the Research and Development (R&D) Office for review and approval. It is then sent to the Director, R&D Technology Transfer Section in VA Central Office. The Technology Transfer Section provides one of three outcomes. They are that the Government:

- (a) Maintains right, title, and interest in, and to, any invention of a Government employee;
- (b) Is entitled to a royalty free license with ownership remaining with the inventor; or
- (c) Claims no interest or license; i.e., all rights remain with the inventor.

(2) **Cooperative Technology Administration Agreements (CTAA)**. The CTAA is developed when the intellectual property or invention is co-owned by the VA and the Academic Affiliate. The CTAs are developed by the TTP staff, Office of General Counsel (OGC) and the Academic Affiliate.

3.

Medical Center Numbered Memorandum 11R-4

(3) Cooperative Research and Development Agreement (CRADA). A CRADA is an agreement between the VA facility and one or more non-Federal parties (such as an academic affiliate) under which VA medical center Directors may accept, retain, and use funds, personnel, services, facilities, equipment, or other resources from collaborating parties in order to conduct R&D in a particular project. This may include the further development of a VA-owned invention and may be entered into in cooperation with a license agreement. CRADAs are negotiated by the VA medical center and regional counsel attorneys. Following review and approval by the Office of General Counsel (OGC), they are returned to the medical center for execution.

(4) Royalties. Royalty income to a VA facility is accepted, monitored, and distributed by the TTP. Centralized handling of royalty income allows compilation of data for evaluating and reporting on the TTP's effectiveness, and ensures compliance with applicable laws; e.g., the current Federal royalty income cap of \$150,000 per year per employee. All intellectual property claims including inventions must be signed off by the ACOS/R and Medical Center Director. The ACOS/R and Medical Center Director are notified if there is a VA interest as 85% of the royalties are returned back to the facility. Therefore, the ACOS/R can require a notification that goes into an open protocol file when there is a royalty claim. The ACOS/R will, in turn, notify the R&D Committee. *Note: Royalties paid to employees from non-Federal sources such as universities are not subject to this ceiling.*

(5) Review. The R&D Committee will review protocols to assure that, when applicable, the above arrangements are in place in situations where a VA researcher has an intellectual property interest. The R&D Committee also has a responsibility to review the potential for institutional conflict of interest, including intellectual property agreements, and to evaluate whether the potential conflict is managed adequately for the protection of human participants.

b. Management of Conflict of Interest

(1) Assumption of conflict of interest. If the VA facility retains a significant financial interest, or if an institutional official with direct responsibility for the HRPP holds a significant financial interest in the invention, then the R&D Committee must assess the potential conflict of interest and weigh the magnitude of any risk to human participants. When reviewing potential institutional conflict of interest, the R&D Committee will assume an inclination against the conduct of human participants research at, or under the auspices, of the institution where a COI appears to exist. However, the assumption may be overturned by the Committee when the circumstances are compelling and the Committee has approved an effective conflict management plan.

(2) Decision making. A key aspect in decision-making is to analyze when it would be appropriate and in the public interest to accept and manage a COI, rather than require that the COI be eliminated. In some cases, the benefits of conducting a proposed research activity at the institution will be potentially high, and the risks will be low. In other cases, the scientific advantages of conducting the research may be speculative and the risks may be great, in these latter instances, the conflict should be avoided by disapproving the research application.

(3) Evaluation of risk. Each case should be evaluated based upon the following:

4.

Medical Center Numbered Memorandum 11R-4

- (a) The nature of the science;
- (b) The nature of the interest;
- (c) How closely the interest is related to the research;
- (d) The degree of risk that the research poses to human participants; and
- (e) The degree to which the interest may be affected by the research.

The R&D committee will consider whether the institution is uniquely qualified, by virtue of its attributes (e.g., special facilities or equipment, unique patient population) and the experience and expertise of its investigators, to conduct the research and safeguard the welfare of the human subjects involved.

(4) Potential actions. Potential actions to be considered to better protect subjects are any (or a combination) of the following:

- (a) Disclosure of the financial interest to potential subjects;
- (b) Not conducting proposed research at the institution, or halting it if it has commenced;
- (c) Reducing or otherwise modifying the financial (equity or royalty) stake involved;
- (d) Increasing the segregation between the decision-making regarding the financial and the research activities;
- (e) Requiring an independent data and safety monitoring committee or similar monitoring body;
- (f) Modifying of role(s) of particular research staff or changes in location for certain research activities, e.g., a change of the person who seeks consent, or a change in investigator; or
- (g) Establishing a research monitoring process, so that the research can be closely scrutinized to ensure that potential conflicts do not undermine the integrity of the work and the VA.

7. REFERENCES

VHA Handbook 1200.5 paragraph 7.A(9)

VHA Handbook 1200.18

OHRP Final Guidance Document. *Financial relationships and interests in research involving human subjects: Guidance for human subject protection.* May 5, 2004.

8. RESCISSIONS

Medical Center Numbered Memorandum 11R-4, dated 11/24/06

9. EXPIRATION DATE

May 22, 2010

Michael K. Wheeler
Director

Distribution: E, H

John D. Dingell VA Medical Center Research Service Guidance on QI/QA vs. Research

Quality Improvement (QI) and Quality Assurance (QA) consist of activities that are undertaken to measure the effectiveness of a process, program or service, the results of which are to be shared only with individuals associated with the process, program or service being evaluated. Research consists of a systematic investigation that is designed to develop or contribute to generalizable knowledge, the results of which are to be shared with both individuals associated with and individuals unassociated with the investigation. In other words, QI/QA results are intended for an internal audience, whereas research is intended for a broader, external audience.

Given that QI/QA initiatives often have the goal of generating knowledge that will guide improvements in limited settings, e.g., clinical departments, health care delivery programs, classroom curriculums, it may be difficult at the outset of such activities to determine whether knowledge acquired as a result of a QI/QA initiatives is "generalizable" or will become "generalizable." Given this difficulty, the WSU IRB has developed the following list, which differentiates between research related activities and QI/QA activities. **In short, activities that measure the effectiveness of a process, program or service AND are designed or intended to be shared with individuals outside of the process, program or service constitute human subject research and require prospective IRB review and approval.**

	Research	QI/QA
Purpose	Test a formal hypothesis	Assess a process, program, or system
Starting Point	A prospectively designed, formal, written research hypothesis	An established set of standards
Benefits	Knowledge sought may not benefit subjects involved in study	Knowledge sought directly benefits process/program/system
Risks/Burdens	May put subjects at risk	No risk, with exception privacy/confidentiality concerns of possible
Data Collection	Systematic data collection	Systematic data collection
End Point	Answer research question	Improve the program/process/system
Testing/Analysis	Determine validity of hypothesis	Compare the program/process/system to established set of standards
Intended Result	Share findings with individuals associated with the investigation and individuals not associated with the investigation	Share findings with only those individuals associated with the process/program/system. If findings are shared with individuals unassociated with the process/program/system, then activities are considered research.

If QA/QI activities do not constitute research, proceed with the activities without seeking further IRB guidance.

But remember... information contained in medical records is confidential and privileged and will only be released with the proper signed authorization of the patient or other legal authority, as outlined in Medical Center Memorandum 001B-17, Release of Medical Information and Research Policy #12, Privacy & Confidentiality.

If unsure as to whether QA/QI activities constitute research, seek IRB guidance.

GUIDELINES FOR SUBMISSION OF A PROPOSAL

1. **Eligibility:** Any clinician with at least a 5/8 FTE VA appointment and any non-clinician investigator awarded eligibility by VA Headquarter is eligible to apply for VA research funding. There are two types of funding: 1) Merit Review and 2) Career Development Program (CDP). The CDP is intended for first time applicants and requires a Letter of Intent (LOI). Due dates vary so contact the research office at 576-4474 or check the submission calendar at <http://www1.va.gov/resdev/funding/process/submission-calendar.cfm>

2. **Timing of Submission of Proposals:** Each type of proposal (Merit Review, Rehabilitation Services, Health Services & CDP) within the VA Research Service has its own submission deadlines and/or requirements, i.e., Rehabilitation requires a Letter of Intent (LOI) and HSR&D requires an Intent to Submit (ITS). The R&D Committee meets on the 1st Tuesday of each month unless circumstances arise to necessitate a change in schedule. Call the Research Office to verify the next meeting date (576-4474). In order to review any application at its next meeting, the Research Office must receive it at least ten working days in advance. Exceptions must be granted by the Chairman. ***This is a minimum requirement that will be enforced.***

Remember that for any application to be complete, the final submission to the R&D Committee must be accompanied by a budget. It is the responsibility of the investigator to meet the deadlines enforced by the R&D Committee. As no proposal can be submitted for VA funding without the approval of the R&D Committee, it is obviously preferable that proposals be submitted with sufficient lead time so they can be reviewed at the R&D Committee meeting at least one month (preferably two) prior to the deadline for submission in Central Office. This planning will permit the revision of incomplete or disapproved proposals, as well as the incorporation of suggestions from the R&D Committee review into the final application. As the competition for funding of both VA and non VA proposals intensifies, the advantage to the investigator of early submissions, which allow him/her to benefit from this local review, increases.

3. **Just-in-Time Submission of Compliance and/or Assurance Documents:** Do not submit any human subjects, animal subjects, or biosafety forms and/or approvals with this application. Research offices will be notified of proposals that are in consideration for funding and the specific just-in-time documentation needed to complete the review process. If a proposal is being considered for funding, the office of the ACOS for R&D must submit, to BLR&D or CSR&D, all required forms and approvals of appropriate R&D subcommittees or their equivalents. These documents will not be accepted prior to this notification. Secondary review, by BLR&D and CSR&D, of human, animal, or biosafety protocols will be conducted and may delay funding the proposal. No proposal will be funded until these forms and approvals are received and accepted by BLR&D and CSR&D.

4. **Elements of Proposals Submitted for Committee Review:** Although the basic elements of any scientific proposals should be familiar to all investigators, the R&D Committee receives a surprising number of proposals that either do not conform to standard format or lack some of the components generally considered essential. It is imperative that proposals submitted to the R&D Committee be in appropriate format before it can be considered for review. This is both to expedite the review process on our part, as well as ensure that those elements, which will be deemed essential by any external review committee, are present. The particular format may vary somewhat depending on the type of submission of the funding agency, so check the website at www.va.gov/resdev or call the Research Office at 576-4474.

INVESTIGATOR RESPONSIBILITIES

1. **RESPONSIBILITIES:**

Investigators are responsible for the following:

- a. Obtaining appropriate education, and certification to conduct research involving human subjects by a program that meets all VA requirements.
- b. Developing a research plan that is scientifically valid, minimizes risk to the subjects, containing a description of the data acquisition and safety monitoring plan that includes the reporting mechanism of adverse events to the IRB, and to other Federal agencies, e.g. FDA. The plan may vary depending on the potential risks, complexity, and nature of the study. A Data Safety Monitoring Board should be part of the monitoring plan when required by NIH or FDA. The use of a DSMB should be considered if there are multiple clinical sites, the study is blinded, interventions are particularly high-risk, or vulnerable populations are included.
- c. Obtaining legally effective informed consent of subjects or their legally authorized representative, if the study involves human subjects. If someone other than the investigator conducts the interview and obtains consent, the investigator should formally delegate this responsibility and the person so delegated should have received appropriate training to perform this activity. The most recently IRB approved VA consent form must be used. The informed consent process must be documented in accordance with Research Service Policy.
- d. Maintaining appropriate oversight of project(s) and staff in order to conduct research effectively and to ensure the rights and welfare of human participants are protected.
- e. Ensuring all study personnel are adequately informed about the research protocol and their research-related duties and functions, including medication counseling well in advance of the staff assuming such responsibility.
- f. Assuming full responsibility for training of all key personnel in all features of the HRPP.
- g. Reporting all Serious Adverse Events (SAE), or Unexpected Events (UE), whether on or off-site, to the IRB with a copy to the VA R&D Committee, in accordance with WSU HIC Policy "Reporting of Unanticipated Problems, Termination, Suspensions, and Serious & Continuing Non-Compliance". If a DSMB is used, all events must be reported to the DSMB and a summary of the DSMB findings must be reported to the IRB and other entities as required. Other adverse events, as defined by the monitoring plan in the protocol, must be reported in accordance with the monitoring plan approved by the IRB and as defined in FDA regulations or other applicable federal regulations.
- h. Obtaining R&D Committee and IRB approval for all amendments to or modification of the research proposal including the consent form or performance site prior to initiating the changes except when necessary to eliminate apparent immediate hazards to the subject.

i. Obtaining initial and continuing R&D Committee and IRB review and approval and for submitting to the R&D Committee and IRB requests for modifications to the protocol. The investigator is expected to know the date of continuing review and that the project is automatically suspended when not approved by the IRB and R&D Committee on schedule.

j. Submitting termination and completion reports when protocols are terminated or completed. A Project Data Sheet, including a brief project summary, should also be included as part of the final report. Upon acceptance of this report by the IRB, this information will be given to the R&D Committee for final review.

k. Following procedures for use of investigational drugs as outlined in Medical Center Number Memorandum 118-303, Investigational Drugs.

l. Following procedures for use of investigational devices as outlined in Research Service Policy #7, Investigational Devices.

m. Providing a progress report on ongoing projects to the R&D Committee on an annual basis.

n. Submitting manuscripts, abstracts, posters and papers to the R&D Committee for review before these works are submitted for publication to professional journals, organizations, etc.

Failure to adhere to these responsibilities will result the termination of the investigator's protocol(s) and may result in disbarment from future VA participation in research projects.

2. REFERENCES

VHA Handbook 1200.5

VHA Handbook 1058.1, Reporting Adverse Events in Research to the Office of Research Oversight

VHA GCP Guidelines

WSU HIC Policies & Procedures

3. RECISSIONS

Investigator Responsibilities, dated 11/15/06.

4. EXPIRATION DATE

October 1, 2010

Richard E. Miller, MD
ACOS/Research & Development

PUBLICATION OF PROFESSIONAL PAPERS

1. PURPOSE

To establish procedures, assign responsibilities, and specify authority for ensuring that the contributions of the Department of Veterans Affairs (VA) to research are appropriately acknowledged and publicly disclosed. The VA Research and Development (R&D) Program encourages free exchange of scientific, technical, and medical information both inside and outside VA. In keeping with this policy, VA investigators are encouraged to report their work at professional meetings and in scientific, technical, and medical publications, and to participate in the activities of their professional organizations. VA and its employees have a responsibility to ensure that the Department receives proper credit for VA-supported research in articles, presentations, interviews, and other forms in which the results of that research are publicized.

2. SCOPE

All investigators will initiate and document references to VA where either direct or indirect support for the research emanated from VA, either in the form of research funding, resources (e.g., facilities or patients), or as a result of the investigator's full-time, part-time, or without compensation (WOC) employment status. This policy extends to all forms of research results including publications, presentations, media interviews, and other professional activities.

3. RESPONSIBILITY

a. The Medical Center Director, or designee, will encourage appropriate presentation and publication of all significant research results to ensure that: VA support for health research is publicly disclosed; VA receives appropriate recognition for its contribution to health research; research presentations are made in a scientifically responsible manner; potential for controversy is anticipated and dealt with appropriately; and that VA research policies and procedures regarding publications and presentations are followed. Medical Center Directors or designees therefore must:

(1) Ensure that manuscripts, abstracts, and other presentations are reviewed by the R&D Committee, or a designee such as the Associate Chief of Staff for Research (ACOS/R&D), prior to presentation or publication. This will ensure that the presentation or publication satisfactorily acknowledges VA support and affiliation, protects the privacy of patients, and indicates that the welfare of human and animal subjects was protected and the appropriate institutional review board approved all research involving human or animal subjects.

2. Research Police #13

(2) Develop and implement procedures to ensure appropriate coordination with local Public Affairs officials.

(3) Develop and implement local procedures to ensure that pending publications and presentations are brought to the attention of VA R&D Communications at the time they are accepted for publication or presentation.

(4) Develop and implement local procedures to ensure observance of any additional policies of the VA Central Office research services regarding the publication and presentation of research results. There are specific requirements for publications by investigators funded by HSR&D and RR&D. Publications by HSR&D investigators shall be coordinated in accordance with procedures described in the VHA Handbook issued by HSR&D, "Required Notification Regarding Publication or Presentation of Research Findings." Investigators funded by RR&D shall refer to VHA Handbooks regarding the RR&D merit review program and the Journal of Rehabilitation Research and Development for additional information.

b. The R&D Committee must perform those responsibilities delegated to it by the Medical Center Director.

c. The ACOS/R&D must perform those responsibilities delegated by the Medical Center Director.

d. The investigator must:

(1) Acknowledge VA support and/or employment in all presentations or publications of research results.

(2) Submit all presentations or publications to the locally designated review groups or individuals prior to submission for publication or other public presentation.

(3) Inform the research office at the local VA medical center at least 8 weeks (or as soon as possible) prior to the expected publication or public presentation.

4. **PROCEDURE**

a. All papers will be submitted for review by the R&D Committee through the service author's Service Chief and the ACOS/R&D at the time of journal submission. Papers by service chiefs will be submitted through the Chief of Staff to the R&D Committee.

b. Review of publications will be carried out by R&D Committee members, giving careful consideration to the following:

3. Research Police #13

- (1) Established editorial expertise and publication practices of recognized scientific journals will be generally relied upon for substantive evaluation of content.
- (2) Any reference made to veteran patients in a publication must be in accordance with VA policy. Any questions should be referred to the Privacy Act Officer (Chief, Benefits & Data Management Service). A very general summary of that policy is:
 - (a) The privacy of veteran patients must be preserved; identities must not be disclosed.
 - (b) VA or station policy must not be misrepresented.
 - (c) When photographs of recognizable features of any patient are to accompany the article, the written consent of the patient, his guardian or nearest relative, as appropriate, must be obtained and submitted with the request for approval to the R&D Committee.
- (3) If appropriate, it is indicated that the welfare of human and animal subjects was protected.
- (4) It is accepted practice in the scientific community that major sources of research support are given recognition in scientific publications, meetings, symposia, etc.

The following credit, whenever applicable, should be insisted upon by investigators who receive research support from VA:

“This material is based upon work supported (or supported in part) by the Office of Research and Development (add as applicable Medical Research Service, Rehabilitation R&D Service, Health Services R&D Service, or Cooperative Studies Program), Department of Veterans Affairs.”

If VA provided no direct research funding, but the research involved the use of other VA resources, e.g., facilities or patients, publications or presentations must contain a similar acknowledgement.

For example, “This material is the result of work supported with resources and the use of facilities at the (name and location of VA medical center).”

- (5) Acknowledgement of VA employment:
 - (a) Authors of clinical and research manuscripts, abstracts and presentations, shall acknowledge their employment according to the following format:

4. Research Police #13

“VA Title, VA Service, John D. Dingell VA Medical Center, Detroit, MI.”

(b) When the author also holds a faculty appointment, the academic title and school also may be acknowledged.

(c) When VA provides the major salary support for the Principal Investigator (i.e., greater than 4/8), it shall be named first, whether or not VA is the primary source of funding and regardless of where the funds are administered. In addition, authors of scientific and research publications are required to list VA employment first if any of the following apply:

- 1 Work was primarily funded from VA resources (greater than 50 percent), either directly or indirectly;
- 2 Research supported was conducted primarily in VA facilities;
- 3 The first author was a junior scientist (e.g., resident, fellow trainee) whose salary may not have been provided by, but who primarily used VA funding or facilities, or whose mentor supervisor was primarily employed or funded by VA.

c. After a paper is accepted for publication and reprints are received, three copies are to be forwarded to the Research Office who will notify VA Research & Development Communications office.

d. **VA Acknowledgement in Media Reports.** News media and other individuals outside VA may not understand the contributions and roles of VA in intellectual advances, or VA’s collaborative relationships with universities and other affiliated institutions. Accordingly, scientists and physicians with VA salaries and/or funding support must, when presenting their work or discussing it with the news media, make a serious and good-faith effort to obtain appropriate recognition for VA. A serious and good-faith effort requires:

- (1) Securing a verbal agreement that VA will be cited in news reports before participating in a media interview, or
- (2) Prior to interviews, providing news media with a document on VA letterhead that:
 - (a) contains the investigator’s name, VA title, and VA medical center,
 - (b) explains the importance to VA of citing the investigator’s VA employment in any resulting feature, and

5. Research Police #13

(c) expresses a preference that the investigator's VA title be used when media time or space limitations permit the use of only one professional title.

(3) The media's failure to acknowledge VA support despite an investigator's good-faith effort to comply will not jeopardize the investigator's funding.

5. **REFERENCE**

VHA Handbook 1200.19 dated June 19, 2001

6. **RESCISSION**

None

7. **EXPIRATION DATE**

October 1, 2008

Richard E. Miller, MD
ACOS/R&D

REPORT OF MONITOR

REPORT OF MONITOR	
VAMC PI	DATE OF VISIT
SPONSOR	STUDY NUMBER (if any)
STUDY TITLE	
MONITOR(S)	PLEASE INDICATE RELATIONSHIP TO RESEARCH:
	<input type="checkbox"/> Sponsor
	<input type="checkbox"/> Clinical Research Organization
	<input type="checkbox"/> VA CSP Monitor
	<input type="checkbox"/> Regulatory Agency
REASON FOR VISIT:	
<input type="checkbox"/> Initiation Visit	
<input type="checkbox"/> Routine/Periodic Monitoring Visit	
<input type="checkbox"/> Close-Out Visit	
<input type="checkbox"/> Pre-licensing Visit (FDA)	
<input type="checkbox"/> Other: please describe _____	
<p>Our policies require an exit interview with the Associate Chief of Staff for Research or his designee for research visits that:</p> <ul style="list-style-type: none">◆ Are conducted by a regulatory agency (i.e., FDA, OHRP)◆ Have any findings, suspicions or concerns of serious non-compliance such as:<ul style="list-style-type: none">○ Failure to adhere to the approved research protocol;○ Failure to adhere to any IRB requirements;○ Failure to meet applicable regulations and/or policies.	
<p>Should your work identify the need for an exit interview, as outlined above, please arrange with the PI (or representative) to schedule this interview or call the Research Office at 313.576.1046.</p>	
<p>If your visit does not require an exit interview, please complete the following, and return this document to the PI when you depart.</p>	
<input type="checkbox"/> Results of this monitoring visit are satisfactory; no concerns of serious non-compliance.	
<input type="checkbox"/> Formal report will follow.	
<input type="checkbox"/> No formal report will be issued.	
Comments:	
SIGNATURE OF MONITOR	CONTACT PHONE
SIGNATURE OF PI	

Policies and procedures cannot possibly address all situations. Please make sure that you exercise good judgment and common sense. Remember that patient needs always come first.

SECURITY FOR RESEARCH LABORATORIES

1. PURPOSE

To establish policy regarding the security of Research Laboratories.

2. POLICY

Research laboratories and inventory will be secured in keeping with the intent and scope of VHA Directive 2002-075, VHA Handbook 1200.6 and 1200.8. The policy applies to all individuals entering the secured area, to include VA employees, without compensation (WOC) employees, contract employees, oversight entities, vendors, employees from other VA services, and visitors.

3. RESPONSIBILITY

a. The Medical Center Director is the Responsible Official (RO). The term Medical Center Director is synonymous with the Facility Director or Chief Executive Officer of a medical center or health care system. The Medical Center Director may appoint one or more Alternate Responsible Official(s) (ARO) to assist in administering this program. The ARO(s) acting in the absence of the RO may conduct all activities required by the RO related to the facility's Hazardous Agents Program.

b. The Associate Chief of Staff for Research (ACOS/R), by and through the Administrative Officer for Research (AO/R), will maintain security policies in keeping with VA directives and policy and ensure compliance with established policies.

c. Research Safety Officer will serve as the Alternate Responsible Official.

d. Human Resources will communicate the results of background checks to the AO/R in a timely manner.

e. Police Service will conduct annual security vulnerability/risk assessments and act as a resource to Research in the creation and monitoring of security policies. Additionally, Police Service will monitor security compliance by walking through the secured area on a regular basis.

f. Responsibilities of Principal Investigator (PI):

(1) Complete appropriate WOC paperwork.

(2) Ensure that research laboratory staff receives and follows all safety and security procedures.

2.

Medical Center Numbered Memorandum 11R-5

(3) Notify the Research Office immediately when any research laboratory staff no longer has a work-related need for authorized access.

(4) Review and certify the accuracy of chemical and biological inventory on an annual basis. The more potentially hazardous items may require more frequent review and certification. The need, and the review/certification standards, will be determined by the Subcommittee for Research Safety (a subcommittee of the R&D Committee) and communicated to the PI.

(5) Ensure that all data security policies and procedures are followed by all staff. Rooms where hardware is located shall be secured, or lockdown systems installed to secure the equipment to a table or desk.

g. It is the responsibility of each authorized individual to:

(1) Access:

(a) Use their keycard only for personal entrance into the secured area.

(b) Use their keycard on each entry into the secured area.

(c) Not allow any individual to follow them through the door.

(d) Report any security violations, including unauthorized individuals, to the AO/R or Police Service.

(e) Turn in their keycard to the Research Office immediately when laboratory access is no longer necessary.

(2) Information Security:

(a) Access only data for which they have authorized privileges and maintain confidentiality of sensitive data or information.

(b) Secure sensitive printed information in approved storage containers when not in use.

(c) Protect their assigned user ids, passwords, electronic signatures, and other access keys from disclosure.

(d) Log off systems before leaving a terminal or microcomputer unattended.

(e) Follow all data security policies & procedures. Report violations of IS security to the facility ISO. (See also Research Policy #16, Research Data Security)

(f) Report violations of privacy to the Privacy Officer. (See also Research Service Policy #12, Privacy & Confidentiality)

3.

Medical Center Numbered Memorandum 11R-5

(g) Complete IS Security, Research Data Security, and Privacy Training at orientation and annual refresher training.

4. DEFINITIONS

a. Terrorist Event. A terrorist event is the unauthorized removal or theft of hazardous agents capable of being used as weapons of mass destruction from research laboratories, including leased and off-site space, and/or the unlawful use of such hazardous agents. It specifically encompasses the illicit and unauthorized use of laboratory facilities (including equipment, supplies, computers, faxes, phones, etc.) for the production, purification, or dissemination of any hazardous agent. The term also refers to the illegal transfer of agents into or out of research laboratories and other research space such as the Veterinary Medical Unit (VMU), storage areas, and offices.

b. Hazardous Agent. A hazardous agent is a biological material including, but not limited to, the Centers for Disease Control (CDC) List of Select Agents (available at <http://www.cdc.gov/od/sap/>) and products of such a biological material, i.e., toxins. (The term also includes highly toxic chemicals or gases that have the potential for being used as weapons of mass destruction, as well as radioactive materials and/or radioactive sources.)

c. Select Agent. A Select Agent is one of a group of agents (viruses, bacteria, rickettsiae, fungi, toxins, and recombinant deoxyribonucleic acid (DNA) designated by the CDC as requiring registration with the CDC Laboratory Registration Program. The regulation of Select Agents is codified in Title 42 Code of Federal Regulations (CFR) Part 72, Additional Requirements for Facilities Transferring or Receiving Select Agents. All Select Agents are included in the list of hazardous agents available at <http://www.cdc.gov/od/sap/>. (Select Agents and Hazardous Agents are synonymous, and are to be handled at the same level of security.)

d. Weapons of Mass Destruction. Weapons of mass destruction include any of the classes of hazardous agents as defined and identified in paragraph 2.d (2) of Appendix A of VHA Directive 2002-075, or combinations of these agents that are capable of inflicting morbidity and mortality on a widespread basis.

e. Secured Area. The secured area refers to research laboratories located on the 4th Floor and the lower level of the John D. Dingell VA Hospital, as well as the animal facility located in the lower level.

f. Sensitive Materials. Sensitive materials include, but are not limited to, any hazardous agents as defined and identified in paragraph 2.d (2) in Appendix A of VHA 2002-075, as well as research equipment and/or supplies used to store, test, destroy or otherwise handle hazardous agents, and laboratory notebooks or other written or computerized records documenting possession of and/or research using hazardous agents.

g. USA Patriot Act. The USA Patriot Act, Public Law 107-56, October 26, 2001, was passed by Congress in response to the terrorist attacks of September 11, 2001. The purpose of the Act is to unite and strengthen America by providing appropriate tools to intercept and obstruct terrorist

4.

Medical Center Numbered Memorandum 11R-5

acts. The law includes provisions to deter and punish terrorist acts, enhance law enforcement investigatory tools, and other purposes such as aid to victims of terrorism. The Act also prohibits certain restricted persons from possessing biological agents or toxins that are identified as select agents in 42 CFR Part 72.

h. Prohibited Persons. As defined by the USA Patriot Act of 2001 (Sec 175b), prohibited persons are:

- (1) Individuals under indictment for a crime punishable by imprisonment exceeding 1 year;
- (2) individuals convicted of a crime punishable by imprisonment exceeding 1 year;
- (3) individuals in fugitive status from any local, state, national, or international law enforcement agency;
- (4) unlawful users of any controlled substance, as defined in 21 USC 802, Section 102;
- (5) illegal aliens or unlawfully in the United States;
- (6) persons adjudicated as mental defective or has been committed to any mental institution;
- (7) aliens (other than an alien lawfully admitted for permanent residence) who is a national of a country that has repeatedly provided support for acts of international terrorism; and,
- (8) has been discharged from the United States Armed Services under dishonorable conditions.

i. Research and Development (R&D) Committee is delegated oversight of matters relating to security of the secured area of Research Service.

5. PENALTIES

Failure to conform to the requirements may result in immediate withdrawal of VA research funding, suspension from the research program, and/or denied access of the secured area. Individuals who knowingly fail to follow the provisions of this policy are subject to disciplinary action proportionate to the severity of the violation, up to and including termination of VA employment or without compensation (WOC) status and criminal prosecution.

6. PROCEDURES

a. Laboratory Access.

(1) Access to research laboratories must be controlled and limited to authorized individuals. No research laboratories will be open to the public. All laboratory areas, including the VMU and storage areas, must include a state-of-the-art keycard system that generates permanent, dated records with identification of persons entering the area and times of entry. Entry must be controlled on a 24-hour/7-day per week schedule. An intrusion alarm system must be present and either connected to or otherwise monitored by Police Service.

(2) Current VA Identification (ID) badges will be used as keycards into the secured area. For employees and WOCs, the VA ID will be electronically programmed to allow entry into designated areas.

5.

Medical Center Numbered Memorandum 11R-5

(3) A record of keycard assignments must be current at all times. Personnel leaving VA employment or no longer working in the research laboratory must adhere to full clearance and checkout procedures to include turning in all identifications, keys, keycards, and other access items.

(4) Authorized health and safety inspectors, emergency response staff, Police Service, inspectors from regulatory agencies, and personnel from VHA oversight offices will have access to the secured area. The nature of that access will be determined on a case-by-case basis, based upon the frequency of access needs, the potential urgency of access needs, and the potential for after-hours access need.

(5) Routine cleaning, maintenance, and repairs are usually accomplished by VA employees who have been granted access by the AO/Research. If it is necessary for contractors to provide these services, they will sign the log book in the research office and will be accompanied by a laboratory staff member.

b. Requirements of individuals granted secured access.

(1) All authorized individuals must wear their VA ID above the waist at all times.

(2) Personnel may enter the secured area only to perform required duties.

(3) Unauthorized persons entering the secured area will be reported to Police Service.

(4) Authorized individuals must use their own card to enter the secured area. Multiple individuals, even when each person has authorization to enter the area, may not enter on one person's card access.

(5) Discrepancies in the legal permission of non-citizens to be in the U.S. will be reported to the appropriate authorities.

(6) Each individual must receive training in: Security Policies & Procedures; Data Security; Emergency Procedures; and Lab Safety Procedures. Research Administration will maintain verification of training.

c. Visitors

(1) Visitor's access is limited to hours where authorized individuals are present.

(2) Visitors must sign in and out, specifying name, affiliation, purpose for visit, time in and out, in the Research Office. They must be accompanied by a Research employee (VA or WOC).

d. Administration

(1) The AO/R will periodically complete and document a review of access records. Any security exceptions will be reported.

6.

Medical Center Numbered Memorandum 11R-5

(2) The AO/R or designee will notify Police & Security of any necessary access terminations.

(3) Irregularities in security access will be reported to Protection and Support Service.

(4) In the event an individual with secured access inexplicably disappears, is suspected to have violated procedures, or committed a security breach, the R&D Committee and Protection and Support Service must be notified immediately.

(5) Security Standards: Physical security must meet appropriate standards determined by the Office of Security and Law Enforcement, regulatory agencies, and/or applicable VA oversight offices. Protection and Support Service will conduct an annual vulnerability/risk assessment of the Research Laboratory area. The AO/R is responsible for informing Police Service of any issues affecting security.

(6) Safety Standards: All individuals given authorized access to the laboratory area must abide by all safety standards as mandated by Occupational Safety and Health Administration, Veterans Health Administration, and the medical center.

(7) Emergency Preparedness Standards: All individuals given authorized access to the laboratory area must be knowledgeable of the R&D Emergency Preparedness Plan.

e. Information Security Breach

(1) Any loss of computer, disk, or files must be reported immediately to the ACOS/Research (or AO for Research) and Police & Security.

(2) The ACOS or AO will immediately notify the Privacy Officer and the Information Security Officer.

7. REFERENCES

VHA Directive 2002-075, Control of Hazardous Materials in Research Laboratory
VHA Handbook 1200.6, Control of Hazardous Agents in VA Research Laboratories
VHA Handbook 1200.8, Safety of Personnel Engaged in Research.
Research Policy #16, Research Data Security
Research Service Policy #12, Privacy & Confidentiality

8. RESCISSIONS

None

7.

Medical Center Numbered Memorandum 11R-5

9. EXPIRATION DATE

September 27, 2010

//signed//

Michael K. Wheeler
Director

Distribution: H

RESEARCH SPACE

1. PURPOSE

To establish policy and guidelines for the allocation of research space.

2. POLICY

VA research is interdisciplinary. Research funding is provided to individual investigators not to VA services or university departments. The primary purpose of VA research space is to support VA-funded research and to support the development of projects that are competitive for VA funding. Therefore:

- a. Space will be allocated to individual investigators only, not to VA Services or academic departments.
- b. Space will be allocated for active VA projects for the duration of the project (See Guidelines, below.)
- c. Unassigned space will be made available temporarily for the development of competitive projects that will then warrant assignment of space.

3. RESPONSIBILITIES

Based on the guidelines outlined below, the VA R&D Committee will advise the Associate Chief of Staff for Research & Development (ACOS/R) on the equitable allocation of research space in the Medical Center. This advice will be transmitted to the Chief of Staff and the Medical Center Director. The total space allocation (VA + University) for each investigator will be coordinated with the Medical School. *Ultimate authority for space allocation resides with the medical center Director.* When necessary a Space Subcommittee will be convened to advise the Director. Members will include the Chief of Staff, ACOS/R, Chairperson of the R&D Committee, Chief of Facilities Management and Associate Dean for Research at Wayne State University School of Medicine.

4. GUIDELINES

a. Peer-reviewed research

Investigators eligible for space allocation: Space assignments will be made on an individual basis to eligible investigators (5/8 FTE VA position or the equivalent) with active (projects that are funded, pending or planned) VA research projects.

The following individuals, in order of priority, qualify for research space in the VA Medical Center.

- Investigators with VA research funding.
- Eligible VA investigators who are funded by NIH or an equivalent peer-review mechanism and have a pending VA research application.
- VA investigators with a VA application currently pending review by a Merit Review Board or

the equivalent.

- Eligible new VA recruits with a planned VA application that will be submitted to VA Headquarters within 12 months of space occupancy.
- Eligible investigators with a planned VA application that will be submitted to VA Headquarters within 6 months of space occupancy.

b. Office Space

Research office space will be allocated on a space available basis, to principal investigators who do not have office space elsewhere in the medical center. Up to one office (sharing may be required) will be allocated to each PI regardless of total funding. When space is limited, the highest priority will go to new VA recruits and VA-funded investigators with VA peer-reviewed research awards.

Unassigned offices will be available for temporary loan. When such space becomes available it will be announced to all VA-funded investigators. The condition for the loan will be agreement to termination with as little as one week notice.

c. Recruitment

Upon request from Department Chairpersons, unoccupied space can be made available for recruitment of investigators who will be eligible for space allocation.

d. Animal facilities

VA-funded projects will have first priority. The priority ranking for all projects will be the same as that outlined above for research space.

e. Annual review

Research space allocation will be reviewed annually by the R&D Committee and adjusted as appropriate. The following will be considered:

- Continued VA funding or continuation of other peer-reviewed funding.
- Academic productivity directly related to the research for which the space was allocated. This is assessed primarily on the basis of high-quality, peer-reviewed scientific publications.
- Research training of students, house officers and clinical fellows. This will be considered but this alone will not constitute justification for continued research space allocation.

f. Lapses or changes in funding

If peer-reviewed funding lapses for a period of more than 2 years, all assigned research space and all VA equipment may revert to Research Service for reallocation.

g. Industry-funded research

Investigators with industry-funded research that is administered by the Metropolitan Detroit Research and Education Foundation can request space for the duration of their funding. The space requested must be appropriate for the project.

5. REFERENCES

M-3, Part I, Chapter 3

6. RECISSIONS

Research Policy #9, dated January 29, 2007

7. EXPIRATION DATE

January 29, 2010

Richard E. Miller, MD
ACOS/Research & Development

INFORMED CONSENT

1. PURPOSE

It is the purpose of the Human Research Protection Program to ensure that research involving human subjects is conducted with due regard to human rights and safety. However, it is the individual investigator who has the ultimate responsibility to protect the rights and safety of subjects. A major requirement of research involving human subjects is that **investigators must obtain the informed consent of prospective subjects before they can be included in research**. Informed consent is a process, not just a form. Informed consent presumes two simultaneous concepts: informed decision-making and voluntary participation. Prospective subjects must be given sufficient information about the research and its risks and benefits to reach an informed decision as to whether they will voluntarily participate.

2. PROCESS

The informed consent process is critical for protecting human research subjects. The principal investigator is charged with the responsibility to conduct the consent interview and obtain consent. If someone other than the principal investigator (such as a study coordinator) obtains consent, then this responsibility should be formally delegated by the principal investigator and the person so delegated should be knowledgeable about all aspects of the study and have appropriate training to perform this activity. Since the consent process is so important, it may be observed by a member of the Clinical Investigation Subcommittee, the Research Compliance Officer or another authorized third party.

The informed consent process should be designed to educate the potential subject in terms he/she can understand. Language used during discussion and words written in the informed consent document should be in "lay terms". Use of scientific jargon and legalese is not appropriate. Investigators are encouraged to ask the subject to explain back fully his/her understanding of the research study and what risks are involved. At some future date, the subject may be contacted by someone from the medical center and asked about his/her understanding of the research and willingness to participate.

The investigator may not involve a human being as a subject in research or conduct any procedures required by a research protocol unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (surrogate).

For VA research conducted at the VA, a legally authorized representative is an individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. A legally authorized representative includes not only a person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian of the person, but also next-of-kin in the following order of priority unless otherwise specified by applicable state law: spouse, adult child

(18 years of age or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older).

For VA research conducted at the academic affiliate or in the community, refer to the definition of legally authorized representative contained in WSU HIC Policy/Procedure Obtaining Permission from Legally Authorized Representative or Family Members (When Participants (Subjects) Themselves are Unable to Give Consent). For individuals who met the DHHS and FDA definitions of "legally authorized representative", the PI must contact the VA District Counsel for guidance.

Surrogate consent for research may be requested and accepted only when the prospective research participant is incompetent (as determined by two VA physicians) and there is little or no likelihood that the patient will regain competence within a reasonable period of time. Before incompetent persons may be considered for participation in research, the CIC and the IRB must find that the proposed research meets all of the following conditions: a) only incompetent patients are suitable; b) favorable risk/benefit ratio; c) voluntary participation; and, d) well informed representatives/surrogates.

As the level of risk increases for a research protocol, so should the threshold for subject capacity to make informed consent. Intelligence, maturity, rationality, and language abilities all impact capacity. Generally, subjects are assumed to be able to make rationale decisions for themselves, unless demonstrated by actions / behaviors or proven otherwise. When potential subjects are likely to be incompetent or have diminished capacity, or when research risks are high, then investigators should consider the impact of capacity on the consent process.

The informed consent process should be conducted in a "neutral atmosphere", one in which there is no appearance of, or attempt to pressure a subject or surrogate to cooperate. The investigator must minimize the possibility of coercion or undue influence. An investigator shall seek consent only under circumstances that provide the prospective subject or surrogate sufficient opportunity to consider whether or not to participate.

Under no circumstances in the informed consent process, whether oral or written, may the investigator include any exculpatory language through which the subject or the surrogate is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The investigator must always use the current, IRB approved, version of the VA 10-1086 consent form to document the consent process.

The subject, or the subject's legally authorized representative, must put his/her initials at the bottom of each page after fully understanding each element. The subject (or the LAR) should place his/her full signature and date of consent on the Subject's Rights page (last page) of the document.

A witness is required to observe the signature of the subject or the subject's legally authorized representative. This third person does not have to witness the entire consent interview. If the subject is competent to make decisions concerning health care, but the subject is unable to read the document (e.g. due to blindness or illiteracy), then the third person must witness both the consent interview and the subject's signature.

The principal investigator (or IRB approved designee) must sign the Subjects Rights page and then make a copy of the signed document. **The signed original form is placed in the investigator's project files.** The consent is scanned into CPRS (Computerized Patient Record System) and the copy is given to the subject or the subject's representative - for the subject's future reference.

3. INFORMED CONSENT DOCUMENT

The VA Form 10-1086, VA Research Consent Form must be used as the consent document.

Language that is used in the consent form should be easily understandable to the prospective subject, or their legally authorized representative. It is required that text be written at an eighth grade reading level. Think of the consent form as a teaching tool, not as a legal instrument. If non-English speaking subjects will be invited to participate in the study, then validated translations of consent forms, written at the eighth grade reading level, should be available.

There are **eight mandatory basic informed consent elements** that must be included in the document. These have been established by the Department of Veterans Affairs, the Common Rule, and the Food and Drug Administration. Seven additional elements may be required, depending on the nature of the research. This document should be as brief as possible, but must cover the eight basic elements and any required additional elements.

a. Required Element One: **Research Statements**

If the treating physician is also the research investigator, some subjects may not realize they are participating in research, but believe they are just being treated for their condition. By specifying the purpose of the research and describing experimental procedures, it is intended that subjects will be able to recognize the difference between research and treatment.

- 1) A statement that the study involves research (i.e. "You are being asked to take part in a research project")
- 2) An explanation of the purpose of the research.

State what the study is trying to achieve (e.g. measure the drop in serum lipid levels after using this new drug) and how this relates to other present knowledge or why this is important to find out (e.g. other lipid lowering drugs are a different class of drugs that have unpleasant side-effects.)

"The purpose of this study is to....."

Sponsorship of a study may impact a subject's willingness to participate. The following statements may be indicated: *"The study is sponsored by _____."*

"The sponsor funds the VA hospital based on the number of research subjects enrolled."

"The sponsor provides a fixed payment to the VA Hospital for performing the study."

3) An explanation of the expected duration of the subject's participation.

The approximate time of involvement in the study should be indicated. The duration of any lengthy procedures, including questionnaires, should be indicated.

4) A description of what procedures will be followed (i.e. "If you consent to participate in this research study...")

Give a step-by-step description of the procedures from selection of patients through follow-up. Identify phases, if appropriate. Include invasive techniques, restrictions on normal activities, long-term follow-up, and the possibility of receiving inactive materials.

If blood is withdrawn, both the frequency of the procedure and the total amount of blood should be indicated.

If investigational drugs, devices, or procedures are used, the following statement may be applicable: *We can not guarantee that you will be able to continue receiving this (drug, device, procedure) after this study is over.*"

5) Identification of any procedures that are experimental.

Make a clear distinction between procedures that are necessary because of the study and those that would be required as part of the subject's usual care. This includes increases in time, complexity, discomfort, and/or prolongation of hospitalization or hospitalization entirely for research purposes.

If the study involves random assignment, the nature and probability of group assignment must be specified: *"Using a procedure similar to flipping a coin, you will have a 1 in ___ chance for receiving a sugar pill instead of ____."*

If the subject and/or treating physician are to be kept blind to group assignment, this fact should be stated.

b. Required Element Two: **Foreseeable Risks or Discomforts**

Informed consent information must describe any reasonably foreseeable risks, discomforts, inconveniences, or harms that are associated with the research. Risks should be listed in descending order of probability and magnitude (risk of death (even if remote) before risks associated with blood draw, for example). Risks may be physical, psychological, social or economic.

If risks can be quantified (e.g. 1 in 1000 persons develop hemorrhage), then include this information.

If blood is to be drawn, include the following risks: pain, bruising, fainting, or infection.

"Risk of venipuncture: The risks of simple blood drawing include commonly, the occurrence of discomfort and/or bruise at the site of puncture; and less commonly, the formation of a small blood clot or swelling of the surrounding area, and bleeding from the puncture site. Rarely, fainting and local infection may occur."

“Risk of arterial puncture: Placement of a catheter or a needle into an artery may cause bleeding or bruising. There is a small possibility that there could be damage to the artery and to your hand. Should this happen, you could require surgery to repair the artery. It is possible that you could develop an infection at the site of the needle puncture.”

Discuss any measures that have been taken to minimize risks to subjects.

For studies involving investigational drugs, devices, or procedures, the following should be included: *“Because this is a new (drug, device, procedure) we do not know all of its effects. You should contact (name of the VA investigator) at (phone, location) if you have any adverse effects.”*

c. Required Element Three: **Reasonably Expected Benefits to Subjects or Others**

Informed consent information must describe any benefits to subjects or to others (i.e. society) that may reasonably be expected from the research. However, care must be taken not to overstate the benefits and create undue influence on subjects. Payment for subject’s participation in a research project is not considered as a benefit of research. Payments or reimbursements should be described in a separate section, see Additional Element Seven: **Payments** .

If there are no clear benefits to the subject, include one of the following:

“It is likely that no direct benefit will occur as a result of your participation in this study.”

“You may not personally benefit from taking part in the research, but the knowledge obtained may help the health professionals caring for you better understand the disease/condition and how to treat it”.

d. Required Element Four: **Appropriate Alternatives**

Informed consent must include a disclosure of any appropriate alternative procedures or courses of treatment that may be advantageous to the subject. Include other accepted therapies or diagnostic procedures available, in lieu of participating in this study. Enough detail must be presented so that the subject can understand and appreciate the nature of any alternatives. It is not sufficient simply to state, “the doctor will discuss alternatives to participating”.

e. Required Element Five: **Extent of Confidentiality**

Informed consent information must describe the extent to which confidentiality of records identifying the subject will be maintained (or not maintained). Research often poses the risk of loss of confidentiality to subjects who participate. Many persons who would not otherwise have access to identifiable, private information about the subject may be involved in research process. Consent information should describe any procedures that the research team will use to protect subjects’ private records. In some research, loss of privacy may be the greatest risk of participation.

The consent must state that the Government Accounting Office (GAO) or the Office of Human Protection (OHRP) may have access to records.

The following statement is required for FDA-regulated research:

Because the research involves articles regulated by the Food and Drug Administration (FDA), the FDA may choose to inspect and copy medical or research records that identifies individual subjects.

This statement must be used if research involves a drug with an IND or a medical device with an IDE. A comparable statement is recommended for any research that is subject to audit or inspection by any funding agency or sponsor.

If the subject's medical records will be reviewed, include the following statement:

"By joining this study, you give your permission to investigators to collect data from your medical records to determine if you are eligible and if you remain eligible to participate in the study."

Include a statement that indicates who will have possession of questionnaires, data, videos, audio cassettes, who will have access to them, how they will be secured, and the timing and method of coding and disposal.

Most likely, research results will be made public, however confidentiality must be maintained. Include a statement like one of the following:

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent."

"No information by which you can be identified will be released or published, unless required by law."

f. Required Element Six: **Compensation or Treatment for Injury**

Informed consent information for research involving more than minimal risk must include the following statement:

The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but in most cases additional compensation is not available. No reimbursement, compensation or free medical care is offered by Wayne State University. (If applicable, DMC hospitals, NIH, etc. could also be included.)

Sponsor language regarding payment for injuries will not be included in the consent.

g. Required Element Seven: **Contact Information**

Informed consent information must include details, including telephone numbers, about whom to contact:

- 1) For answers to questions about the research (now or in the future). The principal investigator and other members of the research team are appropriate contacts for this information.

- 2) For answers to questions about subjects' rights. The R&D Office and the Patient Advocate are appropriate contacts for this information. The Chairperson of the HIC should also be listed as a contact person.
- 3) To voice concerns or complaints. The Research Compliance Officer or Research Office, as well as the Patient Advocate should be listed as contacts.
- 4) In the event of a research-related injury. Depending on the nature of the research, the research team, the Admissions / Triage Clinic, or the Quality Management Office may serve as appropriate contacts for this information.

h. Required Element Eight: **Voluntary Participation Statement**

It is particularly important in the VA context for subjects and prospective subjects to understand and have complete confidence that failure to participate will not jeopardize their VA-provided care. Informed consent information must contain clear statement of the following:

- 1) Participation in research is voluntary.
- 2) Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- 3) The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

“Taking part in research is entirely voluntary”.

“If you decide not to participate in the research, there will be no penalty or loss of benefits to which you are otherwise entitled.”

“You may drop out of the study at any time without penalty. By doing so, you will not lose any benefits that you may be entitled to.”

i. Additional Element One: **Unforeseeable Risks**

For certain types of research, it may be necessary to state that the procedure may involve unforeseeable risks; and, when appropriate, a statement that the research could involve unforeseeable risks to the embryo or fetus, or to the subject if the subject becomes pregnant. If pregnant subjects are to be excluded, this should be stated.

j. Additional Element Two: **Subject Termination**

For certain types of research, it may be necessary to describe circumstances under which the subject's participation may be terminated by the investigator without the subject's consent.

“The investigators of this research may have to end your participation in this study under the following condition(s):

They believe it in your best interest, if you do not follow the study plan, if you experience a study-related injury, or for any other reason.”

k. Additional Element Three: **Additional Costs to Subjects**

For certain types of research, it may be necessary to describe any additional costs to the subject that may result from participation in the study. In some circumstances, it may be necessary to indicate no costs.

“There will be no costs to you for any treatment or testing done as part of this research study.”

l. Additional Element Four: **Early Withdrawal from the Study**

In certain types of research, it may be necessary to clearly state the consequences of a subject’s decision to withdraw from the research, and, if so, how to withdraw safely. If appropriate, include the established procedure for safe and orderly termination of participation in the study. If abrupt termination imposes risks, state the risks.

m. Additional Element Five: **New Findings**

In certain types of research, it may be necessary to state that significant new findings developed during research, which may relate to the subjects willingness to continue, will be provided to the subject.

“If, during your participation in the research project, new information becomes available concerning your condition (disease) or concerning better therapies which would affect your being in the research project, your doctor will discuss this new information with you and help you make a decision about continuing in the research.”

n. Additional Element Six: **Number of Subjects Participating**

For certain types of research, it may be necessary to describe the approximate number of subjects that will be involved in the study. State the number of subjects to be enrolled at this site or nationally (if a multi-site study), if this information would impact a person’s decision to participate.

o. Additional Element Seven: **Payments**

If payment is to be provided to subjects, then the total amount provided and a schedule of payment(s) must be included. How the patients will be paid (i.e. mailed check, Agent Cashier) should also be included. Payment can not be withheld until the end of the study, as this could be considered coercive, forcing a subject to complete the study, although he/she desired withdrawal at an earlier point in time.

4. PROTECTED HEALTH INFORMATION

If a request for waiver of Authorization to Release Medical Records or Health Information is not requested (see HIPPA Privacy Rule Bulletin), the following information must be included in the Informed Consent.

- a. A description of the Protected Health Information to be used or disclosed;
- b. An identification of the persons or class of persons who are authorized to use or disclose it, and the persons or class of persons to whom it may be disclosed;
- c. A description of the purpose of the use or disclosure;
- d. An expiration date or event (end of the research study), or “none”;
- e. A statement that advises research subjects of their right to revoke their authorization in writing

- f. A statement that advises research subjects of the potential that their Protected Health Information may be re-disclosed to other parties. A reference may be made to privacy protection mechanisms that will be provided by the researchers, as documented in the informed consent.
- g. A statement that advises research subjects whether the institution will obtain any remuneration from the disclosure of the Protected Health Information.
- h. A statement must also be included stating that treatment, payment, and enrollment is not conditional on providing authorization (but research-related treatment may be conditioned on providing authorization to disclose the information to the study researchers).

5. REFERENCES

VHA Handbook 1200.5, dated 7/15/03

6. RECISSIONS

Research Service Policy #4, dated 2/13/06

7. EXPIRATION DATE

October 1, 2010

Richard E. Miller, MD
ACOS/Research & Development

INFORMED CONSENT

1. PURPOSE

It is the purpose of the Human Research Protection Program to ensure that research involving human subjects is conducted with due regard to human rights and safety. However, it is the individual investigator who has the ultimate responsibility to protect the rights and safety of subjects. A major requirement of research involving human subjects is that **investigators must obtain the informed consent of prospective subjects before they can be included in research**. Informed consent is a process, not just a form. Informed consent presumes two simultaneous concepts: informed decision-making and voluntary participation. Prospective subjects must be given sufficient information about the research and its risks and benefits to reach an informed decision as to whether they will voluntarily participate.

2. PROCESS

The informed consent process is critical for protecting human research subjects. The principal investigator is charged with the responsibility to conduct the consent interview and obtain consent. If someone other than the principal investigator (such as a study coordinator) obtains consent, then this responsibility should be formally delegated by the principal investigator and the person so delegated should be knowledgeable about all aspects of the study and have appropriate training to perform this activity. Since the consent process is so important, it may be observed by a member of the Clinical Investigation Subcommittee, the Research Compliance Officer or another authorized third party.

The informed consent process should be designed to educate the potential subject in terms he/she can understand. Language used during discussion and words written in the informed consent document should be in "lay terms". Use of scientific jargon and legalese is not appropriate. Investigators are encouraged to ask the subject to explain back fully his/her understanding of the research study and what risks are involved. At some future date, the subject may be contacted by someone from the medical center and asked about his/her understanding of the research and willingness to participate.

The investigator may not involve a human being as a subject in research or conduct any procedures required by a research protocol unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (surrogate).

For VA research conducted at the VA, a legally authorized representative is an individual or body authorized under applicable law to provide permission on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. A legally authorized representative includes not only a person appointed as a health care agent under a Durable Power of Attorney for Health Care (DPAHC), a court appointed guardian of the person, but also next-of-kin in the following order of priority unless otherwise specified by applicable state law: spouse, adult child

(18 years of age or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older).

For VA research conducted at the academic affiliate or in the community, refer to the definition of legally authorized representative contained in WSU HIC Policy/Procedure Obtaining Permission from Legally Authorized Representative or Family Members (When Participants (Subjects) Themselves are Unable to Give Consent). For individuals who met the DHHS and FDA definitions of "legally authorized representative", the PI must contact the VA District Counsel for guidance.

Surrogate consent for research may be requested and accepted only when the prospective research participant is incompetent (as determined by two VA physicians) and there is little or no likelihood that the patient will regain competence within a reasonable period of time. Before incompetent persons may be considered for participation in research, the CIC and the IRB must find that the proposed research meets all of the following conditions: a) only incompetent patients are suitable; b) favorable risk/benefit ratio; c) voluntary participation; and, d) well informed representatives/surrogates.

As the level of risk increases for a research protocol, so should the threshold for subject capacity to make informed consent. Intelligence, maturity, rationality, and language abilities all impact capacity. Generally, subjects are assumed to be able to make rationale decisions for themselves, unless demonstrated by actions / behaviors or proven otherwise. When potential subjects are likely to be incompetent or have diminished capacity, or when research risks are high, then investigators should consider the impact of capacity on the consent process.

The informed consent process should be conducted in a "neutral atmosphere", one in which there is no appearance of, or attempt to pressure a subject or surrogate to cooperate. The investigator must minimize the possibility of coercion or undue influence. An investigator shall seek consent only under circumstances that provide the prospective subject or surrogate sufficient opportunity to consider whether or not to participate.

Under no circumstances in the informed consent process, whether oral or written, may the investigator include any exculpatory language through which the subject or the surrogate is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The investigator must always use the current, IRB approved, version of the VA 10-1086 consent form to document the consent process.

The subject, or the subject's legally authorized representative, must put his/her initials at the bottom of each page after fully understanding each element. The subject (or the LAR) should place his/her full signature and date of consent on the Subject's Rights page (last page) of the document.

A witness is required to observe the signature of the subject or the subject's legally authorized representative. This third person does not have to witness the entire consent interview. If the subject is competent to make decisions concerning health care, but the subject is unable to read the document (e.g. due to blindness or illiteracy), then the third person must witness both the consent interview and the subject's signature.

The principal investigator (or IRB approved designee) must sign the Subjects Rights page and then make a copy of the signed document. **The signed original form is placed in the investigator's project files.** The consent is scanned into CPRS (Computerized Patient Record System) and the copy is given to the subject or the subject's representative - for the subject's future reference.

3. INFORMED CONSENT DOCUMENT

The VA Form 10-1086, VA Research Consent Form must be used as the consent document.

Language that is used in the consent form should be easily understandable to the prospective subject, or their legally authorized representative. It is required that text be written at an eighth grade reading level. Think of the consent form as a teaching tool, not as a legal instrument. If non-English speaking subjects will be invited to participate in the study, then validated translations of consent forms, written at the eighth grade reading level, should be available.

There are **eight mandatory basic informed consent elements** that must be included in the document. These have been established by the Department of Veterans Affairs, the Common Rule, and the Food and Drug Administration. Seven additional elements may be required, depending on the nature of the research. This document should be as brief as possible, but must cover the eight basic elements and any required additional elements.

a. Required Element One: **Research Statements**

If the treating physician is also the research investigator, some subjects may not realize they are participating in research, but believe they are just being treated for their condition. By specifying the purpose of the research and describing experimental procedures, it is intended that subjects will be able to recognize the difference between research and treatment.

- 1) A statement that the study involves research (i.e. "You are being asked to take part in a research project")
- 2) An explanation of the purpose of the research.

State what the study is trying to achieve (e.g. measure the drop in serum lipid levels after using this new drug) and how this relates to other present knowledge or why this is important to find out (e.g. other lipid lowering drugs are a different class of drugs that have unpleasant side-effects.)

"The purpose of this study is to....."

Sponsorship of a study may impact a subject's willingness to participate. The following statements may be indicated: *"The study is sponsored by _____."*

"The sponsor funds the VA hospital based on the number of research subjects enrolled."

"The sponsor provides a fixed payment to the VA Hospital for performing the study."

3) An explanation of the expected duration of the subject's participation.

The approximate time of involvement in the study should be indicated. The duration of any lengthy procedures, including questionnaires, should be indicated.

4) A description of what procedures will be followed (i.e. "If you consent to participate in this research study...")

Give a step-by-step description of the procedures from selection of patients through follow-up. Identify phases, if appropriate. Include invasive techniques, restrictions on normal activities, long-term follow-up, and the possibility of receiving inactive materials.

If blood is withdrawn, both the frequency of the procedure and the total amount of blood should be indicated.

If investigational drugs, devices, or procedures are used, the following statement may be applicable: *We can not guarantee that you will be able to continue receiving this (drug, device, procedure) after this study is over.*"

5) Identification of any procedures that are experimental.

Make a clear distinction between procedures that are necessary because of the study and those that would be required as part of the subject's usual care. This includes increases in time, complexity, discomfort, and/or prolongation of hospitalization or hospitalization entirely for research purposes.

If the study involves random assignment, the nature and probability of group assignment must be specified: *"Using a procedure similar to flipping a coin, you will have a 1 in ___ chance for receiving a sugar pill instead of ____."*

If the subject and/or treating physician are to be kept blind to group assignment, this fact should be stated.

b. Required Element Two: **Foreseeable Risks or Discomforts**

Informed consent information must describe any reasonably foreseeable risks, discomforts, inconveniences, or harms that are associated with the research. Risks should be listed in descending order of probability and magnitude (risk of death (even if remote) before risks associated with blood draw, for example). Risks may be physical, psychological, social or economic.

If risks can be quantified (e.g. 1 in 1000 persons develop hemorrhage), then include this information.

If blood is to be drawn, include the following risks: pain, bruising, fainting, or infection.

"Risk of venipuncture: The risks of simple blood drawing include commonly, the occurrence of discomfort and/or bruise at the site of puncture; and less commonly, the formation of a small blood clot or swelling of the surrounding area, and bleeding from the puncture site. Rarely, fainting and local infection may occur."

“Risk of arterial puncture: Placement of a catheter or a needle into an artery may cause bleeding or bruising. There is a small possibility that there could be damage to the artery and to your hand. Should this happen, you could require surgery to repair the artery. It is possible that you could develop an infection at the site of the needle puncture.”

Discuss any measures that have been taken to minimize risks to subjects.

For studies involving investigational drugs, devices, or procedures, the following should be included: *“Because this is a new (drug, device, procedure) we do not know all of its effects. You should contact (name of the VA investigator) at (phone, location) if you have any adverse effects.”*

c. Required Element Three: **Reasonably Expected Benefits to Subjects or Others**

Informed consent information must describe any benefits to subjects or to others (i.e. society) that may reasonably be expected from the research. However, care must be taken not to overstate the benefits and create undue influence on subjects. Payment for subject’s participation in a research project is not considered as a benefit of research. Payments or reimbursements should be described in a separate section, see Additional Element Seven: **Payments** .

If there are no clear benefits to the subject, include one of the following:

“It is likely that no direct benefit will occur as a result of your participation in this study.”

“You may not personally benefit from taking part in the research, but the knowledge obtained may help the health professionals caring for you better understand the disease/condition and how to treat it”.

d. Required Element Four: **Appropriate Alternatives**

Informed consent must include a disclosure of any appropriate alternative procedures or courses of treatment that may be advantageous to the subject. Include other accepted therapies or diagnostic procedures available, in lieu of participating in this study. Enough detail must be presented so that the subject can understand and appreciate the nature of any alternatives. It is not sufficient simply to state, “the doctor will discuss alternatives to participating”.

e. Required Element Five: **Extent of Confidentiality**

Informed consent information must describe the extent to which confidentiality of records identifying the subject will be maintained (or not maintained). Research often poses the risk of loss of confidentiality to subjects who participate. Many persons who would not otherwise have access to identifiable, private information about the subject may be involved in research process. Consent information should describe any procedures that the research team will use to protect subjects’ private records. In some research, loss of privacy may be the greatest risk of participation.

The consent must state that the Government Accounting Office (GAO) or the Office of Human Protection (OHRP) may have access to records.

The following statement is required for FDA-regulated research:

Because the research involves articles regulated by the Food and Drug Administration (FDA), the FDA may choose to inspect and copy medical or research records that identifies individual subjects.

This statement must be used if research involves a drug with an IND or a medical device with an IDE. A comparable statement is recommended for any research that is subject to audit or inspection by any funding agency or sponsor.

If the subject's medical records will be reviewed, include the following statement:

"By joining this study, you give your permission to investigators to collect data from your medical records to determine if you are eligible and if you remain eligible to participate in the study."

Include a statement that indicates who will have possession of questionnaires, data, videos, audio cassettes, who will have access to them, how they will be secured, and the timing and method of coding and disposal.

Most likely, research results will be made public, however confidentiality must be maintained. Include a statement like one of the following:

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent."

"No information by which you can be identified will be released or published, unless required by law."

f. Required Element Six: **Compensation or Treatment for Injury**

Informed consent information for research involving more than minimal risk must include the following statement:

The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but in most cases additional compensation is not available. No reimbursement, compensation or free medical care is offered by Wayne State University. (If applicable, DMC hospitals, NIH, etc. could also be included.)

Sponsor language regarding payment for injuries will not be included in the consent.

g. Required Element Seven: **Contact Information**

Informed consent information must include details, including telephone numbers, about whom to contact:

- 1) For answers to questions about the research (now or in the future). The principal investigator and other members of the research team are appropriate contacts for this information.

- 2) For answers to questions about subjects' rights. The R&D Office and the Patient Advocate are appropriate contacts for this information. The Chairperson of the HIC should also be listed as a contact person.
- 3) To voice concerns or complaints or question the validity of a study. The Research Compliance Officer or Research Office, as well as the Patient Advocate should be listed as contacts.
- 4) In the event of a research-related injury. Depending on the nature of the research, the research team, the Admissions / Triage Clinic, or the Quality Management Office may serve as appropriate contacts for this information.

h. Required Element Eight: **Voluntary Participation Statement**

It is particularly important in the VA context for subjects and prospective subjects to understand and have complete confidence that failure to participate will not jeopardize their VA-provided care. Informed consent information must contain clear statement of the following:

- 1) Participation in research is voluntary.
- 2) Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- 3) The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

“Taking part in research is entirely voluntary”.

“If you decide not to participate in the research, there will be no penalty or loss of benefits to which you are otherwise entitled.”

“You may drop out of the study at any time without penalty. By doing so, you will not lose any benefits that you may be entitled to.”

i. Additional Element One: **Unforeseeable Risks**

For certain types of research, it may be necessary to state that the procedure may involve unforeseeable risks; and, when appropriate, a statement that the research could involve unforeseeable risks to the embryo or fetus, or to the subject if the subject becomes pregnant. If pregnant subjects are to be excluded, this should be stated.

j. Additional Element Two: **Subject Termination**

For certain types of research, it may be necessary to describe circumstances under which the subject's participation may be terminated by the investigator without the subject's consent.

“The investigators of this research may have to end your participation in this study under the following condition(s):

They believe it in your best interest, if you do not follow the study plan, if you experience a study-related injury, or for any other reason.”

k. Additional Element Three: **Additional Costs to Subjects**

For certain types of research, it may be necessary to describe any additional costs to the subject that may result from participation in the study. In some circumstances, it may be necessary to indicate no costs.

“There will be no costs to you for any treatment or testing done as part of this research study.”

l. Additional Element Four: **Early Withdrawal from the Study**

In certain types of research, it may be necessary to clearly state the consequences of a subject’s decision to withdraw from the research, and, if so, how to withdraw safely. If appropriate, include the established procedure for safe and orderly termination of participation in the study. If abrupt termination imposes risks, state the risks.

m. Additional Element Five: **New Findings**

In certain types of research, it may be necessary to state that significant new findings developed during research, which may relate to the subjects willingness to continue, will be provided to the subject.

“If, during your participation in the research project, new information becomes available concerning your condition (disease) or concerning better therapies which would affect your being in the research project, your doctor will discuss this new information with you and help you make a decision about continuing in the research.”

n. Additional Element Six: **Number of Subjects Participating**

For certain types of research, it may be necessary to describe the approximate number of subjects that will be involved in the study. State the number of subjects to be enrolled at this site or nationally (if a multi-site study), if this information would impact a person’s decision to participate.

o. Additional Element Seven: **Payments**

If payment is to be provided to subjects, then the total amount provided and a schedule of payment(s) must be included. How the patients will be paid (i.e. mailed check, Agent Cashier) should also be included. Payment can not be withheld until the end of the study, as this could be considered coercive, forcing a subject to complete the study, although he/she desired withdrawal at an earlier point in time.

4. PROTECTED HEALTH INFORMATION

If a request for waiver of Authorization to Release Medical Records or Health Information is not requested (see HIPPA Privacy Rule Bulletin), the following information must be included in the Informed Consent.

- a. A description of the Protected Health Information to be used or disclosed;
- b. An identification of the persons or class of persons who are authorized to use or disclose it, and the persons or class of persons to whom it may be disclosed;
- c. A description of the purpose of the use or disclosure;
- d. An expiration date or event (end of the research study), or “none”;
- e. A statement that advises research subjects of their right to revoke their authorization in writing

- f. A statement that advises research subjects of the potential that their Protected Health Information may be re-disclosed to other parties. A reference may be made to privacy protection mechanisms that will be provided by the researchers, as documented in the informed consent.
- g. A statement that advises research subjects whether the institution will obtain any remuneration from the disclosure of the Protected Health Information.
- h. A statement must also be included stating that treatment, payment, and enrollment is not conditional on providing authorization (but research-related treatment may be conditioned on providing authorization to disclose the information to the study researchers).

5. REFERENCES

VHA Handbook 1200.5, dated 7/15/03

6. RECISSIONS

Research Service Policy #4, dated 2/13/06

7. EXPIRATION DATE

October 1, 2010

Richard E. Miller, MD
ACOS/Research & Development

CHECK LIST FOR VA CONSENT 10-1086

PURPOSE OF RESEARCH STUDY

- Must state this is a research study
- Must explain the purpose of the study

DESCRIPTION

- Must describe all research procedures in the study; must identify which procedures are experimental
- Must describe expected duration of subject's participation
- Must state the approximate total number of subjects to be involved in the study.

RISKS

- Must include statement about unforeseeable risks, including privacy risks, if any
- May include a statement that a particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant, which are currently unforeseeable.

BENEFITS

- Must describe the benefits to the subject and benefits to society, not payments to subjects

ALTERNATE COURSES OF ACTION

- Must include a statement that participation in the study is voluntary.
- Must include a statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- Must include a statement about the consequences of not participating in the study
- Must have a statement about any alternative accepted courses of therapy or diagnostic procedures, as well as the potential harms and benefits (if applicable)

STATEMENT OF RESEARCH RESULTS

- Must describe how subject confidentiality will be protected with specific details of privacy & data security
- Must state subjects will not be identified in publications.
- Must state that significant new findings developed during the course of the research that may affect the subject's willingness to continue participation will be provided to the subject.

SPECIAL CIRCUMSTANCES

- Must have a statement about any additional costs to the subject (or none)
- Must include a statement that the subject may discontinue participation at any time, the consequences (if any); and the procedures for orderly termination of participation (if any)
- May have a statement about the circumstances under which the investigators may terminate the participation of the subject without regard to the subject's consent (if any).
- There should not be any exculpatory language through which the subject or the subject's legally authorized representative is made to waive or to appear to waive any of the subject's legal rights, or release or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

PAYMENTS

- Must have a statement about payments to subjects (or none)
- Must have a schedule of payments
- Should state how payments will be made (cash, vouchers, check)

CONFIDENTIALITY

- Must state that the Government Accounting Office (GAO), Office of Human Protection (OHRP) or Office of Research Oversight (ORO) may have access to records.
- If the study is FDA regulated, must state that the FDA may inspect the records

SUBJECTS RIGHT'S PAGE

- The contact persons and phone numbers must be accurate and up to date
- Must include the Compensation or Treatment for Injury statement.

HUMAN STUDIES EDUCATION REQUIREMENTS

1. POLICY

All medical center staff and non-medical center personnel, who conduct research involving human subjects or who are responsible for protecting human subjects at the John D. Dingell VA Medical Center, must complete education and training regarding the rights, safety and welfare of human research participants.

2. RESPONSIBILITIES

- a. VA Central Office has established minimum education requirements for research investigators, research staff, CIC members, R&D Committee members and other individuals with responsibilities for human subject protection. Education requirements are based on VA and federal requirements. The type and amount of training prescribed is specific to each research role and assigned to individuals identified as needing this training.
- b. The R&D Office will maintain records for each mandated education and training activity. It contains a list of all individuals assigned to the activity and the date each person completes the requisite training. Copies of affidavits and certificates will be kept in the employees credentialing file. These files log the training activities of all research investigators, research staff, HSS members, R&D Committee members and all other individuals responsible for human research protection. Access to these files is available to the R&D Coordinator, Chair of R&D Committee, Chair of CIC, and Research Compliance Officer for periodic review and monitoring.
- c. The Research Office will provide each new investigator and clinical coordinator with a copy of the Investigator's Manual which includes all Research polices and procedures. Clinical coordinators will attain bi-monthly training sessions provided by the Research Office.
- d. The Research Compliance Officer prepares quarterly and annual reports that monitor staff compliance with education and training requirements.
- e. Principal Investigators are responsible for ensuring their training and their staffs training is completed as required.

3. **PROCEDURES**

- a. All investigators and research personnel involved in human subject research are required to complete three on-line training courses.
 - Responsible Conduct in Research - Wayne State University's on-line training program available at <http://www.hic.wayne.edu/>
 - Overview of Good Clinical Practice and Human Subject Protection - VA's web base Good Clinical Practice training (appendix A) must be completed annually.
 - Veterans Health Administration (VHA) Privacy Policy Training available at <https://www.ees-learning.net/librix/loginhtml.asp?v=librix> (internet) or <http://vaww.ees.aac.va.gov> (intranet).
- b. Upon completion of the requisite training, individuals must submit a copy of their certificate to the R&D Office that attests the completion of training.
- c. Principal Investigators must attach proof of having completed the currently mandated training at the time new research protocols are submitted to the Research Office for initial consideration.
- d. Individuals who fail to complete the required training will be unable to participate in human subject research activities at this VA Medical Center.

4. **REFERENCES**

VHA Handbook 1200.5, Requirements for the Protection of Human Subjects in Research
MCNM 11R-1, Human Research Protection Plan

5. **RECISSIONS**

Research Service Policy #11, dated 1/6/05

6. **EXPIRATION DATE**

December 29, 2009

Richard E. Miller, MD
ACOS/R&D

ORD and [Collaborative IRB Training Initiatives \(CITI\)](#) have developed a VA training curriculum to satisfy the ORD annual training requirements. This curriculum includes three courses that build upon each other over three years:

1. A Basic Course for those who have **never taken the VA basic course** on Human Subjects Protections and GCP either through CITI or through EES. (EES no longer hosts training after December 2006).
2. CITI 101 Refresher Course consists of a number of short modules for those who have taken the VA basic course.
3. For next year, a CITI 201 Refresher Course for those who have completed the 101 Refresher Course.

ORD requires annual training in **BOTH** protection of human subjects in research and Good Clinical Practices (GCP). The CITI training modules are designed to meet **BOTH** of these training requirements.

CITI will keep track of your expiration dates and email you when you are due to renew your training.

If you have any questions about registering, please send an email to michael.fallon@med.va.gov.

IDENTIFYING RESEARCH PATIENTS IN CPRS

1. PURPOSE

It is the purpose of the Human Research Protection Program to ensure that research involving human subjects is conducted with due regard to human rights and safety. To that end, any participant in a research study (veteran or non-veteran) must be identified in the Computerized Patient Record System (CPRS).

2. PROCESS

The investigator has the responsibility to ensure that each participant enrolled in a research study is “flagged” in CPRS and the Informed Consent is scanned into CPRS. Originals of the Informed Consent will be filed in the patient’s case file.

3. PROCEDURES

The Institutional Review Board (IRB) determines if the patient’s medical record (CPRS) must be flagged to protect the subject’s safety by indicating the subject’s participation in the study, and the source of more information on the study. The medical record may not be required to be flagged if:

- a. The subject’s participation in the study involves:
 - 1) Only one encounter,
 - 2) Only the use of a questionnaire, or
 - 3) The use of previously collected biological specimens.
- b. The identification of the patient as a subject in a particular study (if the study is not greater than minimal risk) would place the subject at greater than minimal risk.

The procedure contained in Appendix A identifies the process for flagging a patient’s record. Appendix B shows the procedure to scan the Informed Consent into CPRS. If any incident occurs involving a patient in a research study, the investigator and/or clinical coordinator identified in the Research Clinical Alert will be notified as appropriate.

4. REFERENCES

Human Research Protection Plan, MCNM 11R-1, dated 1/9/03

5. RECISSIONS

Research Service Policy #10, dated January 31, 2006

6. EXPIRATION DATE

August 1, 2010

Richard E. Miller, MD
ACOS/Research & Development

PATIENT RECORD FLAG

1. Select Menu Option: **DGPF Patient Record Flags Main Menu**

2. You will be given three options:

RM Record Flag Reports Menu ...
FA Record Flag Assignment
FM Record Flag Management

Select: FA Record Flag Assignment

3. You will see the following options:

SP Select Patient EF Edit Flag Assignment
DA Display Assignment Details CO Change Assignment Ownership
AF Assign Flag
Select Action:Quit//

4. At the prompt (//) type SP
(Select Action:Quit// **sp** Select Patient)

Select PATIENT NAME: (enter the patients name)
Patient: ZZNOTREAL,FIVE (000009995) DOB: 04/03/56
ICN: 1011544866V266319 CMOR: DETROIT, MI

5. Once you have the patient select **af** Assign Flag

6. Select a flag for this assignment: **research**

Searching for a National Flag

Searching for a Local Flag
RESEARCH STUDY ACTIVE RESEARCH
...OK? Yes// (Yes)

7. Approved By: **brady, mary jo** BRADY,MARY JO

8. Enter Narrative Text for this record flag assignment:

Patient Record Flag - Assignment Narrative Text
==[WRAP]==[INSERT]===== < Assignment Narrative Text >=====[<PF1>H=Help]=====
Enrolled in research study

9. Would you like to file this new record flag assignment? YES//

Filing the patient's new record flag assignment...

>>> Assignment was filed successfully.

10. Then it shows the flag assignment

RECORD FLAG ASSIGNMENT Jan 06, 2005@16:08:44 Page: 1 of 1

Patient: ZZNOTREAL,FIVE (000009995) DOB: 04/03/56

ICN: 1011544866V266319 CMOR: DETROIT,MI

---Flag-----Assigned--Approved By-----Review Date--Active-Local

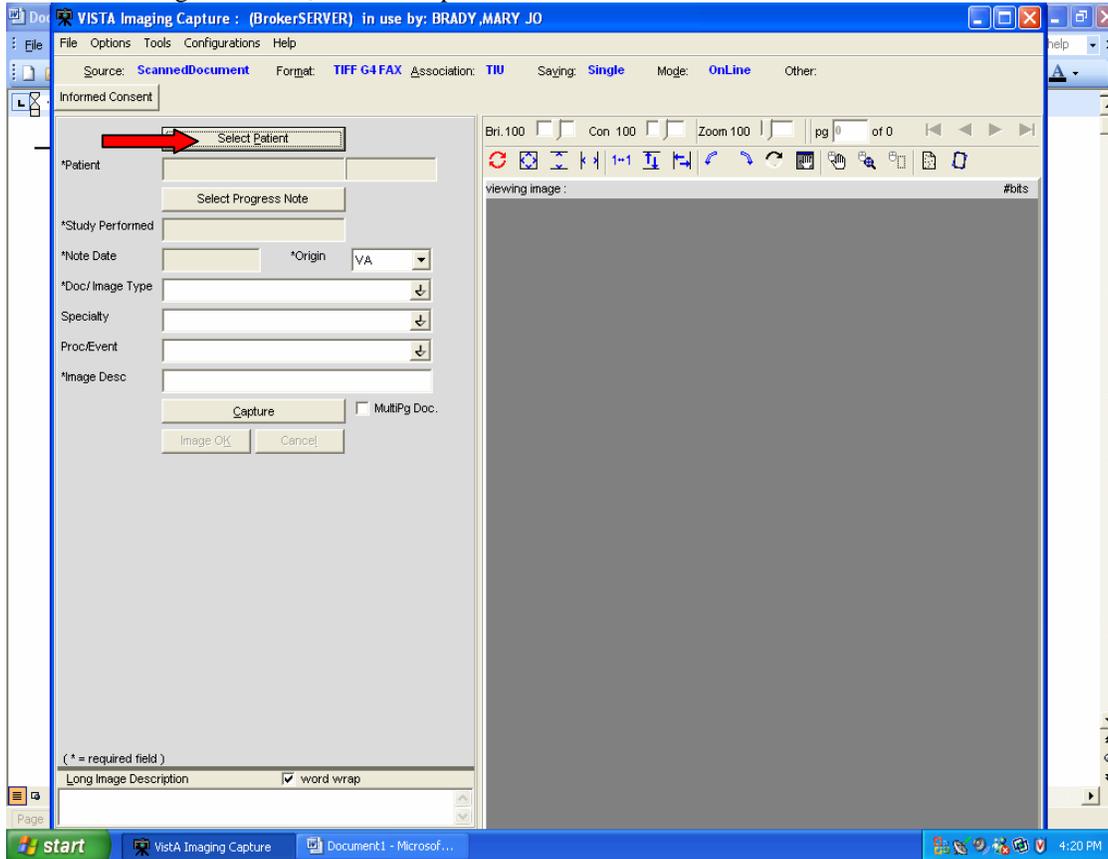
1 BEHAVIORAL 12/16/03 SIEPIERSKI,BARBARA N/A NO NO

2 GUARDIANSHIP 03/25/04 BRADY,ANN M 03/25/05 YES YES

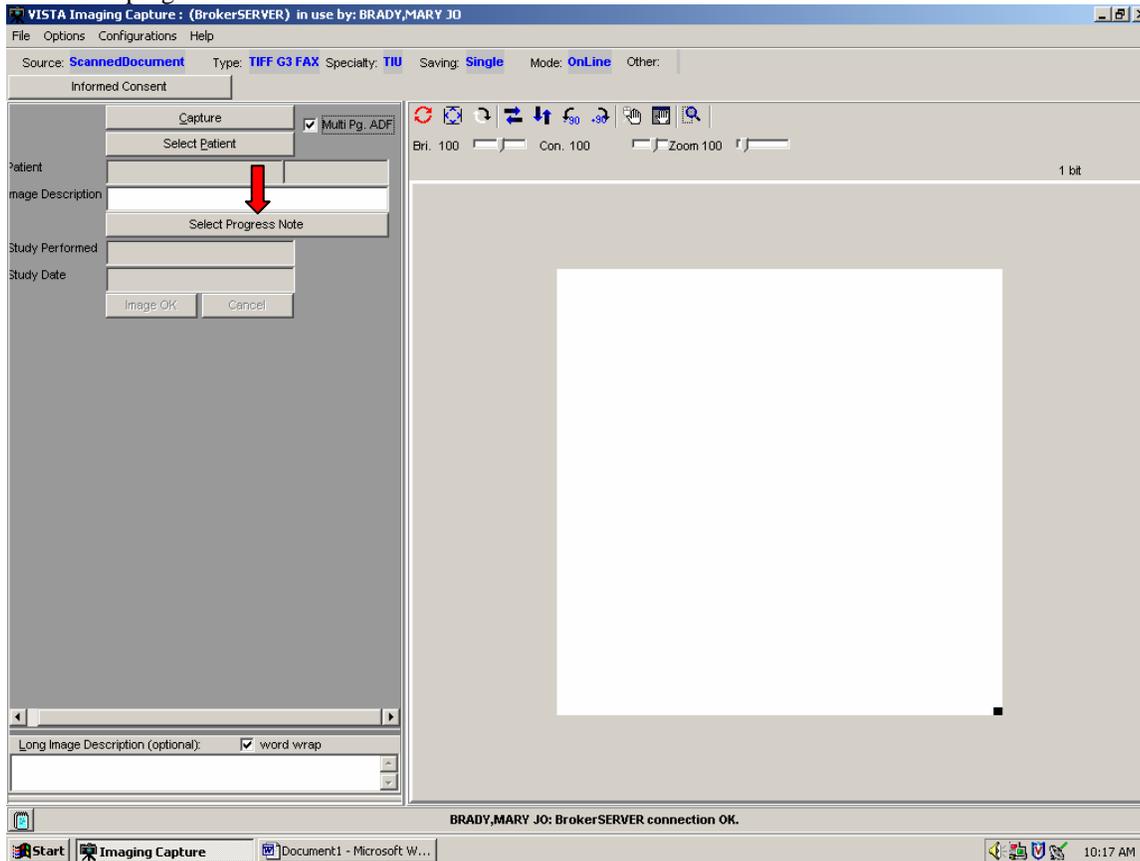
3 RESEARCH STUDY 01/06/05 BRADY,MARY JO 01/06/07 YES YES

Procedure for Scanning Consent Forms

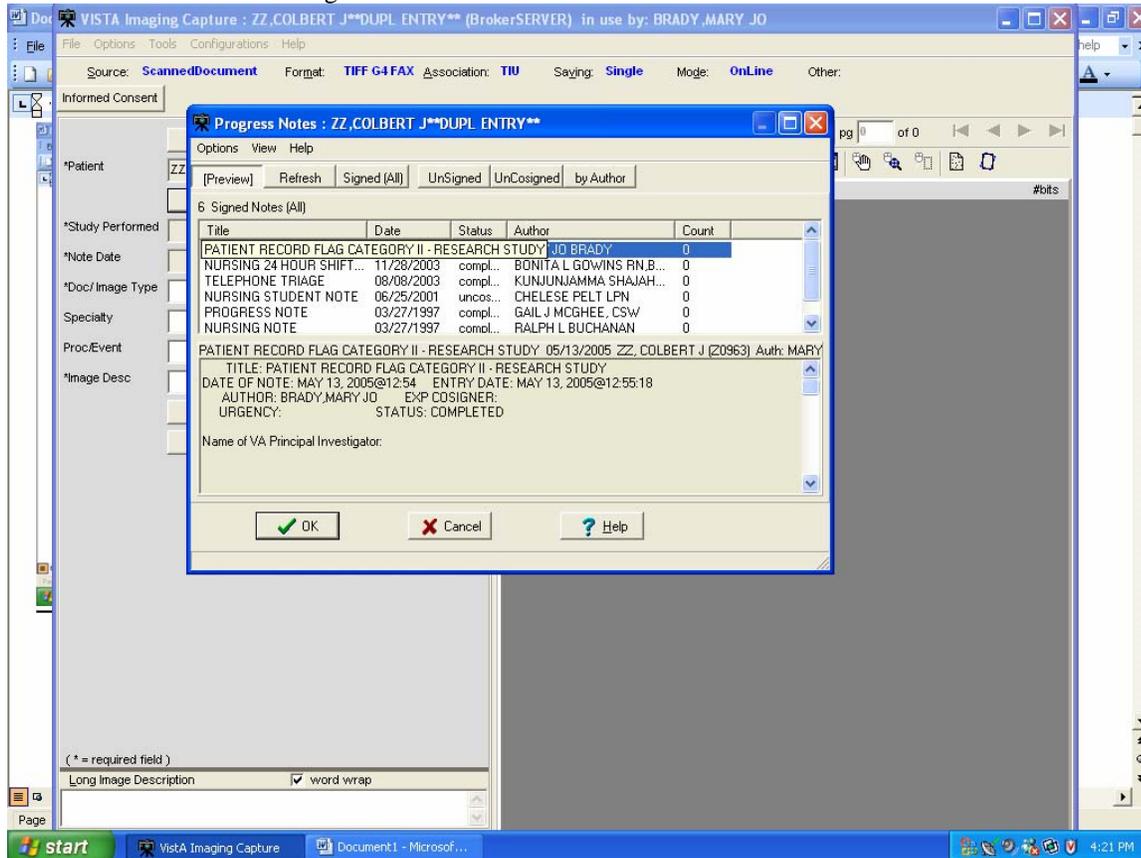
1. Open Vista Imaging Capture program
2. You will log into CPRS, then select patient



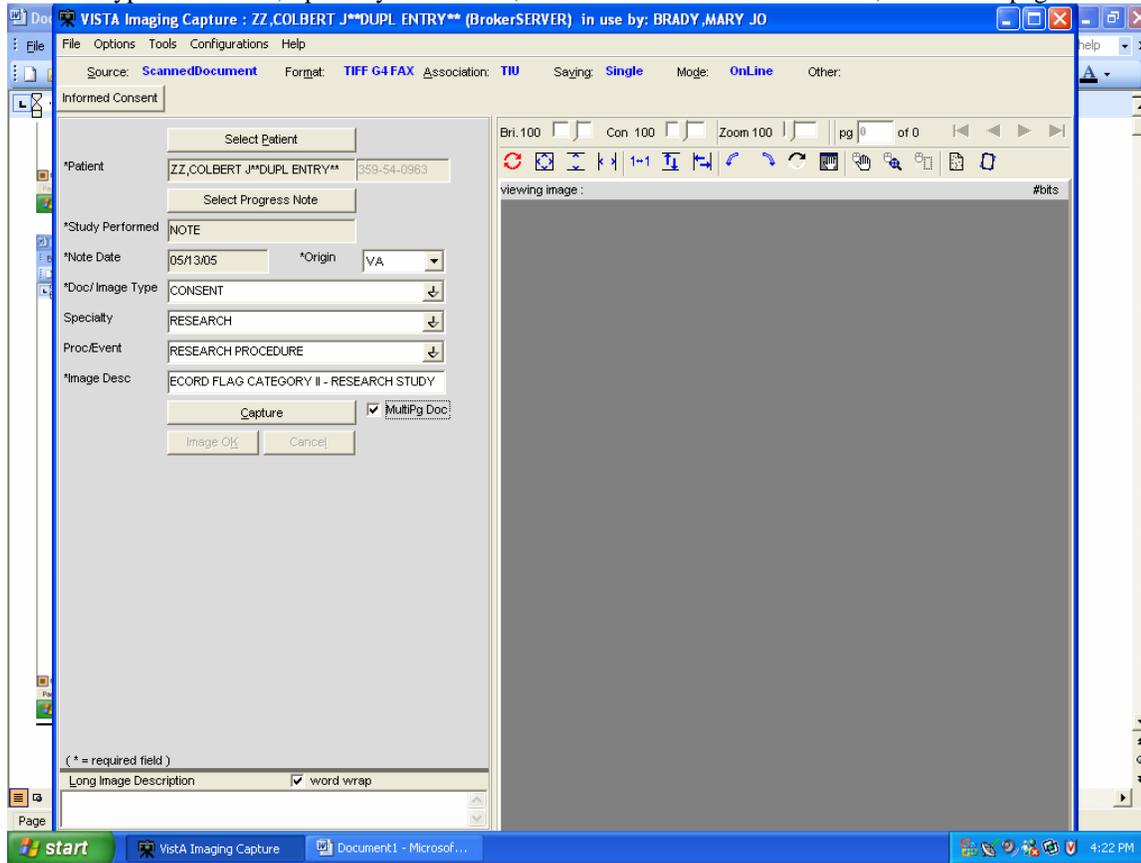
3. Select progress note



4. Select Patient Record Flag



5. Doc type – Research; Specialty – Research; ProcEvent – Research Procedure, click multi page



6. Consent goes in scanner face down, click capture

7. Image OK

11. Check in CPRS using Tools – Vista Imaging

Policy and procedures cannot possibly address all situations. Please make sure that you exercise good judgment and common sense. Remember, patient needs always come first.

INVESTIGATIONAL DRUGS

1. PURPOSE

To establish procedures for obtaining legal approval for the use of investigational drugs by the physician or dentist.

2. POLICY

The use of any investigational drug will meet all requirements of the VA Medical Center and the Food and Drug Administration as described in Appendix A.

3. RESPONSIBILITY

All service chiefs whose personnel utilize investigational drugs are responsible for implementing and monitoring this policy and attached procedures.

4. PROCEDURE

Procedures for utilizing investigational drugs are described in Appendix A. Procedures for emergency use of investigational drugs are described in Appendix B.

5. REFERENCES

VHA Handbook 1108.04, Investigational Drugs and Supplies, dated 10/14/05
VHA Handbook 1200.5, Requirements for the Protection of Human Subjects in Research, dated 7/15/03

6. RESCISSION

Medical Center Numbered Memorandum 118-303 dated October 19, 2003.

7. EXPIRATION DATE

October 17, 2010

Michael K. Wheeler
Director

Distribution: H

PROCEDURES FOR UTILIZING INVESTIGATIONAL DRUGS

1. DEFINITIONS

a. Investigational Drug

(1) A drug that is in clinical evaluation, has not been released by the Food and Drug Administration (FDA) for general use, and is not available through regular channels of interstate commerce.

(2) FDA approved drugs which are used in a non-FDA approved manner under a study protocol (i.e., change in therapeutic indication, dosage, and route of administration).

(3) Any drug designated "investigational" by the FDA.

b. Protocol

The paper that discusses the procedures of the study and the steps taken to reduce risks to the subjects where such risks are real and unavoidable.

c. VA Research Consent Form

This is an explicit and formal agreement (as opposed to implicit) to serve as an experimental subject, given by a legally competent individual or the person responsible as guardian under law for an incompetent person.

d. Subject

Any human participant in any experiment with or without foreseeable physical, mental, or economic risk or jeopardy to the subject's rights as a human being.

e. Subcommittee on Human Studies

The Wayne State University Human Investigation Committee is the authorized Subcommittee on Human Studies.

f. Qualifications of Investigators

The sponsor of an investigational drug (usually the manufacturer) will ask the clinical investigator to supply information on Form FDA 1572, Statement of Investigator.

g. Clinical Trials

(1) Phase I: (Clinical Pharmacology) Objective is to determine toxicity, metabolism, absorption and elimination, preferred route of administration, safe dosage range, and other pharmacological action.

(2) Phase II: (Clinical Pharmacology) Initial trials in the treatment or prevention of the disease for which the drug is intended. Additional pharmacologic studies, performed concurrently in animals, may be necessary for approval to Phase III.

(3) Phase III: (Extensive Clinical Trials) Phase III involves a greater number, assessing the drug's effectiveness, and the most desirable dosage in treating a specific disease.

2. POLICY

a. An investigational drug for clinical use is one for which a sponsor has filed an Investigational New Drug (IND) application with the Food and Drug Administration (FDA) and has been granted approval to use for research or humanitarian purposes by the FDA. Such drugs could be a new chemical compound which has not been released by the FDA for general use and is not available for distribution throughout regular channels of interstate commerce, or it could be an approved drug under investigation in human subjects using a formal protocol to establish new uses, routes, dosage levels, etc.

b. The use of an investigational drug in clinical research must be conducted according to protocol approved by the Research and Development Committee. All investigational drug studies must be reviewed and approved by the WSU IRB prior to starting the research in accordance with WSU HIC policy. There must also be an approved VA Research Consent Form, VA Form 10-1086, before the study can begin. The Pharmacy and Therapeutics Committee must be informed of such studies. Minutes of the Research and Development Committee and the Subcommittee on Human Studies meetings will be made available to the Research Pharmacist and the Chief, Pharmacy Section.

c. After the Research and Development Committee approves a research study employing an investigational drug, the Subcommittee on Human Subjects will forward approval to the investigator and the Research Pharmacist.

d. The patient must be fully informed and consent obtained prior to the use of an investigational drug. The investigator will obtain VA Form 10-1086 and any other required consent agreements.

e. The administration of an investigational drug by any route will be delayed until adequate information concerning the actions, usage, dosage, precautions and toxicity is available for

Pharmacy and appropriate services. When completed, VA Form 10-9012 will serve this purpose. An original will be filed in the Pharmacy.

f. All investigational drugs and other pharmaceuticals required by a study design and supplied by the sponsor must be stored under lock and key in the pharmacy and dispensed and administered in accordance with the procedures indicated below. Pharmaceuticals are not to be dispensed from clinic areas nor physician offices in compliance with VA policy. When a study design requires pharmaceuticals to be used in a clinic for a procedure, or in the operating room, appropriate guidelines must be followed.

g. Only appropriately credentialed professionals may administer investigational drugs provided they have clear and easy access to information and can demonstrate an understanding adequate to allow administration of the drug without increased hazard to the patient (VA Form 10-9012).

h. The drug protocol, pertinent information about the drug and copies of all correspondence with the FDA, local investigator, various local research committees, etc., will be maintained by the Research Pharmacist. This information will be made available to the Chief, Pharmacy Section for distribution to appropriate personnel.

i. Only the Primary Investigator (PI) and Co-Investigators may prescribe investigational drugs.

j. Although the law does not require a physician to file an investigational new drug application form before prescribing an approved drug for unapproved uses, or to submit to the FDA data concerning the therapeutic results, it may be in the best interest of the physician and patient that this is done.

3. PROCEDURE

a. Approval Procedure

(1) The investigating physician will contact the sponsor (usually the drug manufacturer) about the study drug. If the manufacturer agrees to have the physician do the study, the manufacturer will send all the required paperwork that the physician will need. The manufacturer's representative will see the physician to explain the drug, protocol, forms, and to answer any questions the physician may ask.

(2) The investigating physician must get written approval from the Subcommittee on Human Studies, the Research and Development Committee, and a review by the Pharmacy and Therapeutics Committee of drug information summarized on VA Form 10-9012 BEFORE research is started.

b. Prescribing Procedure

(1) The investigator will fully inform the patient concerning the administration of the investigational drug, all inconveniences or hazards to be reasonably expected, the existence of alternative forms of therapy (if any), and the effects upon the patient's health and person that may result.

(2) The investigator will obtain consent of the patient on VA Form 10-1086, and other required consent forms. If the patient is unable to give consent because he/she is unconscious or has been judged incompetent by a court, has a psychiatric disorder, is incapable of comprehending the significance of such action or of exercising appropriate judgment, the consent of the patient's next of kin or guardian will be obtained by signature on VA Form 10-1086. A copy of this form and any other forms required by the protocol will be forwarded to the Research Pharmacist.

(3) The investigator will record a statement in the Computerized Patient Record System (CPRS) that informed consent has been obtained.

(4) An order may be entered electronically by an investigator or physician designated by the Principal Investigator and completed by the Research Pharmacist or other designated pharmacist. Or a Prescription Form will be signed by an investigator or physician designated by the Principal Investigator and forwarded to the Research Pharmacist or designate for filling.

c. Dispensing Procedure

(1) Drugs will only be dispensed when an order has been entered electronically or upon receipt of a completed prescription signed by the authorized investigator or designee.

(2) The prescription must be signed, dated, and bear the patient's name, social security number, quantities prescribed where appropriate, and complete directions for use.

(3) The prescription label, in addition to the information required on other prescription labels, will include the legend, "INVESTIGATIONAL DRUG".

(4) The Research Pharmacist or designee will not dispense investigational drugs until the appropriate forms have been received from the investigator.

(5) Patients will not be charged for investigational prescriptions.

d. Administration Procedure

(1) Once properly trained, medical center personnel, listed on Appendix A, of Medical Center Number memorandum 118-305 may administer investigational medications to patients.

These medications will be administered in accordance with authorized privileges and scopes of practice.

(2) Investigational drugs will not be administered to the patient until the trained clinical coordinator has read and understands the approved information sheet (VA Form 10-9012). Any questions or clarifications will be directed to the pharmacist or principal investigator or designee.

(3) The trained clinical coordinator must confirm the presence of the patient's signed informed consent prior to the administration of the investigational agent.

(4) When the investigational drug order is discontinued, any remaining drug must be returned to the Research Pharmacist.

e. Storage Procedure

(1) A complete record of each drug will be maintained by the Research Pharmacist and shall include the following:

- (a) Name of drug
- (b) Manufacturer
- (c) Quantity received
- (d) Quantity dispensed
- (e) Remaining balance
- (f) Expiration date
- (g) Lot number
- (h) Date of authority to use
- (i) Patient's name
- (j) Patient's number
- (k) Authorized investigator and designated prescriber.

(2) All entries will be initialed by dispensing pharmacist.

(3) The Chief, Pharmacy Section will designate separate storage areas for investigational drugs apart from the regular drugs, stocked under conditions specified by the manufacturer. Such drugs will be maintained under lock and key.

(4) The amount of the investigational drug expected for usage during the investigational study may be kept at the nurses station, to a maximum supply of 7 days. All of the drug remaining on the ward at the conclusion of the study must be returned to the Research Pharmacist by the Clinical Nurse Manager.

(5) Investigational drugs will be deposited in the custody of the Research Pharmacist upon receipt by the investigator, even though the use of the drug may not yet be approved by the Subcommittee on Human Studies and the Research and Development Committee.

f. Medical Center Investigational Drug Dispensing Fees

- (1) Those studies, protocols, or projects approved by the Research and Development Committee and the Subcommittee on Human Studies for which funds are acquired through the cooperation of private, for-profit organizations such as pharmaceutical or industrial companies, will be billed for Pharmacy investigational drug dispensing services. Studies funded by governmental, public and/or non-profit organizations such as the National Institute of Health, Southwest Oncology Group (SWOG), and the VA Cooperative Study Program are exempt from all investigational drug dispensing fees. If a principal investigator wishes to do a study using clinically available formulary drugs for which there are no monies to support the project, the principal investigator may approach the Chief, Pharmacy Section, the ACOS/Research, and the Research and Development Committee to obtain approval to perform such a study without incurring Pharmacy charges.
- (2) Research Service shall inform the investigator(s) prior to protocol approval that funding for pharmacy services are to be included in the protocol budget for all eligible protocols which require dispensing of investigational drugs.
- (3) The principal investigator shall provide the Research Pharmacist with a copy of the protocol prior to final budget approval by the Research and Development Committee. The Research Pharmacist will determine the pharmacy charges based on the expected number of patients to be enrolled, investigational drug dosing frequency, duration of therapy, type of dispensing required, and need for clinical pharmacy services.
- (4) The Research Pharmacist will provide the principal investigator with an "Investigational Drug Service (IDS) Charge Worksheet" describing the services provided and an estimated fee for these services.
- (5) In addition to dispensing fees, protocols funded by private, for profit organizations shall be assessed a study initiation, maintenance, and closure activities fee.
- (6) The principal investigator will be billed for Investigation Drug Service (IDS) activities.
- (7) All monies received for IDS activities shall be deposited directly into an appropriate account.

4. RESPONSIBILITY

a. The principal investigator will be responsible for:

(1) Providing the Research Pharmacist with a copy of the research protocol prior to final budget approval.

(2) Applying to the Research and Development Committee and Subcommittee on Human Studies for approval of the investigation.

(3) Obtaining the FDA IND initial supply of investigational drug from study sponsor and subsequently delivering supply to the Research Pharmacist in care of Pharmacy Section (118CP) VA Medical Center Detroit, MI 48201 for dispensing. The principal investigator may then appoint the Research Pharmacist to coordinate procurement and return of investigational drug.

(4) Adhering to manufacturer and VA storage requirements and adequate security if there is any delay between receipt of drug by the investigator and its transfer to the Research Pharmacist.

(5) Obtaining informed consent from the patient. Pharmacy Section must be provided with a signed copy of the informed consent prior to the dispensing of the investigational drug(s).

(6) Ordering the investigational drug electronically or on a Prescription Form or Physician Order Form.

(7) Monitoring compliance to the study protocol.

(8) Informing the Research Pharmacist and the Research and Development Committee when a study has terminated and must provide directions in writing, to the Pharmacy Section, on the disposition of any remaining drug.

(9) Filing yearly reapplication for protocol to the Subcommittee on Human Studies.

(10) Training clinical coordinators.

(11) Verifying in the patient's electronic chart, that VA Form 10-1086 and any specific Informed Consent required by the protocol have been signed and placed in the patient's medical record before administration of the investigational drug.

(12) Reviewing VA Form 10-9012, Investigational Drug Information Record, noting usual dose, drug action, adverse reactions, and any necessary precautions prior to administering drug to patient.

b. The Research Pharmacist will be responsible for:

(1) Coordinating and assuring the completion of the responsibilities required of the principal investigator and Pharmacy Section as mandated by medical center policy, DEA/FDA policy, VA directives and JCAHO guidelines.

(2) Serving as a member of the Research and Development Committee.

(3) Reviewing all protocols for investigational drug studies to determine the potential impact of the study on Pharmacy Section. This will include determination of IDS charges and subsequent billing for services rendered.

(4) Providing for the receipt, storage, preparation, labeling, dispensing and accounting to assure a continuous supply of investigational drugs for the duration of the study and to properly return or dispose of expired supplies or those remaining after the study is closed.

(5) Developing dispensing guidelines for all active studies in a uniform format containing concise protocol summaries, lists of authorized prescribers, dispensing records and other information needed of pharmacists to dispense investigational drugs, in the absence of the Research Pharmacist.

(6) Assembling, interpreting, and disseminating information regarding investigational drugs to the medical staff, researchers, nurses and pharmacists concerned with their use in VA patients.

(7) Assuring that all required investigational drug data records in the dispensing area are current, accurate and complete and readily available to the study sponsor or other authorized agencies.

(8) Preparing reports to the Chief, Pharmacy Section and/or the ACOS, Research Service on investigational drug utilization review and related topics.

c. The Research and Development Committee will be responsible for the approval of the clinical protocol before the study is undertaken.

d. The Subcommittee on Human Studies will be responsible for approval of the VA Research Consent Form required by the protocol.

EMERGENCY USE OF INVESTIGATIONAL DRUGS

During the clinical investigation of a drug, it may be appropriate to use the drug in the treatment of a patient who is not in the clinical trial, in accordance with a treatment protocol or treatment IND.

The FDA criteria permitting an investigational drug to be used for a treatment under a treatment protocol or treatment IND are if:

1. The drug is intended to treat a serious or immediately life-threatening disease;
2. There is no comparable alternative drug or other therapy available to treat that stage of the disease in the intended patient;
3. The drug is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed; and
4. The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence (21 CFR §312.34).

If all conditions exist, then the emergent use of an IND may be utilized in accordance with 21 CFR §312.36. Submissions for the institution of treatment (including a treatment protocol submitted by an IND sponsor or a treatment IND submitted by a licensed practitioner) are detailed in 21 CFR §312.35. Informed consent is required unless the conditions for exemption are met. The IRB must be notified within 5-working days when an emergency exemption is used.

1. TITLE OF STUDY	6. SOURCE OF DRUG <i>(If other than manufacturer or sponsor)</i>
2. RESPONSIBLE INVESTIGATOR <i>(Individual who signed Form FD-1573)</i>	7. THERAPEUTIC CLASSIFICATION AND EXPECTED THERAPEUTIC EFFECT(S)
3. PRINCIPAL INVESTIGATOR <i>(If different than responsible investigator)</i>	
4. ALL DESIGNATIONS FOR DRUG <i>(Generic and chemical, code, trade-names, other designations)</i>	
5. MANUFACTURER OR OTHER SPONSOR	8. DOSAGE FORMS AND STRENGTHS
	9A. IS THIS DRUG A CONTROLLED SUBSTANCE? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>(If "Yes," complete Item 9B)</i>
	9B. CLASSIFICATION

10. STABILITY AND STORAGE REQUIREMENTS

A. PRIOR TO MIXING, STORAGE SHOULD BE *(Check applicable box(es))*

AT ROOM TEMPERATURE
 IN REFRIGERATOR
 IN FREEZER
 PROTECTED FROM LIGHT
 OTHER *(Specify)*

B. AFTER MIXING, DRUG REMAINS STABLE IN REFRIGERATOR FOR *(Check appropriate box and enter quantity)*

_____ MINUTES
 _____ HOURS
 _____ DAYS

11. DRUG ADMINISTRATION PROCEDURES

A. ROUTES OF ADMINISTRATION <i>(Check appropriate box(es))</i> <input type="checkbox"/> ORAL <input type="checkbox"/> I.V. INFUSION <input type="checkbox"/> I.V. PUSH	B. ADMINISTRATION DIRECTIONS	C. RECONSTITUTION DIRECTIONS
12A. DRUG ADMINISTERED BY <i>(Also complete Item 12B)</i> <input type="checkbox"/> A. PHYSICIAN ONLY <input type="checkbox"/> B. PROFESSIONAL NURSE	12B. ROUTE	13. USUAL DOSAGE RANGE

14. KNOWN SIDE EFFECTS AND TOXICITIES

15A. DOUBLE BLIND? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>(If "YES" complete Items 15B and 15C)</i>	15B. NAME OF INDIVIDUAL WHO HAS CODE DESIGNATION	15C. TELEPHONE NUMBERS DAYTIME EVENING
---	--	--

16. SPECIAL PRECAUTIONS *(Include drug interactions (synergisms, antagonisms), contraindications, etc.)*

17. ANTIDOTE

18. STATUS *(Check one)*

INVESTIGATIONAL PHASE II COMMERCIALLY AVAILABLE
 PHASE I PHASE III OTHER *(Specify)*

19. NAMES OF AUTHORIZED PRESCRIBERS

A.	B.
C.	D.

20. SIGNATURE OF RESPONSIBLE OR PRINCIPAL INVESTIGATOR	DATE	22. PATIENT IDENTIFICATION <i>(I.D. plate or give name - last, first, middle)</i>
--	------	---

21. APPROVED BY

A. SUBCOMMITTEE ON HUMAN STUDIES	
21A. SIGNATURE OF CHAIRPERSON	DATE
B. RESEARCH AND DEVELOPMENT COMMITTEE	
21B. SIGNATURE OF CHAIRPERSON	DATE

INVESTIGATIONAL DEVICES

1. PURPOSE

To establish policy and procedure for the use of, and emergency use of, investigational devices.

2. POLICY

Investigational devices can only be used after:

- a. Appropriate approval of the research protocol and informed consent document for use of the device have been obtained from the VA CIC, the IRB and the R&D Committee; and
- b. The subject, or a legally authorized representative, has fully participated in the informed consent process, including receiving a copy of the original, signed VA Research Consent Form (10-1086).

3. DEFINITIONS

- a. An investigational device is a medical device that is undergoing clinical trials to evaluate safety and effectiveness. Procedures in Title 21 CFR 812 describe how to conduct clinical trials that involve investigational devices. All studies involving investigational devices must obtain an Investigational Device Exemption (IDE) from the FDA prior to use, or be considered to have an approved IDE application (without filing an application to the FDA), based on levels of risk.
- b. Significant risk device means an investigational device that:
 - (1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
 - (2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
 - (3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
 - (4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

4. RESPONSIBILITIES

- a. The investigator is responsible for ensuring that the study is conducted according to agreement with the sponsor, the investigational plan, and applicable FDA regulations, for protecting the rights, safety, and welfare of human subjects under the investigator's care and the control of devices under investigation. The investigator is also responsible for reporting any adverse reactions, unexpected events, subject complaints, sponsor safety alerts or any other information relevant to patient protection to the VA CIC and the IRB in a timely manner.
- b. IRB Review of Medical Devices. All investigational device studies must be reviewed and approved by the WSU IRB prior to starting the research in accordance with WSU HIC policy "Use of Non-Approved Devices in Clinical Care & Research". A determination of Significant Risk (SR) or Non-Significant Risk (NSR) for a medical device is made prior to consideration of approval of the medical device study. The Significant Risk vs. Non-Significant Risk determination must be made by the convened IRB. The criteria for approval of device studies are the same as for any FDA-regulated study.

5. PROCEDURES

- a. The sponsor of a significant risk device must submit an IDE application to the FDA. Once an IDE is granted, then the IRB can consider approval of the study.
- b. A non-significant risk device, by default, does not meet the criteria of significant risk. It is considered to have an IDE application and is studied without FDA oversight, if the sponsor complies with FDA requirements. The IRB must agree that the study meets the criteria for non-significant risk.
- c. Investigators should submit the following:
 - (1) Review of prior data, including risk assessment data previously done by the sponsor or FDA;
 - (2) Source of the device;
 - (3) Literature review;
 - (4) Protocol design;
 - (5) Number of patients to be enrolled;
 - (6) Initial risk assessment and classification as a significant or non-significant device;
 - (7) An IDE from the FDA if the device is significant risk;
 - (8) Expected outcome;
 - (9) Costs;
 - (10) Proposed informed consent.
- d. The investigator must establish a plan for:
 - (1) Procuring or receiving the device;
 - (2) Storing the device;
 - (3) Securing the device

- (4) Dispensing the device
- (5) Disposing of the device upon completion or termination of the study
- (6) Maintaining records to track the devices.

e. Hospital Biomedical Engineering Section

- (1) As mandated by the medical center, all devices, regardless of whether they are investigational or marketed devices, will be inspected by Biomedical Engineering Service.
- (2) Biomedical Engineering may advise the research investigator on the appropriate procedures for storage, security and dispensing.

6. EMERGENCY USE

An exemption under FDA regulations at 21 CFR 56.104(c) permits the emergency use of an investigational drug, device, or biologic on a one-time basis per institution without IRB review and approval. Investigators wishing to use investigational devices in this situation must notify the Chief of Staff prior to use. The Chief of Staff will notify the IRB chair in advance of the use, whenever possible. Wayne State University HIC Policy/Procedure “Emergency Single Time Use of a Test Article (Drug, Biologic, Device)” will be followed.

7. REFERENCES

VA Handbook 1200.5

21 CFR 812

Wayne State University HIC Policy/Procedure “Emergency Single Time Use of a Test Article (Drug, Biologic, Device)”

8. RECISSIONS

Research Policy #7, Dated 11/1/06

9. EXPIRATION DATE

October 1, 2010

Richard E. Miller, MD
ACOS/Research & Development

PRIVACY AND DATA SECURITY

1. PURPOSE

The Department of Veterans Affairs is committed to protecting the personal data of all individuals, including veterans, dependents and employees. Those protections extend to all data formats and media, including electronic, paper, and oral information. A number of VA Directives exist to instruct employees on the proper handling of confidential and Privacy Act-protected data in order to comply with the provisions of the Standards for Privacy of Individually-identifiable Health Information, Title 45 Code of Federal Regulations (CFR) Parts 160 and 164, (Privacy Rule) promulgated by the Department of Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act (HIPAA).

The HIPAA Privacy Rule, while not intended to regulate the conduct of research, does have implications for the use of protected health information in the conduct of research. It contains sections that impose requirements on those involved in research, both individuals and institutions. Many new VA and VA IT Directives also impact how data can be used, stored, transmitted, protected and destroyed.

2. DEFINITIONS

- c. **Covered Entity** – The VHA is a single covered entity for the purpose of complying with the Privacy Rule. This covered entity includes all VHA hospitals and health care systems.
- d. **De-identified Information.** De-identified information is health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.
- e. **Disclosure.** Disclosure is the release, transfer, provision of access to, or divulging in any other manner information outside VHA.
- f. **Minimum Necessary** – The Privacy Rule restricts use and disclosure of PHI. However, it does contain exceptions granting access in certain circumstances. Underlying all the exceptions, however, is the principle that any access should be limited to the minimum amount of information necessary to accomplish the intended purpose of the use or disclosure. (For VHA research purposes, this standard requires a VHA researcher to evaluate the needs of his or her study and to request access only to those pieces of information that are necessary for the complete and accurate development of the research. This is advisable even if a research subject permits more information to be used or disclosed.)
- g. **Privacy Board** – The Privacy Rule requires board approval of waivers or alterations of authorizations for release of PHI. The board can be either an IRB, established under the

provisions of the Common Rule, or a Privacy Board, established according to the provisions of the Privacy rule. Wayne State University Human Investigation Committee is designated as the Privacy Board for research for the John D. Dingell VA Medical Center.

- h. **Privacy Officer.** The Chief, Business Practice is designated as the facility Privacy Officer. The Chief, Health Information Management is the alternate.
- i. **Protected Health Information (PHI)** is individually identifiable health information transmitted or maintained electronically or in any other form or medium, except for education records or employment records, as excluded in the Privacy Rule.
- j. **Research.** For the purposes of this policy, “research” is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge performed by VA employees or appointees (including those serving without compensation) at VA facilities and approved off-site locations
- k. **Sensitive Information** is defined as data that require protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes (1) information whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, (2) proprietary information, (3) records about individuals requiring protection under various confidentiality provisions such as the Privacy Act and the HIPAA Privacy Rule, and (4) information that can be withheld under the Freedom of Information Act (FOIA). Health information de-identified in accordance with VHA Handbook 1605.1 Appendix B would not be considered sensitive information.
- l. **Use and Disclosure of Information** – According to the definitions in the Privacy Rule, information is “used” when it remains within the entity holding the information and it is “disclosed” when it is released outside the entity that holds this information.
- m. **VA Protected Information (VAPI).** VA sensitive information, Privacy Act Information (PAI), Protected Health Information (PHI) or other VA information that has not been deliberately classified as public information for public distribution.

3. **PROCEDURES**

a. **Review Preparatory to Research**

The HIPAA Privacy Rule and VHA policy allow for the access to PHI without an authorization from the individual or a waiver from an IRB or Privacy Board when a VHA researcher is preparing a protocol. However, the researcher must represent that access is only for the purpose of preparing a protocol. The representations necessary for preparatory access are 1) the access is only to prepare a protocol, 2) no protected health information will be removed from the VHA and 3) the protected health information accessed is necessary to the research proposed. This is the only instance of access allowed without authorization or IRB approval. This access is granted only to VHA researchers; non-VHA researchers may not access VHA data for reviews preparatory to research. A request for information must be submitted to the Privacy Officer through Research Service. It must

contain a description of the information required as well as what will be done with the information once obtained. (Appendix A)

b. VHA-Approved Research

- (1) All research activities conducted by VHA Investigators must be approved by a R&D Committee.
- (2) All VHA Investigators conducting VHA-approved research must obtain the authority to use individually-identifiable information as follows:
 - VHA individually-identifiable health information may be used by a VHA Investigator for research purposes provided there is a prior written authorization (Appendix B). A prior written authorization may be incorporated into an informed consent for participation in research (Appendix C).
 - If there is no prior written authorization, VHA individually-identifiable health information may be used by a VHA Investigator for research purposes if there is an IRB waiver of authorization.
 - VHA individually-identifiable information including health information involving employee research subjects, in their capacity as an employee, may be used by a VHA Investigator for research purposes in accordance with VHA Directive 1200 and applicable 1200 series handbooks.

c. Limited Data Set

The limited data set option is less restrictive than complete de-identification but does not allow unfettered access to identifiable information but requires certain safeguards. A limited data set is one that has been stripped of the following elements:

1. Name
2. Street address (specifically, a postal address other than city, State and Zip code)
3. Telephone and fax numbers
4. E-mail address
5. Social security number
6. Certificate/license number
7. Vehicle identifiers and serial numbers
8. URLs and IP addresses
9. Full face photos and any other comparable images
10. Medical record numbers, health plan beneficiary numbers, and other account numbers
11. Device identifiers and serial numbers
12. Biometric identifiers, including finger and voice prints

The key differences between a de-identified data set and a limited data set would be the inclusion, in the latter, of dates and some geographic codes.

The use of a limited data set requires a data use agreement. This document is intended to provide assurance of the limited use or disclosure of the information in the limited data set. Under the Privacy Rule, a valid data use agreement must specify 1) the permitted uses and disclosures of information by the recipient, consistent with the purposes of the research, 2) the limits on who can use or receive the data, 3) that the recipient will not re-identify the

data or contact the individuals, and 4) that the recipient will use appropriate safeguards to prevent use or disclosure of the limited data set other than as permitted by the Privacy Rule and data use agreement or as required by law.

Disclosure of the information in a limited data set does not require review by an IRB or Privacy Board.

- d. Data Security. For all new research protocols, the Principal Investigator must certify that the use, storage, and security of all research information collected for, derived from or used during the conduct of the research will be in compliance with all VA and VHA requirements. This will require completion of a “Data Security Checklist” and a “Principal Investigator’s Certification: Storage & Security of VA Research Information” (Appendix D) for each new protocol. Employees who transport, transmit, access, use, process or store VAPI outside VA facilities are responsible for requesting and obtaining supervisor, Privacy Officer and Information Security Officer approvals (Appendix E).
- e. Theft, Loss, or Compromise of confidential or Privacy-Act protected data or devices used to transport, access or store data must be immediately reported to the employee’s supervisor, the ISO and the Privacy Officer. The Principal Investigator must also follow HIC Policy “Reporting Unanticipated Problems, Suspensions, Terminations, and Continuing and Serious Noncompliance”.

4. **REFERENCES**

VHA Handbook 1200.5, Protection of Human Research Participants

VHA Handbook 1605.1, Privacy and Release of Information

VA Directive 6504, Restrictions on Transmission, Transportation and Use of, and Access to, VA Data Outside VA Facilities

VA IT Directive 06-2, Safeguarding Confidential and Privacy Act-Protected Data at Alternative Work Locations

5. **RECISSIONS**

Research Policy #12, dated March 2006

6. **EXPIRATION DATE**

October 1, 2010

Richard E. Miller
ACOS/Research & Development



Department of
Veterans Affairs



Appendix A
Memorandum

Date:

From: Principal Investigator

Subj: Request for Patient List for Research Study

To: VA Privacy Officer

Thru: ACOS/Research

1. We are planning to submit a research protocol entitled _____ to the VA R&D Committee. *(Or We have a current protocol approved by the R&D Committee entitled _____.)* This protocol calls for identifying patients who have been diagnosed with both high cholesterol and high blood pressure.

2. Please generate a list of VA patients, male or female, diagnosed with high cholesterol and high blood pressure who have not been prescribed either a calcium channel blocker for the last six months or a lipid lowering medication for the last three months. Please provide the following:

Name
Date of Birth
Gender

3. We will use this information to determine if there are an adequate number of potential research subjects. *(You must be very clear about how this information will be used.)*

4. I can be reached in my office at _____ or by pager _____. *(A contact name and number is required.)*

(Give us much information regarding the type of information you want as possible, i.e. patients between 18 and 89 years of age, patients see at the medical center the last year. Also, if you are looking for patients who had a particular procedure, give the diagnostic or billing code.)

Subject Name:

Date:

Title of Study:

Principal Investigator:

VAMC: John D. Dingell VAMC

REQUEST FOR PATIENT AUTHORIZATION FOR ACCESS TO PROTECTED HEALTH INFORMATION

1. By signing this document, you authorize the Veterans Health Administration (VHA) to provide **(insert name)** and his or her research team to access your Protected Health Information (medical chart data) for research purposes. This information may include the following: Hospital records and reports; admission history, and physical; X-ray films and reports; operative reports; laboratory reports; treatment and test results; psychotherapy notes; dental notes; immunizations; allergy reports; prescriptions; consultations; clinic notes; and any other medical records needed by the research team. *(This list may be edited, please delete this line)*
2. Your Protected Health Information will be stored in a secure location and will be used for the following research purposes: *(Insert brief description and delete this line)*
3. I understand that the information to be released may include information regarding the following condition(s): sickle cell anemia, drug abuse, alcoholism or alcohol abuse, testing for or infection with human immunodeficiency virus (HIV)
4. You may refuse to sign this authorization and refuse to allow the disclosure of your Protected Health Information. Your refusal will not affect your ability to receive medical care or benefits at the Detroit VAMC.
5. *(Select one of the following choices and delete the rest)*
 This authorization will expire at the end of the research study;
 This authorization will expire at this date _____;
 This authorization will expire at this event _____;
 or This authorization has no expiration date.
6. This authorization may be revoked at any time by sending a written request to **(name and address here)** If you revoke this authorization, **(insert name)** and his or her research team can continue to use information about you that has been collected. No information will be collected after you revoke the authorization.
7. The Detroit VAMC complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected.

Subject Name:

Date:

Title of Study:

Principal Investigator:

VAMC: John D. Dingell VAMC

8. *Insert the following if the study has a sponsor outside the VHA (i.e., pharmaceutical company):*

As part of the study, we may disclose your information to **(insert name of sponsor)**, the sponsoring company for this research study. We will not share any information with the sponsor unless the sponsor agrees to keep the information confidential and use it only for the purposes related to the study. Any information shared with the sponsor may no longer be protected under federal law.

9. *(Insert the following if the study includes the creation of a database or tissue repository):*

This study includes the creation of a database of information or specimens such as blood, tissue, or other bodily fluids that will be used in future research. By signing this authorization, you agree to allow the information collected in this study to be added to that database.

I have read this authorization form and have been given the opportunity to ask questions. If I have questions later, I understand I can contact Dr. (insert name). I will be given a signed copy of this authorization form for my records. I authorize the use of my identifiable information as described in this form.

X _____ X _____ X _____
 Signature Print Name Date

If signed by a legal representative, state the relationship below and identify the relationship and the authority to act on behalf of the individual.

Relationship:

Department of Veterans Affairs		VA Research Consent Form	
Research Participant's Name (last, first, middle and SSN):		Date:	
Title of Study:	<i>(enter title here on page 1)</i>		
Principal Investigator:	<i>(enter name of PI here on page 1)</i>	VAMC: John D. Dingell VA Medical Center	
<p>The following elements must be included:</p> <p>PURPOSE OF RESEARCH STUDY:</p> <p>DESCRIPTION:</p> <p>RISKS:</p> <p>BENEFITS:</p> <p>ALTERNATE COURSES OF ACTION:</p> <p>STATEMENT OF RESEARCH RESULTS:</p> <p>SPECIAL CIRCUMSTANCES:</p> <p>COMPENSATION:</p>			
<p>VA Form 10-1086(08/07) Page 1 of 3</p> <p style="text-align: right;">Research Participant's Initials: _____</p>			

Research Participant's Name (last, first, middle and SSN):

Date:

Title of Study: *(enter title here on page 1)*

Principal Investigator: *(enter name of PI here on page 1)*

VAMC: John D. Dingell
VA Medical Center

REQUEST FOR PATIENT AUTHORIZATION FOR ACCESS TO PROTECTED HEALTH INFORMATION

1. By signing this document, you authorize the Veterans Health Administration (VHA) to provide **(insert name of Principal Investigator)** and his or her research team to access your Protected Health Information (medical chart data) for research purposes. This information may include the following: Hospital records and reports; admission history, and physical; X-ray films and reports; operative reports; laboratory reports; treatment and test results; psychotherapy notes; dental notes; immunizations; allergy reports; prescriptions; consultations; clinic notes; and any other medical records needed by the research team. *(This list may be edited by the research PI, please delete this line)*

2. Your Protected Health Information will be stored in a secure location and will be used for the following research purposes: *(Brief description to be completed by research PI, please delete this line)*

3. I understand that the information to be released may include information regarding the following condition(s): sickle cell anemia, drug abuse, alcoholism or alcohol abuse, testing for or infection with human immunodeficiency virus (HIV)

4. You may refuse to sign this authorization and refuse to allow the disclosure of your Protected Health Information. Your refusal will not affect your ability to receive medical care or benefits at the Detroit VAMC.

5. *(PI must select one of the following choices and delete the rest)*

This authorization will expire at the end of the research study;

This authorization will expire at this date_____;

This authorization will expire at this event_____;

or This authorization has no expiration date.

6. This authorization may be revoked at any time by sending a written request to **(PI name and address here)** If you revoke this authorization, **(insert name of Principal Investigator)** and his or her research team can continue to use information about you that has been collected. No information will be collected after you revoke the authorization.

7. The Detroit VAMC complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected.

8. *Insert the following if the study has a sponsor outside the VHA (i.e., pharmaceutical company):*

Research Participant's Name (last, first, middle and SSN):

Date:

Title of Study: *(enter title here on page 1)*

Principal Investigator: *(enter name of PI here on page 1)*

VAMC: John D. Dingell
VA Medical Center

As part of the study, we may disclose your information to **(insert name of sponsor)**, the sponsoring company for this research study. We will not share any information with the sponsor unless the sponsor agrees to keep the information confidential and use it only for the purposes related to the study. Any information shared with the sponsor may no longer be protected under federal law. If appropriate insert the following: Because this study involves material regulated by the FDA (Food and Drug Administration), the FDA may choose to inspect records identifying you as a subject in this research.” If appropriate insert the following: Payments to research participants will be issued by Metropolitan Detroit Research & Education Foundation (MDREF). MDREF administrators will access your name, address and social security number to process payments.

9. (Insert the following if the study includes the creation of a database or tissue repository):

This study includes the creation of a database of information or specimens such as blood, tissue, or other bodily fluids that will be used in future research. By signing this authorization, you agree to allow the information collected in this study to be added to that database.

RESEARCH PARTICIPANT'S RIGHTS:

I have read or have had read to me all of the above. Dr. *[insert name of PI]* has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

If you have any questions, concerns or complaints about this study now or in the future, you may contact *[insert name of PI]* or one of *[his/her]* research team members at the following phone number *[insert telephone number]*. If you have questions or concerns about your rights as a research participant or the validity of this study, the Chair of the Human Investigation Committee can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research team, call the Research Office at (313) 576-1000, ext. 61046 to ask questions or voice concerns or complaints or the Patient Advocate at (313) 576-1000, ext. 65158.

The results of this study may be published, but my records will not be revealed unless required by law. In case there are medical problems or questions, I have been told I can call Dr. *[insert name of PI]* at *[insert telephone number]* during the day and *[insert name]* at *[insert telephone number]* after hours.

The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but no additional compensation is available. No reimbursement, compensation or free

Research Participant's Name (last, first, middle and SSN):

Date:

Title of Study: *(enter title here on page 1)*

Principal Investigator: *(enter name of PI here on page 1)*

VAMC: John D. Dingell
VA Medical Center

medical care is offered by Wayne State University. (You can also add, if applicable, DMC hospitals, NIH, etc.)

I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

(Note: If this study will be enrolling only patients who are capable of consenting for themselves, delete all references to the Subject's Legally Authorized Representative.)

X _____ X _____
Research Participant's Signature Date

X _____ X _____ X _____
Signature of Participant's Representative Representative (Print Name) Date
(Only required if subject is not competent.)

X _____ X _____ X _____
Signature of Witness Witness (Print Name) Date
*(Participant's signature **MUST** be witnessed. If subject cannot read, independent witness must observe consent process.)*

X _____ X _____ X _____
Signature of person obtaining consent (Print Name) Date
(Study personnel must be approved by VA IRB.)

Data Security Checklist for Principal Investigators

Name of PI:			
Project:			
Yes	No	N/A	Specific Requirements
			All VA sensitive research information is used and stored within the VA.
			All copies of VA sensitive research information are used and remain within the VA.

If you have answered Yes or N/A to both statements above, stop here.

If the original or copies of VA research information are removed from the VA the following apply: Refer to www.research.va.gov for definitions of research information.

Yes	No	N/A	Specific Requirements
			Permission to remove the data has been obtained from 1) your immediate supervisor, 2) your ACOS/R&D, 3) the VA Information Security Officer (ISO), and 4) the VA Privacy Officer.  Data transportation
			A property pass for the equipment (Laptop etc.) has been obtained.
			The laptop or other portable media is encrypted and password protected. Note: Contact the VA ISO at your facility for encryption issues.
			Data are not transmitted as an attachment to unprotected e-mail messages.
			Names, addresses, and Social Security Numbers (real and scrambled) have been replaced with a code. Note: Names, addresses, and Social Security Numbers (real or scrambled) may only be maintained on a VA server and documentation of the procedure by which the data were coded must remain within the VA.
			Data sent via mail or delivery service have been encrypted. Note: It is preferable to send data on CDs or other media by a delivery service where there is a "chain of custody".
			For data that will reside on a non-VA server: The server has be certified and accredited as required by Federal Information and Security Management Act of 2002 (FISMA). Note: your facilities ISO should be consulted.
			Access to the data is only by those who are authorized to access it and the access is related to VA-approved research.
			Procedures for reporting theft or loss of sensitive data or the media such as a laptop, containing sensitive data are in place and familiar to the researcher and all others who have access to, use, store, or transport the data.

I certify to the best of my knowledge that all VA sensitive information associated with this research study will be used, stored and secured in accordance with all applicable VA and VHA policies and guidance.

Investigator Signature	Date
------------------------	------

Date:

From:

Subj: Authorization to transport and utilize VA sensitive information outside protected environments

To: Information Security Officer

Thru: ACOS/R&D

1. In order to accomplish my duties, I require the capability to store, transport and utilize VA sensitive information outside protected environments, as defined by VA Directive 6504. VA information refers to all information, either electronic or paper-based. My personal information follows:

Principal Investigator:

Project Title:

Research Team Members: (Have each team member initial.)

Primary Contact Phone & Email:

2. Justification for the removal of VA sensitive information outside of protected environments (include where and how information will be used):
3. The sensitive information, as defined in VA Directive 6504, I intend to store, transport and utilize includes (check all that apply):

- Individually identifiable medical, benefits or personnel information
- Information that can be withheld under the Freedom of Information Act
- Financial information
- Research information
- Investigatory information
- Commercial information
- Quality assurance information
- Law enforcement information
- Information that is confidential or privileged in litigation
- Information that could adversely affect the national interest or conduct of federal programs

4. Provide a description of the information (e.g. names, addresses, diagnosis, etc.)
5. The timeframe I will store, transport and utilize VA sensitive information outside protected environments is:
- 30 days
 - 180 days
 - One Year
 - Other:
6. Attach a list of the computers, laptops, and any storage devices that will be used for the project, with model and serial #, location of equipment and whether there will be sensitive information stored on it.
7. I acknowledge that the above statements are accurate and are in compliance with VA Directives 6601 and 6504, Removable Storage Media and Restrictions on Transmission, Transportation and Use of, and Access to, VA information outside protected environments.
8. I acknowledge this document requires renewal upon expiration of the approval timeframe requested above.

Signature

Date

Concurrence and Approval	
Recommend Approval <input type="checkbox"/> Disapproval <input type="checkbox"/> Remarks:	
Service Chief Signature	Date
PRINT OR TYPE NAME HERE:	
Recommend Approval <input type="checkbox"/> Disapproval <input type="checkbox"/> Remarks:	
ACOS/R&D	Date
Concur <input type="checkbox"/> Do Not Concur <input type="checkbox"/> Remarks:	
Information Security Officer	Date
Concur <input type="checkbox"/> Do Not Concur <input type="checkbox"/> Remarks:	
Privacy Officer	Date

PARTICIPANT OUTREACH

1. PURPOSE

The following describes the procedures required to ensure that educational opportunities are offered to research participants, prospective research participants, and community members that will enhance their understanding of research involving human participants at the John D. Dingell VA Medical Center.

2. PROCEDURE

a. The JDDVA utilizes WSU's Community Liaison who presents educational opportunities and outreach activities in various venues, i.e., veterans organizations, schools, churches.

b. The following informational pieces are displayed in the clinic waiting areas, Patient Learning Center, and Research Coordinator offices: "I'm a veteran. Should I participate in research" Here are some things you NEED to know." Department of Veterans Affairs, IB 10-54, Revised 8-02 and "Becoming a Research Volunteer: It's YOUR Decision." OHRP, U.S. Department of Health and Human Services, Office the Secretary, Office of Public Health & Science, Office for Human Research Protections. The accompanying poster is also posted in various research clinics.

c. Each research coordinator has a copy of the accompanying video to "I'm a Veteran. Should I participate in Research" which they either show or distribute to each veteran interested in participating in research. The video is also available in the Patient Learning Center and is shown on patient learning channels.

d. JDDVAMC hosts an annual Research Symposium open to patients and staff for the purpose of raising research awareness in the Medical Center and community. It is designed to celebrate the achievements of VA researchers and the role they play in providing high quality care for veterans and advancing medical science. It also serves to educate veterans, the public, and the media about the research being conducted at our medical center, and its impact on treating and preventing disease and disability. Investigators present their data in poster format and are available to answer questions. Public officials, veteran organizations, and the press are invited to this event. A pamphlet is also prepared which is given to prospective researchers, research participants and various organizations.

3. EVALUATION

JDDVAMC periodically evaluates its outreach activities and makes changes when appropriate. These evaluations take place in an informal, ongoing manner. All research staff will report both positive and negative feedback about all HRPP outreach activities to the Research

Compliance Officer. He/she will then track the input and any changes made to improve outreach activities. He/she will summarize that material for an annual presentation to the R&D Committee. In order to formally evaluate its outreach activities, the RCO will determine:

1. The specific community outreach activities being used.
2. Whether or not these community outreach activities have an evaluative component, and if so what, if any, changes in the outreach activities have resulted from these Evaluations.

4. REFERENCES

AAHRPP Standard V.2

5. RECISSION

None

6. EXPIRATION DATE

October 1, 2010

Richard E. Miller, M.D.
ACOS, Research & Development Service

POSTING RECRUITMENT FLYERS AT THE JDDVAMC FOR NON-VA RESEARCH

a. **PURPOSE:**

Investigators conducting research at other institutions frequently request permission to recruit potential research participants from the VA population, including employees, volunteers and patients. Regardless of the performance site or the sponsor, all such recruitment (e.g. advertisements) must be approved by the VA Clinical Investigation Committee, a subcommittee of the VA R&D Committee, before they can be posted.

b. **POLICY**

Investigators conducting research at non-VA institutions who wish to advertise their research projects at the JDDVAMC may only do so under the conditions described in this procedure. Passive recruitment using flyers is permitted. Active recruitment of subjects (e.g. consenting VA patients in clinics and/or hospital waiting areas) is not permitted, unless the study has been approved by the JDDVAMC IRB. Advertisements and flyers may be distributed only if:

- a. They have been reviewed and approved by the VA Clinical Investigation Committee (CIC), a subcommittee of the VA R&D Committee, and the IRB.
- b. They display the IRB approval stamp which is currently valid; and
- c. They clearly indicate that this is not a JDDVAMC sponsored research project.

3. RESPONSIBILITIES

- a. The Investigator will be responsible for obtaining IRB approval
- b. Completing Appendix A "Agreement with the JDDVAMC."
- c. The CIC will be responsible for reviewing the incoming request and evaluating whether or not the flyer complies with JDDVAMC policy and indicate whether it is acceptable to post on VA grounds.

4. PROCEDURES

- a. Investigators must submit a written request to post research recruitment flyers in the VAMC. Additionally, the investigator must submit a copy of their institution's most recent initial or continuing review IRB approval letter for the study and IRB approved consent form.

- b. The flyer submitted must contain the approval stamp from the host institution's IRB. It must also clearly state that this is not a JDDVAMC sponsored research project. The content should be consistent with JDDVAMC sponsored research flyers and contain:
 - 1) The name and address of the clinical investigator and/or research facility.
 - 2) The condition being studied and/or the purpose of the research.
 - 3) In summary form, the criteria that will be used to determine eligibility for the study.
 - 4) The time or other commitment required of the subjects.
 - 5) A clear statement that the research is not being done at the JDDVAMC
 - 6) The location where the research is being done and the person or office to contact for further information.
 - 7) A clear statement that this is research and not treatment.
 - 8) A brief list of potential benefits (e.g. no cost of health exam).
- c. The incoming request will be reviewed by the CIC to assure whether or not it complies with JDDVAMC policy and the accompanying investigator's agreement with the JDDVAMC (attached).
- d. Once reviewed, the PI will be contacted concerning either the approval of the flyer or the need for modifications.

5. REFERENCE

None

6. RECISSIONS

None

7. EXPIRATION

February 15, 2009

Richard E. Miller, M.D.
ACOS, Research & Development Service

AGREEMENT WITH JOHN D. DINGELL VAMC RESEARCH SERVICE

PRINCIPAL INVESTIGATOR (PI) REQUESTING APPROVAL:
FLYER WILL BE POSTED IN THE FOLLOWING AREA(S):
FOR ANY CONCERNS WITH THE FLYER, CONTACT:
CONTACT INFORMATION :

ASSURANCES:

I CONFIRM THAT THIS RESEARCH PROJECT IS NOT CONDUCTED BY OR COLLABORATIVELY WITH THE VA. <input type="checkbox"/>	
I CONFIRM THAT THIS FLYER WILL BE TAKEN DOWN BY (DATE):	
I CONFIRM THAT THIS RESEARCH PROJECT AND FLYER HAVE RECEIVED THE APPROPRIATE APPROVAL(S) BY WSU IRB: <input type="checkbox"/>	
SIGNATURE	DATE

RESEARCH COMPLIANCE/PERFORMANCE IMPROVEMENT PLAN

1. PURPOSE

To establish and maintain a comprehensive and integrated compliance and continuous quality improvement program of the human research efforts, in accordance with the letter and spirit of applicable laws, regulations and accreditation standards, and in support of the JDD VAMC Human Research Protection Program (HRPP):

- a. To enhance the protection of human subjects who participate in research programs under the purview of the JDD VAMC;
- b. To ensure compliance with the Federal-Wide Assurance (FWA), the Memorandum of Understanding (MOU) between the JDD VAMC and Wayne State University, VA and other federal regulations, state laws, and ethical guidelines for human subjects research;
- c. To encourage continuous improvement in the conduct of human research at JDD VAMC
- d. To promote an institutional culture of responsible research and cooperation between the Research & Development Service and investigators to improve the quality of research; and
- e. To identify potential concerns and provide guidance in their resolution.

2. PROCEDURES

Overview:

The day-to-day implementation of the JDD VAMC HRPP and individuals and activities involved in human subject research are subject to periodic assessment for purposes of assuring the protection of human research subjects through compliance and quality improvement activities. Such assessments will determine the extent to which the HRPP complies with VA and Federal regulations and the adequacy of its processes and documentation. Reviews will be conducted periodically and summarized on an annual basis. Observations will be used for purposes of quality improvement. Areas to be reviewed fall into seven general categories:

- functioning of the R&D Committee;
 - functioning of the IRB;
 - functioning of investigators;
 - institutional responsiveness to questions, concerns and complaints;
 - investigator compliance with policies and procedures regarding the use of investigational drugs & devices;
 - pharmacy compliance with established policies and procedures; and
 - effectiveness of corrective actions/improvement efforts that have been implemented.
- a. The review of the functioning of the R&D Committee will consist of determinations of the committee in the following areas:
 - review and approval of proposals based on Scientific Merit;
 - appropriateness of the research to the Institution's Mission;
 - role of the Investigator at the Medical Center;

- adequacy and appropriateness of the requested space requirements and funding;
 - including requested allocations for personnel, equipment and supplies, and continuing education;
 - annual review of projects; and
 - continuing review of publications.
- b. Oversight and evaluation of the functioning of the IRB will consist of reviewing the following areas:
- confirmation of the appointment of IRB Chair;
 - review of IRB Minutes and confirmation of the subcommittee's decisions; and
 - communication with the IRB.
- c. The review of the functioning of investigators may consist of :
- ensuring that principal investigators and others directly involved with human subjects and human research data collection have received appropriate training in the protection of human subjects;
 - Credentialing/privileging of staff;
 - timely submission of approval documents;
 - the consent process;
 - compliance with inclusion and exclusion criteria
 - study conduct, to include adherence to study protocol and timely and accurate reporting of Adverse Events
 - Data security
- d. The review of the institutional responsiveness to questions, concerns and complaints will consist of (in accordance with the Institution's HRPP/ACOS) the following:
- timeliness of response to the issue;
 - the resolution;
 - satisfaction of the complainant with the resolution
 - participant outreach program
- e. The review of investigator compliance with policies and procedures regarding the use of investigational devices will consist of :
- compliance with Research & Development Service Policy #7, Investigational Devices
- f. The review of Pharmacy compliance with established policies and procedures will consist of:
- compliance with Medical Center Numbered Memo 118-303, Investigational Drugs
- g. The review of effectiveness of corrective actions/improvement efforts that have been implemented will consist of:
- identification of office or committee responsible for review and evaluation;
 - identification of areas with a need for improvement;
 - identification of corrective and follow-up actions with timeline for implementation;
 - analysis of the effectiveness of the corrective action.

3. REVIEW & EVALUATION OF REPORTS

A summary of findings will be reported by the RCO to the Clinical Investigation Committee (CIC) and the R&D Committee and will be documented in the meeting minutes. The results of these observations will be used to identify strengths and weaknesses, educate research staff and to implement planned improvements and monitor and measure the effectiveness of those improvements on a continuous basis. Any findings of non-compliance or research misconduct will be promptly reported to the IRB and appropriate oversight and regulatory body according to applicable policies and regulations. Any remedial or disciplinary actions will be enforced by the MCD.

4. REFERENCES

VHA Handbook 1200.5

5. RESCISSIONS

Research Policy #6, Research Compliance & Improvement Plan, dated 11/9/04

6. EXPIRATION DATE

October 1, 2010

Richard E. Miller, MD
ACOS/Research & Development

SUBJECT RECRUITMENT

Several recruitment issues can be problematic for investigators because they involve money. The following guidelines should be considered when designing a research protocol.

Payment To Subjects

VA policy prohibits paying patients to participate in research when the research is an integral part of a patient's medical care and when it makes no special demands on the patient beyond those of medical care. Payment may be permitted, with prior approval of the Human Studies Subcommittee, in the following circumstances:

1. *No direct subject benefit.* When the study to be performed is not directly intended to enhance the diagnosis or treatment of the medical condition for which the volunteer subject is being treated, and when the standard of practice in affiliated, non-VA institutions is to pay patients in this situation.
2. *Others being paid.* In multi-institution studies, where patients at collaborating non-VA institutions are to be paid for the same participation in the same study at the same rate.
3. *Comparable situations.* In other comparable situations in which, in the opinion of the IRB, payment of volunteers is appropriate.

Prospective investigators who wish to pay research subjects shall indicate in their proposal the justification for such payment with reference to the criteria listed above, and in addition shall:

1. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of the subject;
2. State the terms of the subject participation agreement and the amount in the informed consent document; and,
3. Substantiate that subject payments are fair and appropriate, and that they do not constitute (or appear to constitute) undue pressure on the veteran patient to volunteer for the research study.

Payments to subjects should be placed upon a schedule and prorated based upon the level of participation to date. Payments must not be contingent upon completion of the study.

The IRB and R&D Committee will review all proposals involving the payment of subjects (in excess of reimbursement for travel).

Participation of Non-Veterans as Research Subjects

a. Non-veterans may be entered into VA-approved research studies only when there are insufficient veterans available to complete the study in accordance with 38 CFR 17.45 and 38 CFR 17.92.

John D. Dingell VA Medical Center
Research Information Bulletin

b. All regulations pertaining to the participation of veterans as research subjects including requirements for indemnification in case of research-related injury pertain to non-veteran subjects enrolled in VA-approved research.

Advertisements

All advertising plans and materials for subject recruitment must be reviewed by the IRB. Advertisement information should include the following:

1. The name and address of the investigator;
2. The purpose of research or condition being studied;
3. Summary of eligibility requirements;
4. Incentives (i.e. payments) and benefits for participation (if any);
5. Location for research and whom to contact for more information; and
6. Time commitment required for participants (if appropriate).

Advertisement materials should:

1. Not be misleading to subjects;
2. Not make any claims of efficacy, safety, equivalency, or superiority if investigational drugs or devices are involved;
3. Not overemphasize payment;
4. Not overstate benefits or imply favorable outcomes beyond what is outlined in the consent document and protocol; and,
5. Not be coercive or use undue pressure.

Compensation to Researchers for Enrollment

Compensation to investigators, physicians or other healthcare providers for identifying and/or enrolling subjects will not be allowed. Incentives include payments from study sponsors to research institutions or individuals for purpose of increasing the numbers and/or rate of subject enrollments. Such incentives include monetary payments, reimbursements for travel, or other expenses that may or may not be related to the study. Finder's fees (i.e. payment to physicians or others for referring subjects) and bonus payments (i.e. payments to investigators, study coordinators or institutions for enhanced enrollment [beyond actual costs]) are not acceptable.

Additional cost payments (i.e. payment that is based on additional costs for enrollment beyond what was originally planned) and additional per-subject payment for increased costs associated with enhanced and/or accelerated enrollment or additional procedures, may be acceptable. These matters should be reviewed by the R&D Committee.

More information may be found in Research Service Policy #4, Informed Consent, and VHA Handbook 1200.5.

VA Tissue Banking Program

A human biological specimen is any material derived from a human subject—such as blood, urine, tissues, organs, hair, nail clippings, or any other cells or fluids—whether collected for research purposes or as residual specimens from diagnostic, therapeutic, or surgical procedures.

Biological specimens collected and stored for future research purposes that are beyond the scope of work described in the original protocol and informed consent or those collected under a protocol designed for banking of specimens are considered banked biological specimens.

Human biological specimens collected under a VA-approved protocol are not considered to be "banked" specimens if they are used for only the specific purposes defined in the protocol and are destroyed either when the specific testing/use is completed or at the end of the protocol.

Important Notes:

- If the protocol is 5 years or longer and the specimens are stored off-site at a non-profit institution until the end of the protocol, then the investigator must obtain a waiver from the Office of Research and Development (ORD).
- If the specimens are stored off-site at a non-academic, for-profit institution for **greater than 3 months**, a waiver must be obtained from ORD.

A tissue bank established at a VA site by a VA-paid investigator does not require approval from ORD. The ACOS/R or research office should maintain records of all tissue banks within the facility.

A researcher must obtain a waiver from ORD before banking human biological specimens outside of the VA. In general, an off-site tissue bank must be approved for each protocol. An application for an off-site tissue bank can be obtained from the Research Administration office.

FAQ: Banking of Human Biological Specimens for Research

Q: How do you define human biological specimens?

A: A human biological specimen is any material derived from a human subject—such as blood, urine, tissues, organs, hair, nail clippings, or any other cells or fluids—whether collected for research purposes or as residual specimens from diagnostic, therapeutic, or surgical procedures.

Q: When are specimens considered to be banked specimens?

A: Biological specimens collected and stored for future research purposes that are beyond the scope of work described in the original protocol and informed consent or those collected under a protocol designed for banking of specimens are considered banked biological specimens.

Q: Is all storage of human biological specimens considered banking?

A: Human biological specimens collected under a VA-approved protocol are not considered to be “banked” specimens if they are used for only the specific purposes defined in the protocol and are destroyed either when the specific testing/use is completed or at the end of the protocol.

A: Human biological specimens collected under a VA-approved protocol are not considered to be “banked” specimens if they are used for only the specific purposes defined in the protocol and are destroyed either when the specific testing/use is completed or at the end of the protocol.

If the specimens are sent to a non-VA institution for testing as defined in the protocol, once the specific analyses are performed, the remainder of the specimens must be destroyed or returned to the VA for destruction. If the specimens are destroyed at another institution, that institution must certify the destruction of the specimens in writing.

Q: Is banking of bacteria or fungus samples obtained from human specimens considered tissue banking?

A: No, not as long as the human material has been removed.

Q: Does a VA investigator need approval from the Office of Research and Development (ORD) to establish a tissue bank on a VA campus?

A: No. A tissue bank established at a VA site by a VA-paid investigator does not require ORD approval. However, the ACOS/R should maintain records of all tissue banks within the facility.

Q: Does a VA investigator need approval to bank biological specimens collected from subjects at the VA Medical Center at his/her University affiliate?

A: Yes. If the specimens are banked at a site that is not on the VA campus, ORD approval is required.

Q: I am a Without Compensation (WOC) investigator at the VA. May I apply for an off-site tissue bank?

A: No, but if you add a part-time or full-time VA-paid investigator to your study team, that investigator may submit an application. The VA-paid investigator has ultimate responsibility for VA specimens in that off-site tissue bank.

Q: My colleague received approval to bank specimens at off-site tissue bank XYZ. Do I need ORD approval to bank specimens there?

A: Off-site tissue banks are approved on a per protocol basis (with the exception of some NCI protocols listed in the answer to the next questions), so unless you are banking specimens for the same protocol as your colleague, you need ORD approval.

Q: Where can I find a list of VA-approved off-site tissue banks?

A: Tissue banks approved for **multi-site protocols** are listed below. This list is also posted on the VA R&D website.

The following banks are approved ONLY for the protocol listed:

Protocol	Protocol Acronym	Tissue Bank Name and Location
Action to Control Cardiovascular Risk in Diabetes	ACCORD	Northwest Lipid Metabolism and Diabetes Research Laboratories, Seattle, WA
Chronic Renal Insufficiency Cohort	CRIC	CRIC Study Central Lab & Repository, University of Pennsylvania, Philadelphia, PA
Hepatitis C Long Term Treatment Against Cirrhosis	HALT-C	SeraCare (formerly BBI Biotech), Gaithersburg, MD
Alzheimer's Disease Neuroimaging Initiative	ADNI	National Cell Repository for Alzheimer's Disease (NCRAD), Indianapolis, IN
Atherothrombosis Intervention in Metabolic Syndrome with Low HDL/High Triglyceride and Impact on Global Health Outcomes	AIM-HIGH	Northwest Lipid Research Laboratories, University of Washington, Seattle, WA
Lung Tissue Research Consortium	LTRC	Tissue Processing Distribution Center-Tissue Core Lab, University of Colorado Health Sciences Center, Denver, CO
Idiosyncratic Liver Injury Associated with Drugs: A Retrospective Study	DILIN-ILIAD	NIDDK Genetics Repository (Rutgers University Cell and DNA Repository)
A Multi-Center Longitudinal Study of Drug- and CAM-Induced Liver Injury	DILIN-CAM	NIDDK Genetics Repository (Rutgers University Cell and DNA Repository)
Action for Health in Diabetes	Look AHEAD	Look AHEAD Central Laboratory, University of Washington, Seattle, WA
Diabetes Prevention Program/Diabetes Prevention Program Outcomes Study	DPP/DPPOS	DPP/DPPOS Central Laboratory, University of Washington, Seattle, WA
Genetics of Endophenotypes and Schizophrenia	COGS	Rutgers University Cell and DNA Repository, Piscataway, NJ

In addition, as a result of a letter of understanding with the National Cancer Institute (NCI), the following

NCI-sponsored cooperative tissue banks, are designated as VA-approved if they are used for one of their protocols (for example, the SWOG-supported tissue bank can be used for SWOG protocols without ORD approval):

Clinical Trials Cooperative Groups Tissue Resources, which include American College of Surgeons Oncology Group (ACOSOG), Cancer and Leukemia Group B (CALGB), Eastern Cooperative Oncology Group (ECOG), Gynecologic Oncology Group (GOG), North Central Cancer Treatment Group (NCCTG), National Surgical Adjuvant Breast and Bowel Project (NSABP), Radiation Therapy Oncology Group (RTOG), Southwest Oncology Group (SWOG), Cooperative Breast Cancer Tissue Resource, Cooperative Human Tissue Network, Gynecologic Oncology Group Tissue Network Cancer Prevention Network.

Q: You have an agreement in place with NCI regarding the use of tissue banks that they sponsor. What about other NIH Institutes?

A: Each NIH Institute sets its own policies regarding the repositories it sponsors, and our only agreement to date is with NCI.

Q: Is there a list of elements that must be included in an informed consent when the protocol includes tissue banking?

A: Yes, see attached.

Q: Does the informed consent need to narrowly specify the future uses of the banked specimens?

A: No, the statement about future uses does not have to be very specific. If it is not specific, in the consent form or during the consent process, the PI should explain what such phrases as “related diseases” or “unspecified research” means for the use of the sample and the impact on the subject.

Q: I have specimens that were collected for a protocol that will soon end. Can I use them for a different protocol or test them for something (protein, gene, etc.) not in the original protocol?

A: If banking was not included in the original protocol and informed consent, then in order to use the specimens, you would need to re-consent the patients, or an IRB would need to waive consent, if applicable. If approval is obtained from subjects or the IRB waives consent, the samples would be considered banked samples. All new uses of the samples would have to be approved by the IRB and R&D Committees. If approval is not obtained, then the samples would have to be destroyed.

Q: Our pathology lab has paraffin-embedded specimens that it plans to destroy. Can we use the specimens for research, including genetic testing?

A: Your IRB must make that determination. Please note: clinical samples may NOT be transferred to a commercial (for-profit) entity for research purposes.

Q: Can we bank DNA/blood at a commercial sponsor’s site?

A: Currently, we are not permitting off-site tissue banking at commercial entities, with the exception of NIH-sponsored banks, such as those at Coriell and ATCC. However, specimens may be stored at a commercial sponsor’s site for up to 3 months while waiting for analyses/tests specified in the protocol to be performed. If the analyses/tests cannot be completed within the 3-month limit, a waiver must be obtained from ORD.

Q: I am a VA-paid investigator and would like to bank blood for a study, but our VA Medical Center does not have the facilities to do that. Is there a VA-approved tissue bank that I can use?

A: You may bank samples at any VA Medical Center that has an established tissue bank. Alternatively, you could also use the Massachusetts Veterans Epidemiology Research and Information Center (MAVERIC) core laboratory at the Boston VA. It serves as the Cooperative Studies Program (CSP) Genetic Tissue Core Laboratory. The laboratory provides both local and national VA researchers a convenient, high-quality, low-cost mechanism to include biological specimen handling, storage and analysis in clinical studies. Laboratory capabilities include: coordination of collection, processing, shipment, and storage of serum, plasma, buffy coats and other biological specimens; extraction of DNA from blood, tissue, or serum buffy coat; extraction of RNA; and genotyping. See <http://www.csp.research.va.gov/boston.cfm> for contact information.

Informed Consent for Protocols Involving Tissue Banking

The informed consent under which the specimen was collected must meet all the requirements in Appendix C of VHA Handbook 1200.5 “Requirements for the Protection of Human Subjects in Research.” In addition, the informed consent must clearly address the following:

- **The types of specimens that will be stored and the name and location of the biorepository/tissue bank where they will be stored.**

Example 1: Your blood and DNA samples will be stored at the National Cell Repository for Alzheimer’s Disease (NCRAD) in Indianapolis, IN.

Example 2: Your DNA will be stored at the Rutgers University Cell and DNA Repository in Piscataway, New Jersey.

- **The types of future research that the sample will be used for.**

Example 1: Your DNA and serum will be stored for genetic testing. Genetic testing will be restricted to testing for genes related to dementia.

Example 2: Your blood samples will be used for studies of any major disease or health condition, including genetic studies.

Example 3: Your samples will be used for research on Alzheimer’s disease and related diseases.

Example 4: see Example 3 in the next section.

- **If the specimen will be shared with other researchers for approved research protocols.**

Example 1: The National Institute on Aging (NIA), a component on the National Institutes of Health (NIH), will make your DNA and clinical data available to other qualified scientists.

Example 2: Your blood will be shared with other qualified researchers at the Bronx VAMC.

Example 3: If you give permission, samples may be shared with other research laboratories studying the genetics of type 2 diabetes and the development of heart and blood vessel diseases, other major disease, health conditions, or risk factors.

I agree to allow my genetic sample to be studied for genes related to any major disease or health condition or risk factor.

I agree to allow my genetic sample to be studied only for genes related to diabetes, blood pressure, blood cholesterol abnormalities, heart disease, or other risk factors for heart disease or for diabetes.

 I agree to allow my genetic samples to be used only for this study.

- **The length of time the specimen will be stored.**

Example 1: Your samples will be stored for 15 years and then destroyed.

Example 2: Your samples will be stored until none is left.

Example 3: Your samples will be stored indefinitely.

- **If the specimen will be labeled with a code that doesn't contain any personal identifiers (i.e., protected health information as defined by HIPAA) and if the subject's clinical data will be linked to the specimen.**

Example 1: The sample and your clinical data will be assigned a code that does not contain your name, initials, SSN, date of birth, or other unique identifiers.

Example 2: All identifiable information about you will be removed from the research specimen. Your sample and data will be identified by a code.

- **When and under what conditions research results will be conveyed to the subject, the subject's family, or the subject's physician.**

Note: Laboratories that test human specimens cannot report patient specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of individual patients unless the laboratory is Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified.

Example 1: These tests are being done for research purposes only; you and your doctor will not be informed of the results.

Example 2: Reports about research done with your samples will not be given to your or your doctor because they will not have any direct clinical benefit to you at this time.

Example 3: Because these results have no clear meaning for you at this time, we will not report the results of the XYZ testing to you. XYZ testing is not a proven marker for Alzheimer's disease.

- **The steps necessary for the subject to withdraw from the study and any future studies in which the specimens may be used. The consent must indicate what will occur to the data collected to that point and that the specimen and the code that links the subject's clinical data to the specimen will be destroyed.**

Example 1: You may withdraw your consent at any time. Please notify Dr. XXX at <phone number> to withdraw your consent. Your DNA, plasma, and all links to your clinical data and any data obtained from this research study will be destroyed.

Example 2: You may withdraw your consent at any time. Please notify Dr. XXX at <phone number> to withdraw your consent. Your DNA, plasma, and all links to your clinical data stored in the repository will be destroyed. However, any de-identified samples that have been shared with other researchers cannot be destroyed.

Example 3: You may ask the researchers to stop using your health information at any time. Contact Dr. XXX at <phone number>. The research team will continue to use any information that they have already collected to ensure the integrity of the research. However, no new information will be collected from you.

- **Disclose any potential commercial benefits and if the subject will receive money or other benefits.**

Example 1: Your specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value. You will not receive any money or other benefits derived from any commercial or other products that may be developed from the use of the specimens.

Example 2: The use of your sample may result in inventions or discoveries that could become the basis for new procedures of diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed. Commercially available products may be developed from these samples. There are no plans to share any of these profits with you.

- **Disclose any intent to perform genetic tests.**

Example 1: Genetic tests will be confined to testing for genes relating to liver diseases, including hepatitis and cancer.

Example 2: Genetic material (DNA) will be isolated from the blood or tissue sample that you donate. It will be used to test for genes relating to prostate cancer.

- **Disclose any potential risks to the subject or the subject's family. Potential risks may include breach of confidentiality, which may lead to discrimination in the areas of employment, insurability, social stigmatization, or psychological stress caused by disclosure of adverse information to the subject or the subject's family.**

Example 1: It is theoretically possible that genetic information about you could lead to denial of insurance or employment. Therefore, information about you will not be given to other family members (unless you give permission, or unless you need a representative at a later date), insurance companies, or employers.

Example 2: The study results might be stressful to you if we were to find that you carry a gene for a neurological disease.

Example 3: We will make every effort to protect your confidentiality and make sure that your identity does not become known. All written information will be stored in a locked file cabinet, and electronic data will be encrypted. A limited number of staff members will have access to the data. However, there is a slight risk of a breach of security.

CLINICAL INVESTIGATION COMMITTEE (CIC)

1. PURPOSE

The purpose of the Clinical Investigation Committee (CIC), as a subcommittee to the R&D Committee, is to review all projects involving human subjects for a) scientific merit, b) ethics, 3) compliance with VA regulations and d) Impact of budget on VA resources. Based on these reviews, the CIC will recommend one of the following: 1) approval to submit the application to the HIC for review, 2) not approved – revisions required, or 3) not approved for submission to the HIC. CIC review is necessary before the research can be submitted to the WSU HIC with all components required for evaluation of the protocol for the protection of human subjects.

2. PROCEDURES

a. New Applications

1. Principal Investigators must complete the R&D Request to Review and submit it with appropriate attachments.
2. Completed applications received on or before the 10th of the month will be reviewed at the next CIC meeting. Investigators will receive reviews within 10 working days of the meeting. If approved, the investigator will submit the application to the Wayne State University Human Investigation Committee for review by one of their four Institutional Review Boards.
3. If the HIC requests revisions, other than minor revisions, it must resubmitted to the CIC.
4. After approval by the HIC the protocol will be returned to the Research Office for final approval by the R&D Committee.

b. Amendments and Changes in Approved Research Procedures and Consent Forms

The CIC must conduct a review of all proposed modifications to approved research projects, including even minor changes and modifications to informed consent forms prior to submission to the HIC. The changes must be approved prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject.

c. Continuations

1. The CIC will conduct substantive and meaningful continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

2. During the continuing review, the CIC takes the following into consideration:
 - changes to the research;
 - adverse event reports; safety reports, including IND, IDE and MedWatch;
 - reports of unanticipated problems, involving risk to subjects, and if available data safety monitoring reports;
 - protocol violations and/or deviations;
 - overall investigator non-compliance, including non-compliance with IRB requirements for frequency of periodic continuing review
 - informed consent document(s).

3. **REFERENCE**

VHA Handbook 1200.5
Wayne State University, HIC, Standard Operating Procedures

4. **RESCISSION**

Research Service Policy #2, dated 3/1/06

5. **EXPIRATION DATE**

October 1, 2010

Richard E. Miller, MD
ACOS/R&D

Clinical Investigation Committee (CIC) Review Checklist

Investigator:				
Protocol Title:				
Reviewer:				Date:
Scientific Integrity	Yes	No	N/A	Comments
1. Are procedures consistent with sound research design				
2. What is the importance of knowledge reasonably expected				
3. Do resources and time appear sufficient for study completion				
4. Are study personnel, including PI, appropriate and trained				
5. Is the research designed to answer proposed question				
6. Are participants unnecessarily exposed to risk				
7. Are vulnerable populations protected				
8. Is payment reasonable				
9. Is tissue banking appropriate				
10. Is PI able to recruit required number of subjects from population				
Protocol Summary Form Review				
1. Is there a complete protocol, including references				
2. Is the Principal Investigator/Co-Investigator(s) identified				
3. Is contact/location information complete				
4. Is the Agency/Sponsor identified				
5. Is the type of submission clearly identified				
6. Is a request for expedited review attached, if applicable				
7. Is the appropriate expedited category selected				
8. Are investigational drugs involved				
9. Is there a completed 10-9012				
10. Is the IND Drug Information sheet attached/signed/dated				
11. Is the Marketed Drug Info sheet (drug insert) attached				
12. Is there an investigational device				
If yes, is the IDE device information attached				
13. Does the proposed research involve the use of radiation requiring the review of the Radiation Safety Officer				
14. Does the proposed research involve the use of banking of human subject specimens requiring CRADO approval				
15. Is there a Conflict of Interest form attached				
16. Are the Survey/Questionnaire instruments attached				
17. Does the application provide appropriate study population identification				
18. Does the proposed research describe where the research (setting) is to be conducted				
19. Does the protocol involve the use of genetic testing				
20. Does the protocol involve the use of biosafety hazards requiring biosafety committee approval				
21. Does the protocol identify physical, psychological, social and/or economic risks that may result from participation in the research				
Subject Selection and Recruitment				
1. Does the protocol describe the methods used to identify and recruit potential subjects				
2. Does the protocol contain information about scientific and ethical justification for excluding classes of person who might benefit from the research				

3. Does the protocol contain:	Yes	No	N/A	Comments
• subject inclusion criteria				
• subject exclusion criteria				
• Information about the nature of compensation offered to subjects for participation in the research				
• Information about proposed advertisements or recruitment methods for subjects.				
4. If an advertisement (flyer, banner, email notice) is to be used, is it included in the submitted materials				
Confidentiality				
1. Does the protocol describe methods used to obtain information about participants				
2. Does the proposed research protocol describe provisions for protecting the confidentiality of research data				
3. Does the proposed research protocol describe who will have access to the research data				
4. Is there a completed Data Security form				
Informed Consent Required elements				
1. A statement that the study involves research				
2. Purpose of research				
3. Expected duration of the subject's participation				
4. Description of the procedures used to conduct the research				
5. A statement identifying any experimental procedures used				
6. Description of any reasonably foreseeable risks or discomforts				
7. Description of any potential benefits from the research, either to subject or to others				
8. Description of alternative procedure or sources of treatment available to subject				
9. Statement describing the extent (if any) to which confidentiality of records will be maintain				
10. Statement that regulatory authorities, including the FDA (if applicable), may inspect the records				
11. For research involving more than minimal risk, the statement: "The VA will provide necessary medical treatment should you be injured by participation in this study. You will be treated for the injury at no cost to you, but no additional compensation is available."				
12. An explanation of who to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject				
13. Statement that participation is voluntary				
14. Statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled				
Additional Elements of Informed Consent, if Necessary				
1. Statement that the treatment or procedure may involve unforeseeable risks to the subject (or embryo or fetus, if subject may become pregnant)				
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.				
3. VA resources (medical and/or psychological) that participants might require as a consequence of this study are available.				
4. Additional costs to the subject consistent with Federal laws concerning veterans' eligibility for medical care treatment				

	Yes	No	N/A	Comments
5. Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.				
6. Statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.				
7. Approximate number of subjects involved in the study				
8. Will the subject receive payment related to participation in the study				
9. If yes, is the amount and schedule of payments contained in the consent form				
10. If yes, is the amount of and schedule of payments non-coercive				
11. Should participant's CPRS record be flagged				

Additional Comments:

Reviewer Signature:

RESEARCH AND DEVELOPMENT COMMITTEE

1. PURPOSE

The R&D Committee is responsible, through the Chief of Staff to the Director, for maintaining high standards throughout the R&D program. These standards include those assuring the scientific quality of research projects, adequate resource allocations, protection of human subjects in research, and safety of personnel engaged in research. The R&D Committee advises the Director on professional and administrative aspects of the R&D Program. All R&D activities within the facility, whether funded or unfunded, are within its purview. No research may be undertaken without R&D Committee and appropriate subcommittee(s) review and approval. Members are appointed by the Director in accordance with Medical Center Bulletin #10.

2. RESPONSIBILITIES FOR REVIEW OF RESEARCH PROGRAM

The Research and Development Committee advises the Director on professional and administrative aspects of the research and development program. The committee exercises organizational stewardship by optimizing resources committed to research. All research and development activities within the facility, whether funded or unfunded, are within the purview of the R&D Committee. These responsibilities will include:

- a. Planning and developing broad objectives of the research and development program so that it supports the patient care mission of the facility;
- b. Determining the extent to which the research and development program has met its objectives;
- c. Reviewing the budgetary and other resource needs of the R&D Program, at least annually, and making appropriate recommendations regarding these needs. This includes space, personnel, equipment, supplies, training, use of animal facilities and other common resources;
- d. Annually evaluating IRB performance to include whether the number and composition of the IRB(s) is appropriate to the volumes and types of human research and compliance with VA regulations and guidelines.
- e. Reviewing and evaluating all subcommittees (listed below);
 - (1) Clinical Investigation Committee. The Clinical Investigation Committee (CIC) reviews all projects involving human subjects for a) scientific merit, b) ethics, c) compliance with VA rules and regulations governing and d) VA budget prior to review by the IRB. Approval of the CIC is necessary before a VA research proposal can be

submitted to the WSU HIC.

- (2) Subcommittee on Research Safety (SRS): This Committee will 1) review all research proposals involving safety hazards for compliance with all applicable regulations, policies and guidelines pertinent to biological, chemical, physical and radiation hazard prior to submission for R&D funding. The review shall include a risk assessment of the facilities, level of containment, laboratory procedures, practices, training and expertise of personnel involved in the specific research conducted including recombinant DNA research; 2) annually review all on-site research programs involving safety hazards regardless of funding source; and 3) coordinate all safety-related activities in research laboratories including safety training, safety inspections, accident reporting and liaison activities with all facility safety committees and officials.
- (a) Research Safety Committee: Medical Center Numbered Memorandum 001F-154 states that Service Chiefs are responsible for “Establishment of a Service Safety Subcommittee within their services comprised of not less than five (5) members with representation of all sections within the service.” This subcommittee will be a subcommittee of the SRS and will report to the SRS who in turn will report to the R&D Committee and is required to:
- Investigate and analyze accidents and fires occurring within the service they represent and report their findings and recommendations in monthly minutes.
 - Study and recommend to the HLC on Coordination of the Environment of Care (Safety Committee), ways and means of improving safety and fire protection within the organization and establishing safe work practices.
 - Perform safety inspections, review employee injuries, and provide safety training.
 - Annually review the Safety Manual/Chemical Hygiene Plan for effectiveness.
- (3) The Institutional Animal Care and Use Committee (IACUC): is formally titled the Animal Investigation Committee (AIC) for Wayne State University, this medical center (John D. Dingell VAMC) and WSU affiliated health care institutions. The AIC has the responsibility for performing the review and oversight functions required by PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, the Animal Welfare Act, the USDA Animal Welfare Act Regulations and Standards, the requirements in VA Handbook 1200.7, and any other federal regulations that impact IACUC function. The IACUC is also responsible for performing a self-assessment review of the program of animal care and use and an inspection of the animal facilities and husbandry practices at least every 6 months. As part of this semi-annual inspection, the IACUC observes safety issues within all laboratories that use animals. Any safety concerns are brought to the attention of (a) the investigators and research staff, (b) the Department of Laboratory Animal Research (DLAR) employees, and (c) IACUC members, as

appropriate.

3. RESPONSIBILITIES FOR REVIEW OF RESEARCH

The Research & Development Committee is responsible for reviewing all research for scientific quality and appropriateness to promote the maintenance of high scientific standards, protection of human subjects, welfare and appropriate use of animals, safety of personnel, security of research laboratory and VA data, availability of adequate resources and relevance of research to the VA's mission. These responsibilities include:

- a. Evaluating critically the quality, design, desirability, and feasibility of each new research and development proposal to assure maintenance of high scientific standards, scientific quality and appropriateness of all research involving human subjects, privacy and confidentiality, data security, the role of the investigator and the investigator's qualifications, adequate safety measures and the proper use of animals;
- b. Annually reviewing continuing research or development projects to assess the activities that have occurred, the progress of the research, and any issues that may impact the progress of the research including compliance activities. If the research involves the use of veteran's data, the review must include an assessment of the means used to protect that data.

4. PROCEDURES

- a. Applications for review, continuations, amendments, and reports of unexpected/adverse events will be submitted in the format established by the Human Investigation Committee or the Institutional Animal Care & Use Committee of Wayne State University and Research Service standard operating procedures.
- b. An initial review of projects requires a review by a convened meeting at which there is a quorum consisting of a majority of voting members.
- c. The R&D Committee may approve, approve with conditions, or disapprove a research project. The final approval of the R&D Committee may only occur after all applicable subcommittees have granted final approval. If the R&D Committee finds that it has received insufficient information to review the research, it may defer the review until all required information has been obtained.
- d. Once approved by the R&D Committee, the research becomes VA-approved research. Research may be initiated only after R&D Committee approval has been obtained.
- e. "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 protocols that are to be submitted to VA, other Federal agencies, or other entities for funding consideration must undergo a preliminary review and receive concurrence from the R&D Committee prior to submission of the protocol to VA or other Federal agencies or entities under a "Just-In-Time" procedure. Concurrence of the R&D Committee does not represent approval to conduct the research. The investigator must submit the protocol to the R&D Committee for

- f. Investigators must notify the IRB and the ACOS/R&D promptly of any serious adverse events or unanticipated problems involving risks to subjects or others, and any serious or continuing non-compliance with applicable regulatory requirements or determinations of the designated IRB of which they become aware. The IRB or the ACOS/R&D will promptly notify both the Chairperson of the R&D Committee and the Compliance Officer of any serious adverse events, unanticipated problems or issues of non-compliance.
- g. Quality assessment/improvement activities and compliance will be reviewed by the Compliance Officer in accordance with Research Service Policy. The Compliance Officer will report to the R&D Committee.
- h. Use of Investigational Drugs will be in accordance with MCNM 118-303.
- i. Use of Investigational Devices will be in accordance with Research Service Policy #7

4. REFERENCES

VHA Handbook 1200.1 dated March 2, 2007

5. RECISSIONS

Research & Development Service Policy #1, dated November 1, 2006

6. EXPIRATION DATE

January 8, 2011

Richard E. Miller, MD
ACOS/Research & Development

RESEARCH AND DEVELOPMENT COMMITTEE

1. PURPOSE

The R&D Committee is responsible, through the Chief of Staff to the Director, for maintaining high standards throughout the R&D program. These standards include those assuring the scientific quality of research projects, adequate resource allocations, protection of human subjects in research, protection of VA data and safety of personnel engaged in research. The R&D Committee advises the Director on professional and administrative aspects of the R&D Program. All R&D activities within the facility, whether funded or unfunded, are within its purview. No research may be undertaken without R&D Committee and appropriate subcommittee(s) review and approval.

2. RESPONSIBILITIES

The Research and Development Committee advises the Director on professional and administrative aspects of the research and development program. The committee exercises organizational stewardship by optimizing resources committed to research. All research and development activities within the facility, whether funded or unfunded, are within the purview of the R&D Committee. Research Policy #1, Research & Development Committee elaborates on those responsibilities.

3. MEMBERSHIP

The members of the R&D Committee are appointed by the medical center Director and must reflect the types of research being conducted at the facility. The Committee must consist of at least five voting members. The members need to have diverse backgrounds with consideration to race, gender, ethnicity, and expertise.

a. Voting members are appointed by the medical center Director in writing and serve terms of 3 years. Members may be reappointed without any lapse in time if it is deemed in the Committee's best interest. The membership consists of representatives from each of the following groups:

(1) At least two members from the VA facility's staff who have major patient care or management responsibilities.

(2) At least two members who are VA investigators actively engaged in major R&D programs or who can provide R&D expertise.

(3) In facilities affiliated with academic institutions, at least one member who holds an academic appointment, and is either a full-time Federal employee or a part-time permanent Federal employee.

b. All voting members must be compensated full-time or permanent part-time Federal employees. A voting member may fill more than one criterion for required membership, for example, the member may have both major patient care or management responsibilities and be actively engaged in major R&D programs.

2.

Medical Center Bulletin No. 10

c. Permanent ex officio (non-voting) members are the Director, Chief of Staff, Associate Chief of Staff for Research and Education, the Administrative Officer to the Associate Chief of Staff for Research and Education, Research Compliance Officer, facility Information Security Officer and the facility Privacy Officer.

d. Alternate members, if any, serve if they are formally appointed as alternate members and serve terms of three years. The roster must identify the primary member(s) for whom each alternate member may substitute. Alternate members are formally appointed in writing by the medical center Director.

e. Ad hoc members may be invited to assist the R&D Committee requiring expertise beyond that available on the Committee. Ad hoc members may not contribute to a quorum or vote.

f. 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 1 year, he may be reappointed without any lapse in time. He will preside at all regularly scheduled meetings of the Research and Development Committee and will conduct these meetings so as to accomplish the stated objectives. He/she will be responsible for the preparation of a business agenda to be completed several days prior to the meeting date, the actual compilation and preparation of which may be delegated to the Administrative Officer. When so requested by action of the committee or by consultation with the Associate Chief of Staff, he/she may form a temporary subcommittee for purposes of study and recommendation of research and development projects.

g. All members of the R&D Committee must fulfill the educational requirements specified by VHA Office of Research & Development (ORD) and other applicable Federal regulations found on ORD's website.

4. MEETINGS

The committee will meet the first Tuesday of each month at 3:00 p.m.

5. MINUTES

Minutes of meetings will be recorded, signed by the Chairperson, Associate Chief of Staff for Research, Chief of Staff and the Director as approving authority.

6. SUBCOMMITTEES

The Research and Development Committee will appoint the following subcommittees to assume specified responsibilities: Subcommittee on Research Safety and Clinical Investigation Committee.

3.
Medical Center Bulletin No. 10

7. REFERENCES

VHA Handbook 1200.1

8. RESCISSIONS

Medical Center Bulletin No. 10 dated October 2006

9. EXPIRATION DATE

February 5, 2011

Denise M. Deitzen
Acting Director

Distribution: D, H, All Dentists

Subcommittee on Research Safety (Biosafety) (SRS)

1. PURPOSE

Ensuring personnel safety in research laboratories and prescribe policies involving the use of potential hazards encountered in these settings, including, but not limited to:

- a. Biohazards, such as:
 - (1) Pathogens and/or etiologic agents corresponding to Biosafety Levels (BSL) 1-4, and
 - (2) Organisms and viruses containing recombinant deoxyribonucleic acid (DNA) molecules.
- b. Chemical hazards.
- c. Physical hazards.

2. DEFINITIONS

- a. **Biohazards.** Biohazards include, but are not limited to, the following:
 - (1) Pathogens and/or etiologic agents, human and non-human primate tissues including blood and body secretions, and human cell lines corresponding to BSL 1-4 (see subpar. 6a);
 - (2) Toxins produced by microbial organisms (see Centers for Disease Control and Prevention (CDC)-National Institutes of Health (NIH). Biosafety in Microbiological and Biomedical Laboratories 4th Edition p. 237);
 - (3) Poisonous, toxic, parasitic and venomous animals or plants;
 - (4) Recombinant DNA molecules (see subpar. 6g.);
 - (5) Select agents, as specified in Title 42 Code of Federal Regulations (see reference listed at paragraph 6.b);
 - (6) Animals experimentally or naturally exposed to any of the above (see CDC-NIH. Biosafety in Microbiological and Biomedical Laboratories 4th Edition pp. 53-75).
- b. **Chemical Hazards.** Chemical hazards include any substance or mixture of substances with properties capable of producing adverse effects on the health and/or safety of humans (see subpar. 6c(9)). Chemical hazard categories include, but are not limited to, the following:
 - (1) Corrosives;
 - (2) Toxic substances (poisons, irritants, asphyxiates);
 - (3) Sensitizers;

- (4) Carcinogens, mutagens and/or teratogens;
 - (5) Flammables; and
 - (6) Explosives.
- c. **Physical Hazards.** Physical hazards include, but are not limited to, the following (see subpar. 6c(4)):
- (1) Ionizing and non-ionizing radiation,
 - (2) Noise,
 - (3) Vibration,
 - (4) Extremes of temperature and pressure,
 - (5) Explosive hazards,
 - (6) Electrical hazards, and
 - (7) Mechanical hazards.

3. **RESPONSIBILITIES**

- a. Reviewing all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines prior to submission for R&D funding. This includes a review of all research applications for funding that will be conducted at the VA facility or by VA personnel with VA funding located off-site.
- b. Annually reviewing all active research protocols involving biological, chemical, physical, and radiation hazards, regardless of funding status or source. The date of continuing review will be based on the date of SRS approval. Research protocol changes not included in the original application must be documented on an amended RPSS (see VA Form 10-0398, App. G) and must be submitted to and reviewed by SRS prior to the implementation of the changes.
- c. Ensuring that a complete list of all products containing chemicals designated or identified by OSHA and/or EPA as “hazardous” has been submitted to the Safety Officer for review and approval prior to the submission of a protocol for local review.
- d. Medical Center Numbered Memorandum 001F-154 states that Service Chiefs are responsible for “Establishment of a Service Safety Subcommittee within their services comprised of not less than five (5) members with representation of all sections within the service.” This subcommittee is required to:
 - (1) Investigate and analyze accidents and fires occurring within the service they represent and report their findings and recommendations in monthly minutes.
 - (2) Study and recommend to the HLC on Coordination of the Environment of Care (Safety Committee), ways and means of improving safety and fire protection within the organization and establishing safe work practices.

(3) Perform safety inspections, review employee injuries, and provide safety training.

This subcommittee will be a subcommittee of the SRS and will report to the SRS who in turn will report to the R&D Committee.

- e. The Research Service Safety Committee, through the SRS, will be responsible for:
 - (1) Coordinating follow-up evaluations to ensure that deficiencies cited during inspections are permanently and effectively abated, and
 - (2) Reporting follow-up results to the R&D Committee.
 - (3) Reporting operational problems or violations of directives to the Research Safety Coordinator and the Research Office within 30 days of occurrence or detection, unless SRS determines that a report has been previously filed by the PI.
 - (4) Ensuring that all laboratory personnel receive annual research specific safety training
 - (5) Annually evaluating the effectiveness of the laboratory's Chemical Hygiene Plan and making necessary revisions.
 - (6) Ensuring the proper reporting of injury and illness trends to the R&D Committee, as appropriate, and ensuring the review of investigation reports of all lost-time injuries and all significant adverse environmental events.
- f. Identifying the need for health surveillance of personnel involved in individual research projects; and if appropriate, advising R&D Committee and Employee Health Practitioner on the need for such surveillance.
- g. Ensuring the collection of appropriate personnel samples to make employee exposure determinations whenever the proposed use of laboratory chemicals may potentially exceed OSHA Permissible Exposure Limits or Action Levels.

4. PROCEDURES

- a. All research projects involving biological, chemical, physical, and radiation hazards must be approved by SRS and then by the R&D Committee prior to commencement. SRS must review proposed research at convened meetings at which a quorum (majority of voting members) is present. **NOTE:** *In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting. A quorum must be maintained for each vote to occur. If a quorum is not maintained, the protocol must be tabled and only non-protocol related issues may be discussed.*
- b. The review of the Research Protocol Safety Survey (RPSS) (see VA Form 10-0398) must include a risk assessment of the facilities, level of containment, laboratory procedures, practices, training and expertise of personnel involved in the specific research conducted including recombinant DNA research.

- c. The SRS will provide written notification of the results of SRS review to the R&D Committee, the Research Office, and the PI.
- d. The SRS will maintain adequate documentation of all SRS or equivalent subcommittee activities and will forward minutes to the Research Office.

5. REFERENCES

VHA Handbook 1200.8, dated June 7, 2002

6. RECISSIONS

Research Service Policy #5, dated 11/1/06

7. EXPIRATION DATE

January 8, 2011

Richard E. Miller, MD
ACOS, Research & Development

Policies and procedures cannot possibly address all situations. Please make sure that you exercise good judgment and common sense. Remember that patient needs always come first.

CONTROLLED SUBSTANCES IN RESEARCH

1. PURPOSE

Due to their abuse potential, scientists using items identified by the US Department of Justice, Drug Enforcement Administration (DEA) or the Department of Veterans Affairs Veterans Health Administration (VHA) as controlled substances must adhere to extensive licensing, registration, storage, security, use, and disposal regulations.

2. POLICY

Principal Investigators (PIs) using controlled substances in their laboratory research (including research animals) are subject to federal regulatory requirements, as outlined in this Policy. Please note that these requirements (including licensing/registration with regulatory agencies) are separate from and in addition to any that apply to medical practitioners (i.e., MDs and MD/PhDs conducting laboratory research must also obtain licensure/registration for laboratory use of controlled substances). Researchers planning work with controlled substances must be aware of and comply with federal statutes and regulations for these materials.

This policy covers materials containing any quantity of a substance with a stimulant, depressant, or hallucinogenic effect on the higher functions of the central nervous system, and having the tendency to promote abuse or physiological or psychological dependence, as designated in federal controlled substance schedules and policies. Controlled substances may only be used for duly authorized, legitimate medical or scientific research purposes, to the extent permitted by a registrant's license and registration, and in conformity with federal statutes and regulations.

3. RESPONSIBILITIES

a. The Medical Center Director is charged with the authorization of Principal Investigators to conduct research with controlled substances. Every Principal Investigator seeking to use a controlled substance in a research study must be authorized by the Medical Center Director. The Administrative Officer for Research & Development (R&D) Service will assist in acquiring authorization.

b. ACOS Research or the Administrative Officer Research (designee) is responsible for:

(1) Establishing policies and procedures for the use of controlled substances in research.

(2) Serving as the primary contact for the Controlled Substance Program Coordinator for the monitoring and reporting of the Controlled Substance Program within

2.

R&D

(3) Providing Pharmacy Service with a copy of the approved research protocol and a listing of authorized users approved by the Director for that protocol.

(4) Reporting any loss, theft, unauthorized use or other violation of federal law pertaining to controlled substances within Research to the Director.

c. The Principal Investigator is responsible for:

(1) Adhering to federal regulatory requirements when working with controlled substances. Every Principal Investigator must be authorized to conduct research with controlled substances.

(2) Authorizing members of their laboratory staff to work with controlled substances, provided staff have passed the required background checks that are initiated by the Research administrative office and sent to Human Resource Management Service. Principal Investigators are responsible for submitting a list of authorized users in each lab to the Administrative Officer of R&D Service.

(3) Principal Investigators, Research Assistants, Lab Technicians and any other person previously convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, revoked, or surrendered may not be authorized for work with these materials. New employees will be screened and checked for offenses prior to being authorized access to controlled substances. Authorized staff must follow all of the rules and regulations outlined here, and are also obliged by law to immediately report any loss or diversion of controlled substances to their PI and ACOSResearch.

d. The Medical Center Controlled Substance Program coordinator will review monthly inspections of the controlled substances. The controlled substance inventory form will confirm compliance with the program and regulatory requirements. The ACOS Research or his/her representative will be immediately notified if discrepancies are found in controlled substance inventory. After one working day, unresolved discrepancies will be reported per medical center policy.

e. The Chief, Pharmacy Service serves as a consultant to the ACOS/R&D Service for establishing policies and procedures for controlled substance usage that conforms to federal regulations and policy to ensure the licensure, purchasing, storage, security, use, recordkeeping and disposal of controlled substances meet federal and VHA requirements. Pharmacy Service will order, receive, distribute and arrange for destruction all Schedule II–V controlled substances used in Research.

4. PROCEDURES

a. Purchasing/Ordering Controlled Substances

(1) All Controlled substances used in the Medical Center must be coordinated by the Pharmacy Service.

3.

(2) Pharmacy Service will be responsible for ordering and purchasing all Schedule II through V controlled substances using standard Pharmacy purchasing procedures.

(3) Controlled Substance Order forms will be brought or sent to the Pharmacy Office.

(4) Pharmacy Service will order the drug by the close of business on the next business day after receipt of order request.

(5) Controlled substances in Schedules II through V will be delivered to the Pharmacy. Pharmacy will notify the investigator when the controlled substances arrive and arrange for the investigator or authorized user to pick up the item.

b. Storage and Security Controls

(1) Controlled substances possessed, kept, or otherwise stored in a manner or location not in compliance with state or federal law are subject to seizure and forfeiture. Failure to comply with applicable requirements may also result in a suspension of purchasing privileges and a ban on the use of controlled substances in future experiments conducted at the Detroit VA.

(2) In order to guard against theft or diversion, all controlled substances - regardless of schedule - must be kept under double lock, and accessible only to authorized personnel. The number of authorized staff must be kept to the minimum essential for efficient operation, and the stocks of controlled substances to the smallest quantity needed.

(3) All controlled substances must be stored in a refrigerator or locked cabinet. Regardless of schedule, all controlled substances must be kept locked in their storage location except for the actual time required for authorized staff to remove, legitimately work with, and replace them.

c. Recordkeeping

PIs must maintain complete and accurate inventory records for all controlled substances on Research Service controlled substance inventory form (Appendix A). These records must be kept separate from all other records and documents, in or near the primary work area, and available for inspection during regular work hours. The use of codes, symbols, or foreign languages in identifying a controlled substance or person in the record is prohibited. In the event that any controlled substances are lost, destroyed, or stolen, the kind and quantity of the material and the date of discovery of such loss must be recorded in detail. **A loss of the controlled substance inventory form is considered a loss of a controlled substance.** After use is completed, the inventory form must be returned to Pharmacy for review.

(1) Receipt of Controlled Substance: Only those staff listed as authorized users by the PI form may receive controlled substances from the pharmacy.

(2) Use of Controlled Substances: All use of controlled substances will be noted on the

4.

controlled substance inventory as a perpetual inventory of each dispensed item. Each time a controlled substance is removed for an experiment, the PI must record the date, time, describe the use, and the volume removed. The PI must also verify that the remainder is correct. If there is a discrepancy, it must be reported immediately to the ACOS/Research, Pharmacy and the Controlled Substance Program Coordinator.

(3) Inventory of Controlled Substances: The Medical Center Controlled Substance Program coordinator, will perform monthly unannounced inspections of the controlled substances. If the investigator or designee is unavailable for the inspection the Medical Center Controlled Substance Program Coordinator will contact the Administrative Officer of R&D Service to arrange for the inspection. Entries on the controlled inventory form will confirm compliance with the program and regulatory requirements. The ACOS Research or his/her designee will be immediately notified if discrepancies are found in the controlled substance inventory. After one working day, unresolved discrepancies will be reported per medical center policy.

d. Disposal

Expired material or unused product for all Schedules II through V must be returned to the Pharmacy. The Principal Investigator or authorized designee will contact the Pharmacy when drug is expired, there is product that must be wasted or when the drug is no longer needed. The controlled substances submitted for disposal must contain the following information to be received for processing and disposal: all units must be appropriately labeled with contents, strength, quantity, Principal Investigator, laboratory name and location. The Pharmacy will prepare a return receipt for signature by the authorized person (Lab Technician, Research Assistant) submitting the material. A copy of this form will be given to the person returning the material. This form should be kept until after the next Medical Center Controlled Substance Inspection for documentation of return.

e. Reporting of Loss, Destruction, Theft, or Unauthorized Use

Thefts, suspected thefts, unauthorized uses, or other losses of any controlled substance must be reported to the ACOS Research immediately upon discovery. Principal Investigators must also document the incident in writing for submittal to the DEA within 72 hours. The written statement must describe the kinds and quantities of controlled substances, and the specific circumstances involved. Where the controlled substances are stolen, lost, or destroyed in transit, the consignee will also be required to prepare a similar report and include documentary evidence that local authorities were notified. The registrant should retain a copy of the statement.

f. Accepting Controlled Substances from Collaborators

Investigators wishing to accept controlled substances from collaborators must coordinate the transfer with Pharmacy Service. Advance notice of the transfer must be given. The controlled substances may not be delivered to the PIs laboratory. It must be delivered to the Pharmacy. All other aspects of the policy described here will apply.

5.

6. RESOURCES

Administrative Officer, R&D	Ext. 3106
Controlled Substance Coordinator	Ext. 3512
Pharmacy	Ext. 3233
Police Service – Officer on Duty	Ext. 3375

7. REFERENCES

Manual M-2, Part VII, Pharmacy Service
VHA Handbook 1108.1, Controlled Substances (Pharmacy Stock)
VHA Handbook 1200.7, Use of Animals in Research
MCNM 118-302, The Inspection Of Controlled Substances, Precious Metals, and VA Form
10-2577F – Controlled Substance Prescription Pads

8. RESCISSIONS

None

9. EXPIRATION DATE

November 16, 2008

Michael K. Wheeler
Director

**Research & Development Service
SOP#2**

**PROCEDURE TO REQUEST CONTROLLED SUBSTANCES
FOR ANIMAL RESEARCH**

This SOP is to establish procedures to implement and enforce MCNM 11R-3 “Controlled Substances in Research”.

PROCEDURES:

1. *Controlled Drug Authorization - - Animal Use Form* (attached) is to be completed by the Principal Investigator (PI). The form must list all of the controlled drugs that appear in the approved protocol(s) as well as technicians approved to assist on this protocol. This form will be signed by the ACOS/R&D or designee.
2. When a controlled substance is needed, an individual listed on the Controlled Drug Authorization can report to the inpatient pharmacy window (LL100) between the hours of 7:30 am and 3:30 pm. He/she will sign for receipt of the controlled substances and receive a Controlled Substance Log.
3. Once the controlled substances are obtained, they must be kept in a locked cabinet. The Controlled Substance Log must be kept near the controlled substances always documenting an accurate current inventory of each of the controlled substances. A separate log must be kept for each controlled substance.
4. Each month, police inspectors will make an unannounced visit to all areas stocking controlled substances to account for all controlled substances that were dispensed by pharmacy and to check the current inventory and that all doses have been documented on the Controlled Substance Log. Completed Controlled Substance Logs with an inventory balance of zero should be given to the Administrative Officer for Research who will return them to pharmacy.

**CONTROLLED DRUG AUTHORIZATION – ANIMAL USE
 Research Service**

PRINCIPAL INVESTIGATOR		RESPONSIBLE VA CLINICIAN (IF APPLICABLE)	
NAME OF PROJECT (s)			PROTOCOL #
<input type="checkbox"/> Pending	<input type="checkbox"/> Approved	Date Approved:	Expiration
<input type="checkbox"/> Pending	<input type="checkbox"/> Approved	Date Approved:	Expiration
<input type="checkbox"/> Pending	<input type="checkbox"/> Approved	Date Approved:	Expiration
Authorized Drug (s):			
<p>I hereby authorize the following DVAMC staff to assist me in the study named above and to sign prescriptions or orders for study drugs to be dispensed from the DVAMC Research Pharmacy Service. <u>Their signature below indicates their familiarity with the protocol and the study medications required by the protocol.</u></p>			
Printed Name		Signature	
<p>I certify that the study medications will be administered under my supervision or under the supervision of the above-named Co-investigators responsible to me, and that these medications will not be supplied to any other investigator. I certify that each of these individuals has been appropriately credentialed by the DVAMC to perform such duties and have completed the animal protection education requirements necessary for participating on DVAMC approved research projects.</p>			
Room #			
PRINCIPAL INVESTIGATOR			Date
RESPONSIBLE VA CLINICIAN (if applicable)			Date
ACOS/R&D OR DESIGNEE			Date

Policies and procedures cannot possibly address all situations. Please make sure that you exercise good judgment and common sense. Remember that patient needs always come first.

**OCCUPATIONAL HEALTH AND SAFETY PLAN FOR RESEARCH PERSONNEL
WITH ANIMAL CONTACT**

1. PURPOSE

The purpose of the Occupational Health and Safety Plan is to ensure health and safety awareness and protection and intervention for people who have contact with research animals. The plan also ensures compliance with federal regulations (e.g. OSHA, EEOC) and state regulations (e.g. MDPH, MIOSHA), and recognizes and abides by professionally developed standards established by select organizations that may apply to institutions performing research involving the use of animals.

2. RESPONSIBILITIES

a. The Medical Center Director, as the Institutional Official (IO) is responsible for ensuring that the animal research program has the resources and support necessary to comply with all federal regulations and guidelines that govern animal research and protection of personnel involved in animal research. The IO is the point of contact for correspondence addressing animal research with the United States Department of Agriculture (USDA), the Public Health Service (PHS), and the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). However, because this VA Medical Center uses the affiliate's (Wayne State University) Public Health Service (PHS) Assurance, the Director of Laboratory Animal Research assumes the role of the IO for PHS correspondence to comply with PHS Policy.

b. The ACOS/R&D is responsible for ensuring proper oversight and care of all research animals housed on VA property, as well as research animals purchased with VA funds, no matter where they are housed. He/she is also responsible for developing and implementing a program for personal hygiene, protective safety measures, safe use of hazardous materials, and preventive medicine for personnel engaged in the care and use of research animals.

c. The Institutional Animal Care and Use Committee (IACUC) is responsible for performing the review and oversight functions required by PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, the Animal Welfare Act, the USDA Animal Welfare Act Regulations and Standards, the requirements in VA Handbook 1200.7, and any other federal regulations that impact IACUC function. The IACUC is also responsible for performing a self-assessment review of the program of animal care and use and an inspection of the animal facilities and husbandry practices at least every 6 months. As part of this semi-annual inspection, the IACUC observes safety issues within all laboratories that use animals. The John D. Dingell VA Medical Center utilizes the Wayne State University IACUC. Any concerns are brought to the attention of (a) the investigators and research staff, (b) the Division of Laboratory Animal Resources (DLAR) employees, or (c) IACUC members, as appropriate.

2. Medical Center Numbered Memo 11R-2

d. The Division of Laboratory Animal Resources (DLAR) operates the animal housing sites on campus and procures all research animals. DLAR is responsible for maintaining a safe working environment for employees and students within the animal facility. DLAR is also responsible for providing education and training to personnel on the care and use of animals in research and teaching, including safe animal handling techniques.

e. Employee Health Physician conducts pre-employment physical examinations, orders appropriate tests, reports results, maintains medical records, conducts an annual review of workers with animal contact to detect problems in the early stage and ensure that required immunizations are current and identifies those employees who are adversely affected by hazard exposure and takes appropriate action.

f. Investigators are responsible for identifying occupational hazards, minimizing risk in their work environment, ensuring compliance with program requirements, and ensuring that all of their employees using animals have been properly trained and equipped to perform their job duties safely. Training involves both initial and annual training requirements in safety and animal care issues.

g. Animal Contact Personnel are responsible for identifying and reporting unsafe working conditions to their supervisor or principal investigator, complying with occupational health requirements (e.g. health and risk assessments), and complying with all other institutional health and safety policies and procedures.

3. SCOPE

a. All personnel need to participate in the Preventive Medicine Program if they have exposure to animals or parts of animals. A determination of what constitutes animal contact needs to include consideration of such factors as animal species, microbiological status of the animals, and frequency of animal contact. Commercially bred virus antibody free rodents pose significantly less infectious disease risk than primates, ruminants, dogs, cats, and other animal species in which the microbiologic status is unknown.

(1) **Basic Program Content.** Key elements of a preventive medicine program for employees with animal contact includes:

(a) Medical Evaluation. A pre-employment physical exam is conducted to ensure that a prospective new employee is capable of the physical demands of the position.

(b) Medical History. A medical history of each employee which includes a record of allergies, immunizations, immunosuppressive diseases or the use of immunosuppressive medicaments, and physical limitations needs to be taken and held on file.

(c) Periodic Post-employment Survey. An annual survey of workers with animal contact to detect problems in the early stage and ensure that required immunizations are current. This evaluation is in the form of a questionnaire.

3. Medical Center Numbered Memo 11R-2

(d) Occupational Safety Training. Personnel who have contact with experimental animals receive training in the proper handling of the animals with which they will work. Personnel are instructed to avoid unnecessary risk when working with animals, and to seek expert assistance when in doubt. Training includes the use of protective clothing, equipment, and hygiene practices. Personnel receive annual training in Universal Precautions, where applicable.

(2) Reporting Injuries and Illness. Injuries, animal bites, animal scratches, and cuts sustained in the animal facility or research laboratory are reported promptly to the employee's supervisor. The employee will be referred to the Employee Health Physician, and VA Form 2162, Report of Accident, will be completed.

(3) Personal Hygiene. An important factor in protecting the health of personnel engaged in animal care or research is personal hygiene. All employees need to understand the importance of personal hygiene and specific measures that are to be taken routinely to protect themselves against zoonotic agents found naturally in experimental animals as well as hazardous agents used experimentally in approved biomedical studies using animals. Hand washing is a crucial safety measure for safeguarding personnel in the animal facility. Although the proper use of disposable gloves provides an effective means of preventing hand contamination, hands can easily become contaminated during the removal of contaminated gloves.

(4) Protective Clothing and Disposable Items. Protective clothing is provided to employees, as appropriate, and the employees are required to wear it. Disposable protective items such as gloves, masks, and head and foot covers, and gowns or other body cover are to be provided when use of these items is required. Protective clothing may not be taken away from the work site. Outer garments worn in the animal facility or other animal use areas should not be worn in human patient care areas.

(a) Hearing Protection. The noise level in animal facility areas may reach potentially damaging levels, particularly in cage washing areas and dog housing rooms. Ear protection will be provided whenever noise levels exceed those permissible levels established by the Occupation Safety and Health Administration (OSHA) regulations or whenever requested by an employee. The animal facility supervisor will assume responsibility for ensuring the appropriate use of ear protection.

(b) Eye Protection. Protective eyewear should be used by employees who handle corrosive or otherwise dangerous liquids or vapors. Goggles or other devices that completely shield the eyes will be provided by the medical center.

(c) Other Precautions. Personnel should be trained to avoid hand contact with their eyes, face, mouth, or other body surfaces with contaminated gloves or hands.

(d) Special Circumstances. Special equipment and clothing may be required when personnel are engaged in studies that involve hazardous agents. The specific measures needed are to be appropriate for the agents used, as determined by the Safety Officer in consultation with the investigator and the Veterinary Medical Officer (VMO).

4. Medical Center Numbered Memo 11R-2

(5) **Smoking, Eating, Drinking, and Cosmetic Application.** Smoking, eating, applying cosmetics, installing contact lenses and similar procedures are prohibited within the animal facility or in animal study areas except in designated areas that are free of potentially contaminated materials. Employee food and beverages should be stored only in refrigerators and/or freezers designated exclusively for such use.

(6) **Hazardous Agents**

Safety in VA research laboratories is the responsibility of the VA Subcommittee on Research Safety (SRS). These responsibilities include inspections, training, investigation, documentation, and safety program review. (Refer to the Research Laboratory Safety Manual and Chemical Hygiene Plan.) Additional safety measures may be needed to protect personnel who use or work in the animal facility when research involving biological, chemical, or radiological agents is being conducted. The specific measures needed are dependent on the risk to human and animal health represented by the agent, and the difficulty involved in containing the agent.

(a) **Procedure:**

1 Before experimental animals are treated with any hazardous agent, an approved copy of the Animal Component of Research Protocol (ACORP), with the signature of the Safety Officer needs to be on file in the Research Office. The signature of the Safety Officer indicates that written instruction on handling the animals, caging, and animal wastes are available.

2 These instructions are to be prepared for the husbandry staff by the VMO with assistance from the principal investigator and the Safety Officer. Instructions should be placed in a waterproof pouch that can withstand exposure to water and disinfectants, then posted outside the animal room where they are readily visible for the duration of the experiments.

3 Personnel who work with animals exposed to hazardous agents are to be trained in proper procedures to work with the animals and related waste and equipment. Training should be provided in accordance with the safety program established by the VA SRS. Documentation of such training needs to be made before employees manipulate experimental animals treated with hazardous agents.

(7) **Biological Agents.** The Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) handbook, Biosafety in Microbiological and Biomedical Laboratories, describes the minimum containment requirements that are to be followed when microbial pathogens are used in the laboratory and in the animal facility. A copy of the most recent edition of this manual should be available in the local Research Office. Contact the CDC Office of Safety, (404) 639-2173, for information on how to obtain a copy of the manual.

(8) **Universal Precautions.** Universal Precautions is an approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious

5. Medical Center Numbered Memo 11R-2

for Human Immunodeficiency Virus (HIV), Herpes B Virus (HBV), and other bloodborne pathogens. Intended primarily for personnel working directly with human blood components, other body fluids and excreta, and unfixed tissues, Universal Precautions is relevant to all personnel working with potentially infectious materials in animal studies. Personnel working with animals treated with such materials should receive annual training in Universal Precautions to comply with the Bloodborne Pathogen Standard.

(9) **Chemical Agents and the Material Safety Data Sheet**

(a) Although all chemicals and drugs are potentially dangerous, special concern is necessary when working with known carcinogens, mutagens, immunosuppressive agents, toxic drugs, potent steroids, agents of unknown pharmacological activity, and other chemicals listed as hazardous waste by the Environmental Protection Agency (EPA).

(b) All chemical agents purchased commercially are to have a Material Safety Data Sheet (MSDS) that accompanies the shipment of the chemical. Purchasing offices should forward the MSDS immediately to the Research Office from where it should be distributed to the using investigator and the animal facility. The animal facility should maintain an MSDS logbook.

(10) **Radioactive Agents**. The safety principles for work with radionuclides are similar to those for work with other hazardous agents with some important additions:

(a) The Radiation Safety Officer is to review and approve, or require specific procedures that are to be followed when using radionuclides in animals.

(b) Personnel working with radionuclides are to be trained specifically for work with these materials.

(c) All acquisition and disposition of radionuclides are to be in accordance with the Nuclear Regulatory Commission (NRC) regulations covering these materials.

4. **GENERAL SAFETY CONSIDERATIONS**

a. New employees will receive service specific training and orientation beginning on the first day of work in Research Service. Each staff member must be trained in job-specific safety issues at the start of their assignment, when duties change and annually thereafter.

b. It is the responsibility of all employees to follow good safety practices common to all laboratory operations. Each staff member must read the research safety manual and sign and date a statement attesting to the fact that the individual has read, understands and will adhere to safety policy set forth in the manual. This must be done on an annual basis.

c. Refresher safety training will be conducted bi-monthly and all employees are expected to attend.

6. Medical Center Numbered Memo 11R-2

d. All employees are expected to complete assigned Learning Management System (LMS) classes.

e. All employees will receive training on new equipment or current equipment and procedures on an as needed basis. Each PI must ensure that each staff member is trained in the appropriate care, use and maintenance (if applicable) of each instrument the staff member will use. If required, assistance in equipment training is available through the Research Office.

5. **REFERENCES**

VHA Handbook 1200.7

Wayne State University Animal Contact Occupational Health and Safety Program
Guidelines

Research Laboratory Safety Manual and Chemical Hygiene Plan

6. **REVISIONS**

Occupational Health & Safety Plan for Research Personnel With Animal Contact (11R-2),
dated 5/2/03

7. **EXPIRATION DATE**

May 9, 2010

Michael K. Wheeler
Director

Distribution: D, H



John D. Dingell VA Medical Center

Procedures for Hiring VA Paid Research Positions

Temporary employees (employed less than one year with no benefits):

1. Provide OF-612 (application) and/or curriculum vitae and OF306 with a short job description (one paragraph) or functional statement and requested date of hire, at least two weeks prior to the requested date of hire to the Research Administration Office.
2. Human Resources will determine if the employee meets the qualifications for the requested position and will schedule the employee for a physical, if necessary. Once the results of the physical are received, Human Resources will contact the employee regarding the start date.
3. New employees are required to attend New Employee Orientation. When NEO is completed, they will report to the Research Office and receive a copy of their position description and performance standards and will then report to the PI for in-service training.

Term Appointments (employed more than one year – up to 4 years; eligible for benefits)

1. Classified position description – proceed to 3;
2. Unclassified position description – provide two to three paragraph description of duties to Research Administration office. A position description will be prepared and classified, which assigns the grade level which determines the salary.
3. Provide OF-612 (application) and/or curriculum vitae and OF306. The position normally will be announced using the VA Delegated Examining Unit, a process which takes approximately two weeks to post the vacancy, three weeks for accepting applications; and two weeks to process the final certificate of potential candidates.
4. Once the certificate is received and a candidate selected, Human Resources will set up a physical, if necessary and notify the candidate of a start date.
5. The employee will be required to attend New Employee Orientation as described above. They will receive a copy of their position description and performance standards from the Research Office and will then report to the PI for in-service training.

Schedule B employees (employees GS-11 and above)

1. Classified position description – proceed to 3;
2. Unclassified position description – provide two to three paragraph description of duties to Research Administration office. A position description will be prepared and classified, which assigns the grade level which determines the salary.

3. Provide OF-612 (application) and/or curriculum vitae and OF306. Human Resources will set up a physical and notify the candidate of a start date.
4. The employee will be required to attend New Employee Orientation as described above. They will receive a copy of their position description and performance standards from the Research Office and will then report to the PI for in-service training.

Salary Guidelines for Entry Level R&D Personnel 2006

Position Title	Level of Responsibility	Education* & Experience	GS Level & Salary Range
Research Technician	Requires close supervision in performing standardized assignments. Performs functions such as glassware washing and/or observing scientific techniques.	High School No Experience	GS-2 to GS-4 \$22,246 to \$27,248
Research Assistant I	Requires close supervision in performing standardized routine tests. Collects and analyzes data, and prepares reports. Some innovation and problem solving required.	Bachelor's Degree No Experience	GS-4 to GS-5 \$27,248 To \$30,486
Research Assistant II	Receives occasional supervision in performing standardized routine tests. Collects and analyzes data, and prepares reports. Innovation and problem solving required. Provides some experiment design.	Bachelor's Degree 1 year or lab courses in college	GS-5 to GS-7 \$30,486 to \$37,763
Senior Research Assistant	Receives minimal supervision. Performs tests, collects and analyzes data and prepares work reports. Innovation and problem solving required. Able to provide design of experiments to achieve project objectives.	BS Degree w/courses in field of research 3 years Experience	GS-7 to GS-9 \$37,763 to \$46,192
Research Associate	Receives minimal supervision. Exercises judgment, creativity, solves problems, takes independent action. Assists in experimental design & responsible for specific phases of projects. Supervises & trains junior staff.	Masters Degree w/ courses in field of research 5 years Experience	GS-9 to GS-11 \$46,192 to \$55,889
Senior Research Associate	Research Associate qualification plus ability to write grant applications to major funding agencies such as VA Merit Review or NIH.	Doctor's Degree in field of research 5 years Experience	GS-11 to GS-13 \$55,889 to \$79,657
Research Coordinator	Requires some supervision but can assume independent actions and responsibilities to relieve executives. Handles finances, manuscripts and grants.	Experience or Bachelor's Degree With no or some Experience	GS-4 to GS-7 \$27,248 to \$37,763
RN Study Coordinator	Provides data analysis, prepares patient data forms, consents patients, monitors vital signs, and performs procedures within scope of duty.	RN W/ 2-4 YR Degree 1 Year Experience	Nurse 01, level 2 or 3 \$46,985 to \$52,400
NP Study Coordinator	Provides data analysis, prepares patient data forms, consents patients, monitors vital signs, performs physical exams, and performs procedures within scope of duty.	Nurse Practitioner Degree 1 Year Experience	NP Level I/II \$50,300 to \$57,900
Statistician	Analyzes data independently and provides an assessment of data as it relates to trends and statistical significance. Ability to organize data according to scientific requirements.	Bachelors or Masters Degree/Statistics 3 Years Experience	GS-9 to GS-11 \$46,192 to \$55,889

*Equivalent experience may substitute for the degree requirements at 2 years of experience for 1-year college education.

WITHOUT-COMPENSATION (WOC) EMPLOYEES

WOCs are persons working at the VA facility whose salary comes from the University or other independent funding or unpaid students volunteering as a requirement to do laboratory research for coursework credit. A WOC appointment allows these people to legally work at the VA facility and, in cases of emergency such as injury or sickness related to their work, would entitle them to emergency medical care at the VA. A WOC application and all other necessary forms can be obtained from the Research Office (VA Medical Center, Room B4270) or at www.va.gov/detroitresearch.

A WOC EMPLOYEE CANNOT BEGIN WORK AT THE VA PRIOR TO RECEIVING APPROVAL FROM HUMAN RESOURCES.

The following forms should be completed and submitted for all WOC employees.

- WOC application
- I-9 with appropriate documentation if non-citizen
- OF-612, Application or copy of CV or Resume
- OF-306, Declaration of Federal Employment
- Fingerprint request form

Packets should be completed with the assistance of the Principal Investigator and then returned to Research. The PI will also instruct the WOC on appropriate lab safety and verify competency to perform required duties. These packets will then be forwarded to Human Resources. If the appointment is for over six months, you will be notified by email from HR that you need to complete a SF-85, Questionnaire for Non-sensitive Position on-line. After completion of the SF-85 and appropriate review and signature by the Chief of Resources, the WOC will be notified that the appointment has been approved. The WOC will pick up the appropriate paperwork in Research and may then secure a VA badge from Police & Security. Police & Security must see two pieces of photo ID in order to issue a VA badge. A WOC appointment must be renewed annually. If a WOC leave his/her VA appointment, he/she must return the badge. WOCs may not be issued keys. The PI must sign for, and is liable for, any keys. When leaving VA employment, you must notify the Research Office and return your badge.

HUMAN RESEARCH PARTICIPANT STUDIES

All staff involved in the conduct of Human Research Studies at the Detroit VAMC, directly or indirectly, must be credentialed. These are the additional forms necessary for credentialing. Should you have specific questions regarding these documents, please contact the Research Office at 313-576-1000, x63430. A resident with a VA badge must complete the training listed below and Resident/WOC application form.

- Scope of Practice (instructions below)
- Copy of Professional License (if applicable)

Instructions for completion of Scope of Practice Form:

1. Name: Employee's / Research Coordinator's full name and title.
2. Service Line: (i.e. Oncology, Mental Health, Cardiology, etc.)
3. Principal Investigator / Supervisor: Listed in the study protocol as responsible for all study activities and the immediate supervisor of the employee.
4. Secondary Supervisor: Co-investigator assuming responsibility for study activities and may supervise employee.
5. Routine Duties: Duties /procedures employee is authorized to perform.

Requested - This should be initialed by employee to verify understanding and willingness to perform procedure, granted or not granted by PI.

Granted - Initialed by PI, if the procedure is to be performed by employee.

Not Granted - Initialed by PI if procedure is not to be performed by employee.

6. Miscellaneous Procedures / Duties: PI / Supervisor should disclose any additional duties / procedures to be performed by employee, not previously listed.
7. PI Statement: Enter employee's name and date.
8. Signature Blocks: PI, secondary supervisor (if applicable), and employee should sign and date where indicated. Other signatures will be obtained by research administration.

TRAINING REQUIREMENTS

All research personnel are required to complete four on-line training courses.

- VHA Privacy Policy and VHA Cyber Security training <https://www.ees-learning.net/librix/loginhtml.asp?v=librix>
- VA Research Data Security & Privacy training <http://www.vcampus.com/vcekpvalo/>
- VA Biosecurity training at <http://www.research.va.gov/programs/biosafety/default.cfm>

All research personnel involved in human subject research are also required to complete:

- Responsible Conduct in Research - Wayne State University's on-line training program available at <http://www.rcr.wayne.edu/>
- Good Clinical Practice and Human Subject Protection – annual requirement. *Overview of Good Clinical Practice & Human Subjects* and the *Good Clinical Practice – Update* courses are available through [Collaborative IRB Training Initiatives \(CITI\)](#). The VA Office of Research & Development (ORD) will accept the completion of the CITI group called "VA Only" (see below). NOTE: You can find all options for fulfilling VA human research training requirements at <http://www1.va.gov/resdev/programs/pride/training/options.cfm>

GCP and Human Subjects Protection Training Through CITI

<https://www.citiprogram.org/default.asp>

In collaboration with CITI, VA is providing three CITI curriculum groups that satisfy the annual requirement for training in both Good Clinical Practice and ethical principles of human research protection.

1. **VA Only:** Choose this group if you only need to take the nine VA GRP/GCP modules to satisfy minimum annual requirement for training in both Good Clinical Practice and ethical principles of human research protection. In this group, you will satisfy VA but not CITI minimum requirements for training.
2. **VA GCP plus CITI Biomedical Research Training:** Choose this group if you want to satisfy VA AND CITI training requirements for staff involved in biomedical studies involving human subjects. Biomedical studies include those involving drug and device studies and trials.
3. **VA GCP plus CITI Social/Behavioral Research Training:** Choose this group if you want to satisfy VA AND CITI training requirements for staff involved in social or behavioral studies involving human subjects.

Note: To have access to these groups, you must register as a member of the John D. Dingell VA Medical Center on the CITI site. You will not see these groups when registered on the CITI site with your affiliate unless your affiliate has agreed to allow access to the to VA GRP/GCP modules.

Very Important! If your affiliate university requires CITI training, we encourage you to check with your IRB or research office to make sure that you can take all required university and VA modules at the same time. If you do not currently have access to the VA modules when registered on the CITI site through your affiliate, please ask your VA research office or IRB coordinator to contact us, and we will be happy to try to arrange such access. Otherwise, to gain access to the VA modules, you will have to register a second time (second username and password) with CITI and choose your local VA station as your institution as part of the registration process. This will allow you to gain access to the VA modules by choosing one of the three groups described above.

If you have any questions about registering, please send an email to michael.fallon@med.va.gov.