



Department of Veterans Affairs
Jesse Brown VA Medical Center
Research and Development (537/151)

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Standard Operating Procedures

Title: R&D SOP

Version: Revised Version 3.3

Effective Date: March 10, 2008

Approved by:

Israel Rubinstein, M.D.,
Chairman, R&D Committee

4-14-08

Date

Joseph DeSimone, Ph.D.
ACOS for R&D

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Date

Wendy Weinstock Brown, M.D. MPH
Chief of Staff

4/17/08

Date

James S. Jones
Medical Center Director

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820 S. Damen Avenue
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March 10, 2008
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Standard of Operating Procedures For Research & Development Committee and Subcommittees at the Jesse Brown VA Medical Center (JBVAMC)

PURPOSE:

To describe the structure, responsibilities, and functions of the Research and Development (R&D) Committee and Subcommittees.

POLICY:

- A. The R&D Committee at Jesse Brown VA Medical Center is governed by the Federal Policy codified in VHA Handbook 1200.1. These standards are for all research activity within the Jesse Brown VA Medical Center. The standards include those concerning the scientific quality of research and development projects, protection of human rights, laboratory safety, and welfare of animal subjects used in research and development and financial oversight of Research Service. To stimulate a high-quality research program that is responsive to investigators and that maintains compliance with all applicable regulations.
- B. The primary function of the Research and Development Committee is to assure continuous quality within the Jesse Brown VA Medical Center Research and Development (R&D) Programs by:
 - (1) Critically evaluating the quality, design, desirability, and feasibility of each new and continuing research and development application for all research projects or awards programs that involve human subjects, laboratory procedures or animal experimentation. All research and development activities, whether funded or unfunded by the VA or other sources, are within its purview.
 - (2) Providing oversight of programs and reporting activities to assure maintenance of high scientific standards, protection of human subjects, adequate safety measures, safety data monitoring during research, proper use of animals and fiscal responsibility.
 - (3) Planning and developing broad objectives of the R&D so that it supports the patient care mission of the facility.
 - (4) Recommending policies on the recruitment and development of personnel supported by R&D funds.
 - (5) Determining the extent to which the R&D Programs have met its objectives.

(6) Advising the Associate Chief of Staff for Research and Development (ACOS), Chief of Staff (COS) and the Director on professional and administrative aspects of the Research and Development Program.

(7) Fulfilling such other functions as may be specified by the Director.

C. **MEMBERSHIP** to the Jesse Brown VA Medical Center R&D Committee is by appointment of the Director and consists of representatives from each of the following groups:

(1) At least one from each, but not more than three members collectively, representing the Deans' Committees of the affiliated universities appointed by the University's Vice Chancellor for Research (OVCR) shall sit on the Jesse Brown VA Medical Center Research and Development Committee, as required by the Department of Veterans Affairs, Veterans Health Administration handbook 1200.1.

(2) At least two but not more than four members from the Jesse Brown VA Medical Center staff, selected because they have major patient care or management responsibilities. The R&D Committee membership can be supplemented as needed by advisors or consultants who possess the expertise required to perform an appropriate scientific review.

(3) At least one but not more than three members who are VA employees, selected because they are actively engaged in major research or development programs or can provide research or development expertise.

(4) Whenever possible, one member of the Committee selected according to the criteria listed above should have expertise in biostatistics and research design and another in animal research techniques and biomedical study settings.

(5) The members should have diverse backgrounds and should include at least one non-physician.

(6) Ex-officio members except for those required by VA regulations are appointed by the Director. Ex-officio members include:

(a) Non-Affiliated member representing the VA Population

(b) VA mandated Ex-officio members are the Director, COS, and the Administrative Officer, R&D, without vote, and the ACOS, R&D, with vote.

(c) The Chair of each standing subcommittee is an ex-officio member of the committee, but may be appointed as either a voting or non-voting member.

(d) Other Ex-officio members may be appointed to assure representation from all major divisions of Research and applicable components of

Jesse Brown VA Medical Center (i.e.: RR&D, HSR&D, Radiation Safety, etc.).

- (7) Each member may recommend a “designated alternate”, who is authorized to represent the member (and vote) when s/he is unable to attend a meeting. The “designated alternate” must be appointed by the committee prior to attendance.
- (8) The Committee may utilize advisors who are selected to perform specific tasks and who do not have a vote.
- (10) All members of the R&D Committee and its standing subcommittees, other than those who are ex-officio and the University Representative:
 - (a) Must be employees of the Federal Government, with or without compensation.
 - (b) Must commit a major portion of their professional time to the VA except for representatives of the Dean’s Committee.
 - (c) The R&D members rotate off for one year each 3 year term.
- (11) All R&D committee and Human Research Subject Subcommittee members are required to complete the VA mandatory annual training CITI Training Course in The Protection of Human Research Subjects, VHA Privacy Policy Training, VA Cyber Security Awareness, and VA Research Data Security and Privacy
- (12) All R&D committee members, chairman, and ACOS are required to sign a Statement of Disclosure. The R&D member must disclose any known potential conflict of interest to the committee chair at the start of the meeting and leave the room during discussion and vote.

Leadership and Subcommittees

- (a) The R&D Committee (and each standing subcommittee) will elect a chair from the membership, exclusive of ex-officio members for a 1-year term. The R&D Committee has one Vice Chair. The ACOS and Chair will select a Vice Chair for 1 year. The Vice Chair assumes the responsibility of the chair during his/her absence.
- (b) The Animal Care and Use Subcommittee (ACUS), Research Safety and Common Resource Subcommittee and Laboratory and Office Allocation Space Subcommittee are established by the R&D Committee; the members will be nominated by the Committee and appointed by the Director. The committee membership will be for 3 years and rotate off for one year to be eligible for an additional three-year term.
- (c) Other standing subcommittees as are necessary to accomplish the R&D Committee’s responsibilities in areas such as safety, budget, and scientific review are appointed by majority vote of the R&D Committee. The R&D Committee will establish the frequency of standing subcommittee meetings.

(14) If the R&D committee member or Subcommittee's member wishes to resign from the committee at least a 30 days notice is required.

(15) The R&D Service is responsible for providing adequate administrative staff to support the work of the R&D Committee and its standing subcommittees.

D. R&D COMMITTEE'S SPECIFIC RESPONSIBILITIES:

- (1) (1) The R&D Committee will meet monthly not less than 11 times per year except for 1 month during the summer.
- (2) The R&D Committee will critically review the IRB's recommendations related to all research protocols and all grant application regarding the quality, design, desirability, and feasibility of each grant proposals that includes human subjects, laboratory procedures and animal experimentation. Proposals include studies using VA funds, as well as funds from outside organizations, where there is any commitment of resources (patients, space, personnel, money) on the part of the VA.
- (3) The R&D Committee can disapprove a study approved by the IRB, but the Committee cannot approve a study that has been disapproved by the IRB.
- (4) If the R&D Committee disapproves a proposal, the reason for disapproval shall be noted in the report to the IRB.
- (5) It is the responsibility of the R&D office Human Study Research Specialist to collect all necessary documents related to new protocols, continuing review protocols, and amendments from the IRB and the investigator.
- (6) The Human Study Research Specialist will include these items on the meeting agenda and the R&D full committee review packet each month.
- (7) The full R&D committee will review all exempt protocols prior to approval and then re-review all approved Exempt Protocol each year.
- (8) Although the UIC IRB reviews all documents related to the research protocol, including HIPAA documents, the JBVAMC R&D Committee serves as the Privacy Board for the JBVAMC. Therefore, the R&D Committee has the final responsibility for review and approval of all HIPAA authorizations and waivers.
- (9) The R&D Committee APPROVAL, conditional or otherwise, must be obtained in writing prior to the start of any research project.
- (10) The R&D committee will evaluate the productivity of the members of the Research and Development Service, by reviewing submitted a publication, at least every year. This evaluation can be accomplished during review of the each investigator current curriculum vitae.
- (11) The R&D committee is responsible to maintain overall functions and activities of each subcommittee.
- (12) All Subcommittees will work under supervision of the R&D committee, which are as follows:
 - (a) Animal Care and Use Subcommittee (ACUS)
 - (b) Research Safety & Common Resources Subcommittee
 - (c) Laboratory & Office Allocation Space Subcommittee

E. Specific responsibilities involving human research subjects:

The R&D Committee reviews annually the IRB(s) and the membership of the IRB(s) as appropriate given the research being reviewed. The R&D Committee will review the structure and performance of the IRB annually according to the following parameters:

- (1) The Jesse Brown VA Medical Center is affiliated with the UIC /NU Collaborative IRB. The R&D Committee will review the IRB member information sheet in detail to check the qualifications, their role in the IRB, status either scientist or non-scientist or physician scientist, and their expertise in the field of science.
 - (2) Ensure that the IRB has a balance of men and women, drawn from a diverse cross-section of the Chicago communities' racial and ethnic groups.
 - (3) Ensure that IRB members have expertise in a range of health and behavioral sciences, familiarity with relevant standards of professional conduct and practice, and knowledge of vulnerable or special populations; including children, prisoners, pregnant woman, handicapped children, and mentally disturbed persons.
 - (4) Ensure that the IRB's composition meets the requirements of the federal regulations and the International Conference on Harmonization in so far as it is congruent with FDA regulations.
 - (5) Ensure that the IRB conducts its business with the participation of the following persons: Voting members, alternate voting members, and ad hoc consultants.
 - (6) Assess the qualifications and experience of the IRB Chair.
- (d) The R&D committee reviews quarterly telephone audit reports conducted by the R&D human study specialist to evaluate performance improvement related to informed consent process.
- (e) The R&D committee reviews quarterly report from the VA pharmacy to evaluate research documentation deficiency.
- (f) The Human Subject Research Specialist will forward a quarterly feedback questionnaire to the all VA representatives related to serious or continuing non-compliance or unanticipated problems posing risks to subjects for the R&D Committee review.
- (i)** The R&D committee it responsible for nominating the VA representatives on the IRB. These representatives will serve for a period of 3 years and can be re-appointed for the next 3 years. Each VA representative must be approved by the JBVAMC Medical Center Director.

- (k) In agreement with the R&D committee, it is responsibility of the affiliate IRB to issue expiration notices of human research protocols 90, 60, and 30 days.
- (l) The R&D Committee will review IRB meeting minutes on regular basis.
- (m) When proposed research involves individuals who may not be able to provide informed consent for themselves, the R&D relies on affiliate IRB determination.
- (o) The R&D Committee will make determination of flagging protocols in CPRS. Refer to JBVAMC Policy **Flagging Medical Records** for more information and specific procedures.
- (p) The R&D committee will review research related information security and confidentiality breaches and report to the VA privacy officer. The VA Privacy Officer will serve on the R&D Committee member as a non-voting member.
- (q) The R&D committee will monitor the conduct of research investigators to ensure the safety of subjects and adherence to operational. This will be done when adverse events or imminent threats of adverse events in research conducted on site that result in the IRB taking substantive action(s). It is the R&D Committee's responsibility to report to ORO or other agencies as required the outcome of the IRB's review of these events. It is also the responsibility of the R&D Committee to report to the ORO or other agencies unreported death of a research subject.
- (r) Conflict of Interest Disclosure Conflict of interest issues will be managed by affiliate IRB.
- (s) The R&D committee follow the UIC policy regarding the handling of all allegations of non-compliance related to VA investigators Refer to the UIC Policy **Reporting of Complaints and Allegations of Non-Compliance to the Collaborative JBVAMC/NU/UIC IRB (UIC IRB#4) from the JBVAMC and NU Performance Sites**. for specific policies and procedures.
- (t) The R&D Committee will follow the UIC policy **Emergency Use of a Test Article** for approval of research that involves the emergency use of an investigational drug or device.

(9) Studies utilizing animals will be reviewed by the Animal Care and Use Subcommittee prior to the R&D Committee review and approved VA studies will be reviewed annually thereafter, for the duration of the project. The Animal Care and Use Subcommittee should include no more than five persons as follows:

At least one member of the parent R&D committee, a staff or consultant Veterinary Medical Officer who is a VA employee, with or without compensation, and who serve ex-officio with a vote, two to four investigators who are involved significantly in studies using animal subjects, and members other than those who are ex officio serve terms not to exceed 3 years, on staggered appointments. The

Subcommittee on Animal Studies is responsible for reviewing all use of animal subjects, including proposed and ongoing studies, as they relate to animal welfare laws, regulations, and policies. Review includes the appropriateness, quality, availability of the selected animals, the humaneness and appropriateness of procedures and conditions surrounding animal subjects before and throughout the study, as well as the adequacy and availability of essential animal research facilities support. The subcommittee evaluates the animal facility at least annually to identify deficiencies relevant to animal welfare laws, regulations, or policies, recommends appropriate corrective actions, and reports on corrective measures taken. The subcommittee members will be nominated by the R&D Committee and appointed by the Director. The committee membership will be for 3 years and rotate off for one year to be eligible for an additional three-year term.

(10) The Research Safety and Common Resources Subcommittee is responsible for evaluating all equipment requests and recommending to the R&D Committee whether it is justified and documented. The subcommittee membership includes at least one member of the parent R&D committee, one scientist, AO/ ACOS R&D, and one investigator. The subcommittee members will be nominated by the R&D Committee and appointed by the Director. The committee membership will be for 3 years and rotate off for one year to be eligible for an additional three-year term.

(11) Laboratory and Office Allocation Space Subcommittee is established by the R&D Committee, the members will be nominated by the Committee and appointed by the Director. The committee membership will be for 3 years and rotate off for one year to be eligible for an additional three-year term. The R&D committee will review and approve any recommendations of the Space and Allocation subcommittee, to assure appropriate use of VA resources.

(12) The R&D Committee may not approve any study disapproved by either of the IRB or Animal Care and Use Subcommittees, but may disapprove a study approved by either subcommittee. It is the R&D's responsibility to notify the IRB or Animal Care and Use Subcommittee of the reasons for disapproval.

(13) The Radiation Safety Committee, which is not a part of the R&D subcommittee will review each study proposing the use of radioisotopes prior to the start of the study and any concerns and deficiencies regarding use of radioactive materials will be forwarded to the R&D committee. The R&D committee will not approve any study involving radioisotopes without approval of Radiation Safety Committee. The Radiation Safety Officer is one of the members in the R&D Committee.

Minutes of each R&D Committee meeting will be recorded and these minutes will be reviewed and approved by the Committee prior to forwarding to Chief of Staff and the Director for approval. The R&D office will keep the original signed minutes, along with all attachments, which include attendance sheet, attendance roster, and guest if any, and vote recorded. The following signatures are required: Chairman, R&D Committee, ACOS for R&D, Chief of Staff and Medical Center Director.

Each subcommittee will record minutes of each meeting and will review and approve these minutes prior to forwarding to the R&D Committee for review and approval. The R&D Service will maintain an archive of the original, signed minutes for each subcommittee meeting.

The Chair of the R&D Committee and each subcommittee will assure that notifications of committee decisions and responses to other correspondence are prepared and delivered in a timely manner.

The R&D committee will review the resources of HRPP, which include but are not limited to:

- a) Personnel,
- b) Materials and Supplies
- c) Space
- d) Capital Equipment
- e) Training and Education

E. RESPONSIBILITIES:

1. The R&D Committee is responsible for the scientific quality and appropriateness of all research and development that involves VA research participants, VA investigators, or VA facilities.
2. Each research program will be formally reviewed at a minimum of once per year. In addition to the assessment of scientific progress, the R&D Committee will oversee the budget, resource needs, and the relationship of each research program to the total R&D activity of the facility.
3. The R&D Committee will rely on the affiliate IRB regarding:
 - COI management
 - Protocol Deviations, Violations and Exceptions procedures
 - Handling of Complaints or Allegations of Non-compliance
 - Reporting Procedures for Unanticipated Problems Involving Risks to Subjects or Others; Serious or Continuing Non-Compliance; and Suspensions and Terminations
 - UPIRSO/Adverse Events policy and review
 - Emergency use of investigational drugs or devices

F. RECORD RETENTION: Records are the property and responsibility of the local research office. All records need to be accessible for inspection and copying by authorized representatives of VA, OHRP, FDA and other authorized entities at reasonable times and a reasonable manner. The research records must be retained for a minimum of 5 years after the completion of the study, and in accordance with VHA's Records Control Schedule (RCS 10-1), applicable FDA and DHHS regulations, or as required by outside sponsors.

G. PROCEDURES: Staff members who wish to conduct human subject research are required to be a JBVAMC employee. Staff members who wish to apply for human subject research must have a faculty member as the principal investigator and are to discuss their plans at the earliest possible stage with the ACOS for R&D, who may refer the investigator to appropriate members of the Research Service for consultation. In all matters related to research, the R&D Committee will be the ultimate quality control instrument, augmented and supplemented, as indicated, by the application process in VA Headquarters.

In order to make certain that review processes are conducted in a compliant manner, all Research policies and procedures will be reviewed, revised as needed, and submitted to the R&D Committee for discussion and approval. The R&D Committee is the final authority to communicate (letter) with the investigator regarding approval/disapproval / table protocol, and any noncompliance issues. The R&D office will conduct VA regulation and R&D protocol submission requirement updates twice a year for all investigators and their research team.

The R&D Committee will meet monthly. Minutes of the R&D Committee meeting will be prepared to accurately reflect the business conducted by the Committee. Minutes will be reviewed by the Chairperson and the ACOS / R&D and presented to R&D members for approval at the next convened meeting of the Committee. After approval by the R&D Committee, the minutes will be signed by the Chairperson and the ACOS / R&D and forwarded to the Chief of Staff and Hospital Director for final review and signature. The ACOS / R&D will present an overview of R&D Committee activities to the Clinical Executive Board on a monthly basis.

Members of the Committee will be appointed by the Hospital Director for a term of three (3) years. The ACOS / R&D in concert with the R&D Committee will identify and nominate candidates for membership to the Hospital Director.

H. TRAINING HUMAN RESEARCH OVERSIGHT. At the time of appointment and annually all members of the R&D Committee, and the VA representatives in IRBs (which review VA human research protocols) will receive training in the regulatory and ethical requirements for the conduct of studies involving human participants. Documentation of the required human research training for the VA will be maintained in the Research Office.

REFERENCES:

VHA 1200.1 and 1200.5

UIC Policy Reporting of Complaints and Allegations of Non-Compliance to the Collaborative JBVAMC/NU/UIC IRB (UIC IRB#4) from the JBVAMC and NU Performance Sites.

UIC Policy Emergency Use of a Test Article

**Required Education and Training for Research Activities At
the Jesse Brown VA Medical Center (JBVAMC)**

1. PURPOSE

To describe the required education and training criteria for investigators and their research teams involved in research activities, R&D Committee members, VA representatives in IRBs, and R&D Office staff dealing with human subject protection program at the Brown V A Medical Center.

2. POLICY

To ensure that all Principal Investigators, key research personnel, R&D Committee Members, VA Representatives in the IRBs, and R&D Office Staff involved in Human Subject Research protection Program who participate in research activities are properly trained to conduct and/or review studies in a compliant, safe, ethical manner.

3. RESPONSIBILITY:

- a. The Associate Chief of Staff for Research and Development (ACOS/R&D) is responsible for communicating education and training requirements to researchers and for making training programs available to investigators, key research personnel, R&D Committee Members, R&D Office Staff, and VA Representatives in the IRBs.
- b. Investigators are responsible for complying with training and education requirements and ensuring that all members of their research teams are properly prepared to participate in research activities.
- c. R&D Committee Members, R&D Office Staff, and VA Representatives in the IRBs are responsible for complying with training and education requirements.

4. PROCEDURES:

As of June 2003 all key research personnel conducting human subject research requiring Institutional Review Board (IRB) and the R&D Committee review, must provide proof of mandatory VA training. Renewal of this training must be done annually and valid training certificates provided to the R&D Office. The documentation of training must be on file in the R&D Office prior to submission prior to the review of any new research proposal, continuing review, or amendment. In addition, all proposals submitted to the VA Office of Research and Development (ORD) for review and funding must also include such training documentation.

Effective January 1, 2007, the Overview of Good Clinical Practice & Human Subjects courses are available through **Collaborative IRB Training Initiatives (CITI)**. All options for fulfilling VA human research training requirements are located at <http://www1.va.gov/resdev/programs/pride/training/options.cfm>.

VA mandated training must be completed annually. All training courses were designed and implemented by the VA Central Office. These trainings are mandatory for R&D Committee members, VA representative in the IRB, and the R&D office staff dealing with the human research subject protection program.

Human Subject Research Protections VA mandatory annual training:

CITI Course in the Protection of Human Research Subjects
<http://www.citiprogram.org/>

VA Research Data Security & Privacy -
[https://www.vcampus.com/vcekpvalo/servlet/ekp?TX=SELFREGISTRATI
ON](https://www.vcampus.com/vcekpvalo/servlet/ekp?TX=SELFREGISTRATI
ON)

VHA Privacy and VA Cyberspace -
[https://www.vcampus.com/vcekpvalo/servlet/ekp?TX=SELFREGISTRATI
ON](https://www.vcampus.com/vcekpvalo/servlet/ekp?TX=SELFREGISTRATI
ON)

Research (Laboratory) Safety Training is required for all staff involved in laboratory-related activities; the type and extent of this training will be evaluated and provided by the facility Safety Officer; this training must be renewed on an annual basis.

Radiation Safety Training is required for all research staff whose duties will involve using radio-isotopes in laboratory space; the type and extent of this training will be evaluated and provided by the Radiation Safety Officer; this training must be renewed on an annual basis.

Animal Care and Welfare Training is required for staff involved in animal research protocols "Working with the VA IACUC"
<http://www.researchtraining.org/>

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Credentialing of Individuals Involved in Human Subjects Research at the Jesse Brown VA Medical Center (JBVAMC)

1. **PURPOSE.** To describe the process and procedures regarding the credentialing of research personnel at the Jesse Brown VA Medical Center

2. **POLICY.** To require that all employees involved in human subjects research (Title 38, Title 5, possess adequate credentials and training to ensure thorough understanding of the protection of human subjects and the ethical conduct of research.

3. **BACKGROUND:** The Department of Veterans Affairs (VA) is guided by ethical principles set forth in the Common Rule, Food and Drug Administration (FDA) regulations, and the Belmont Report. With the increased complexity of research and the advent of new technologies, all Veterans Health Administration (VHA) personnel involved in human subject's research must demonstrate and maintain the appropriate education, training, and experience to provide the highest level of protection to human subjects.

4. DEFINITIONS:

a. Background Investigations:

This term refers to the investigation of the applicant's past history to a degree that is commensurate with the risk level assigned to the employee's Functional of Research Duties and Responsibilities.

b. Belmont Report:

This term refers to the "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on April 18, 1979.

c. Common Rule:

This term refers to a common set of regulations governing human subject's research which are codified at Title 38 Code of Federal Regulations (CFR) Part 16.

d. Credentialing:

Credentialing is the formal, systematic process of verifying, screening, and evaluating qualifications and other credentials that include education, licensure, relevant training, experience, and competence.

5. PROCEDURES:

a. Credentialing and validation of qualifications applies to all members of the

research team (except administrative staff) and includes the following:

- (1) Research staffs who interact with patients via telephone
- (2) Research staffs that collect and analyze laboratory specimens or data.
- (3) Research staff that perform laboratory tests and work with data.
- (4) Research staff with or Without Compensation (WOC) appointment.

b. Credentialing and validation of qualifications are not required for the following:

- (1) Research staff who are based at an affiliate or other outside institution and who will not access VA patients/data or access VA space for research activities.
- (2) Outside biostatisticians.
- (3) Outside laboratory technicians.
- (4) Community volunteers who represent the VA on an Institutional Review Board or the Research & Development (R&D) Committee.
- (5) Participants in data safety monitoring boards who are recruited from non-VA institutions.
- (6) Clinical personnel who periodically perform tests on research patients as part of their routine duties.

c. Individuals involved in human subjects' research will receive appropriate training in the ethical principals and good clinical practices for human subjects research on an annual basis.

d. All employees involved in human subjects' research will have appropriate background investigations; Human Resources personnel will oversee the background investigation procedures.

e. All employees involved in human subjects' research will be credentialed and have relevant qualifications appropriately validated, including licensure and educational verifications from primary sources.

f. All employees involved in human subjects research will have approved clinical privileges or functional statements of research duties and responsibilities that are consistent with their assigned activities. Specifically, Licensed Independent Practitioners (LIPs) will be credentialed through the VetPro procedures within the Chief of Staff's Office. Non-LIP research staff will be credentialed through the Research Office. Professional licenses will be confirmed annually.

g. Employees involved in human research will undergo employment screening via the List of Excluded Individuals and Entities (maintained by the Department of Health and Human Services) and the Department List (maintained by the Food and Drug Administration) .

h. Re-credentialing will be required every two years.

i. Employees involved in human subjects' research are responsible for knowing and adhering to the scope of practice or clinical privileges that have been approved for them.

j. Employees involved in human subject's research are responsible for knowing and adhering to the applicable statutes, regulations, and policies related to the conduct of human subjects research.

k. Employees involved in human subjects' research are responsible for completing required training in the ethical principles and acceptable human research practices on an annual basis.

l. Employees involved in human subjects' research are responsible for engaging only in human subjects' research activities that have been approved, as required by VA regulations and policies, by the R&D Committee.

REFERENCES:

a. Title 21 Code of Federal Regulations (CFR) Parts 50, 56, 312, and 812

b. Title 38 USC Section 7304

c. Title 38, CFR Part 16

d. VA Handbook 5005, Staffing, Part II, Chapter 3, Section B

e. VHA Manual M-3, Part I, Chapters 2, 3, and 9

f. VHA Directive 1200.5 "Requirements for the Protection of Human Subjects Research"

**ASSURANCE OF COMPLIANCE AND QUALITY IMPROVEMENT
FOR THE HUMAN RESEARCH PROTECTION PROGRAM
AT THE JESSE BROWN VA MEDICAL CENTER (JBVAMC)**

1. **PURPOSE:** To establish polices and procedures for evaluating the effectiveness and compliance of the Jesse Brown VA Medical Center (JBVAMC) Human Research Protection Program (HRPP). To describe the Research and Development (R&D) responsibilities and procedures for monitoring all compliance requirements of the Human Research Protection Program (HRPP) at the JBVAMC. To describe procedures for conducting conducts quality improvement activities in the JBVAMC HRPP.
2. **POLICY:** To conduct an ongoing, continuous Quality Improvement program and to ensure compliance with policies, regulations, and laws which pertain to human research protections for research conducted at the JBVAMC.

3. **DEFINITIONS:**

Research Non-compliance: Failure to follow institutional policies, procedures, stipulations, decisions, state or federal law, or VHA Handbook 1200.5.

Serious Non-compliance: All no-compliance substantially affecting participants' rights and / or welfare, or impacting upon the risks or benefits is serious non-compliance.

Continuing Non-compliance: The systematic and habitual disregard of restrictions, procedures, stipulations, or decisions of the IRB.

Allegation: An allegation is an assumption made by a party that must be proved or supported with evidence.

Confirmed Report. In the context of HRPP, a confirmed report refers to non-compliance that is supported by incontrovertible factual information.

Research (scientific) misconduct. Fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the academic community for proposing, performing, or reviewing research, or reporting research results. Misconduct does not include honest error or honest differences in interpretations or judgments of data.

Suspension: A temporary withdrawal of approval of some or all research, or a permanent withdrawal of approval of some research activities.

Termination: A permanent withdrawal of approval of all research activities.

4. **RESPONSIBILITIES:** The responsibilities for ensuring compliance and for overseeing quality improvement activities for the JBVAMC HRPP are as follows:

4.1.1. Medical Center Director. The Medical Center Director is responsible for

the overall assurance of protections for human research participants within the JBVAMC. As the designated Institutional Official, the Medical Center Director can exercise the authority to suspend or terminate research as deemed necessary, including for the protection of human participants.

4.1.2. Associate Chief of Staff for Research and Development: The ACOS R&D is delegated the responsibility for the implementation, conceptual oversight, and administrative leadership of the HRPP with regard to ensuring compliance and quality improvement. Questions regarding these policies should be directed to Joseph DeSimone, Ph.D., ACOS for Research and Development, at 312-569-6683.

4.1.3. Human Subject Research Specialist: The HSRS is responsible for the day-to-day monitoring of the HRPP, including ongoing quality improvement activities, the implementation of needed improvements, and the follow-up of corrective actions for non-compliance, education, and training. The HSRS also is responsible for the review and evaluation of reports, audits, compliance assessments, and quality improvement activities as related to human research protections.

4.1.4. Administrative Officer for R&D (AO R&D): The AO R&D is responsible for the organizational support and deployment of resources that are required to maintain compliance with HRPP activities, including the conduct of human subject research compliance audits

5. RESPONSIBILITIES AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OR REPORTS OF NONCOMPLIANCE WITH HRPP REQUIREMENTS:

5.1. The JBVAMC defers to the IRB policies and procedures for the review of situations involving allegations or reports of noncompliance and the handling of problems determined by the IRB to be unanticipated problems involving risks to subjects or others (UPIRSOs).

5.2. Complaints and/or allegations of noncompliance in human research conducted at the Jesse Brown VA Medical Center will be referred to the affiliated IRB to handle according to UIC policy. If complaint involves a VA dept or employee other than research personnel or related to human subject research, the complaint will be handled by the appropriate VA regulations and department.

5.3. Remedial action for and consequences of findings of noncompliance will be established for each incident. These include but are not limited to compliance audits, letters of reprimand, suspension and/or termination of research protocol, and restrictions on serving as an investigator on human subject protocols.

5.4. Findings will be reported to the VA Medical Center Director and all other appropriate parties and authorities.

5.5. In addition to retrospective audits of compliance with the HRPP, any allegation or report of noncompliance which arises will receive responsive examination as follows:

5.6. Any employee of the JBVAMC or member of a research team (including Without Compensation Employees) who becomes aware of a violation, or who believes there may be a violation of IRB or HRPP regulations, requirements, or

determinations should promptly report.

- 5.7. Any participant in a human research study, their designated representatives, or members of the community are also encouraged to report any activities or behaviors that they believe may be noncompliant or inappropriate.
- 5.8. These incidents may be reported to the IRB, or the JBVAMC R&D Office, Patient Advocate, or Privacy Officer. Regardless of the source of the complaint, all allegations and reports of noncompliance will be reported to the IRB.
- 5.9. The handling of subject complaints will be conducted per the Collaborative IRB policy and the UIC SOP *Research Subject Complaint Policy, Version 1.1, 8/13/2007*.
- 5.10. The IRB will review all instances of non-compliance per the UIC Collaborative IRB policy and will communicate with the JBVAMC VA Research Office whether allegations of non-compliance are confirmed, whether reports of non-compliance are serious or continuing, whether additional information is needed, and if any corrective actions need to be taken.
- 5.11. The JBVAMC Medical Center Director may take additional corrective actions, including suspension or termination of protocols, restrictions on privileges to conduct research, or potential disciplinary actions against perpetrators of violations. The Medical Center Director will report corrective actions to the IRB and R&D ACOS.
- 5.12. The Medical Center Director will follow all required VA policies, including VHA 1200.5, for reporting to regulatory agencies.

6. COMPLIANCE WITH CHANGES IN HRPP POLICIES AND REGULATIONS:

Officials delegated as responsible for the HRPP (i.e., ACOS/ R&D, Medical Administration Specialist, AO/ R&D) will closely monitor all policies and regulations which pertain to HRPP compliance requirements. Strategies for effective monitoring will be as follows:

- 6.1. The Medical Administration Specialist and other officials, as appropriate, will participate in recurring training in order to remain cognizant of all changes in HRPP policies and regulations. When changes are identified, they will be promptly reflected in local policies and procedures at the JBVAMC and quickly disseminated to institutional officials, members of research review committees, and human research personnel via the HRPP Handbook and through ongoing educational activities.
- 6.2. Communications from the VA Office of Research and Development, the VA Office of Research Oversight (ORO), and the VA Center on Advice and Compliance Help (COACH) will be closely monitored in order to maintain a keen awareness of changes in HRPP policies and regulations so that compliance can be maintained.

7. COMPLIANCE AUDIT AND MONITORING:

7.1. The R&D Office actively seeks feedback about its research program through surveys, focus groups, interviews or other methods. The R&D Office routinely tracks the following QI factors:

- Identify areas that need improvement
- Recommendations made and actions taken to implement improvements
- Results of QI activities including pre- and post- evaluation measurements

7.2. On a quarterly basis the R&D Office performs telephone audits to actively seek feed back from current research subjects

7.3. The R&D evaluates HRPP effectiveness and conducts quality improvement activities. Evaluation includes measuring, assessing, and improving compliance with institutional HRPP policies, assurances and other requirements for the protection of human subjects in research.

7.4. The R&D monitors the performance of investigators to ensure compliance with HRPP and IRB requirements by evaluating the following:

- Using only IRB-approved advertisements and subject recruitment materials
- Using only IRB-approved consent forms
- Signing and dating the consent form
- Documenting consent in the case history, if subject is a VA patient
- Obtaining IRB approval prior to initiating changes to the protocol or consent form, except where necessary to eliminate apparent immediate hazards to subjects
- Reporting all unanticipated problems involving risks to human subjects
- Reporting all protocol deviations
- Adherence to HRPP policies
- Adherence to IRB approved protocols and conditions

7.5. The R&D monitors performance of investigators in implementing informed consent requirements. The institution evaluates the following:

- Obtaining consent prior to initiating any research related procedures
- Using only IRB-approved consent forms
- Signing and dating the consent form
- Documenting consent in the case history, if subject is a VA patient
- Providing a copy of the consent form to the subject or legally authorized representative

7.6. The R&D also monitors its responsiveness to questions, concerns and complaints by:

- Timeliness of response to questions and complaints
- Satisfaction with responses

7.7. On a quarterly basis, the JBVAMC R&D Office will provide a written summary of compliance audits and monitoring activities to the R&D Committee.

7.8. Compliance audits for the HRPP are conducted as follows:

7.8.1. Compliance Audits of Project Files. A minimum of five (5) human research project files will be audited per quarter to ensure completeness of records, including original applications, IRB documentation, investigator communications, and synchronization with computerized tracking systems. The file audit will ensure that accurate and complete records are maintained and include at the minimum the following information: (1) date of original IRB approval, (2) date of original R&D Committee approval, (3) date of most recent IRB approval, and (4) date by which next IRB continuing review must occur.

7.8.2. Compliance Audit of Informed Consent Documentation. A minimum of five (5) medical records of human participants from the each of five selected projects will be audited on a quarterly basis. One medical record for each selected project will be audited for each project minimum of one participant. Each subject's file will be reviewed for (1) placement of consent document within the medical record, (2) appropriate signatures, (3) subject met enrollment criteria, and (4) use of current IRB approved consent document.

7.8.3. Compliance Audits of VA Training Records. The VA training log, which documents all mandatory VA annual training for the VA representatives in the IRB, the R&D Committee members, R&D office staff, investigators and their research team will be audited for training compliance; an audit of the training records for all research personnel will be conducted on a quarterly basis.

7.9. If gaps in performance are identified through any of its monitoring activities or other sources, the institution will implement corrective action (e.g., changes policy, procedure, communication, implements education or other such intervention) to improve.

7.10. If gaps in performance were identified and corrective action implemented, the institution will reassess performance to the effectiveness of the action taken.

7.11. Results of compliance audit activities pertaining to the HRPP will be maintained on file in the R&D Office for a minimum of seven (7) years.

8. OVERSIGHT OF THE IRB:

8.1. A key procedure for ensuring compliance and quality improvement for the HRPP is careful oversight of IRB activities. Specific oversight is accomplished as follows:

8.2. On a monthly basis the JBVAMC R&D Office reviews the VA active project list provided by the IRB pertaining to VA-related projects to up-date.

8.3. The minutes of all IRB meetings are reviewed by the R&D Committee for consideration of VA-specific issues including the following:

- protection of VA research subjects
- presence of at least one VA representative during IRB review.
- content and accuracy of informed consents
- IRB analysis of risks and benefits including designation of minimal risks
- special considerations and protections for vulnerable or potentially vulnerable populations
- consideration of privacy and confidentiality protections
- continuing review of previously approved research (i.e., amendments, adverse events)
- use of expedited review or other procedures requiring review of less than the full IRB
- granting exemption from Federal requirements for IRB review
- granting waivers for documentation of informed consent
- granting waivers of any elements of informed consent
- the contents and accuracy of the VA HIPAA authorization and/or granting a waiver of HIPAA authorization documents.

8.4. The R&D Committee monitors specific IRB activities from a compliance standpoint as follows: (a) qualifications and experience of new IRB chairpersons, (b) appropriateness of IRB membership and experience in the context of research under review, (c) participation of representatives and/or advocates for vulnerable populations, (d) adequacy of IRB policies and procedures, (e) appropriate monitoring of adverse events, (f) timeliness of review process, (g) appropriateness of number of IRBs in relation to workload volume, and (h) the thoroughness of the review process.

8.5. The R&D Office submits a HRPP IRB Performance and Oversight report annually to the R&D Committee for review.

8.6. On a daily basis the IRB point of contact person and JBVAMC R&D Medical Administration Specialists are in touch to maximize communication, facilitate collaboration, and ensure compliance with all HRPP requirements.

9. Handling Research Subject Complaints:

9.1. The JBVAMC recognizes that it must be responsive to the concerns of research participants. The Research and Development Office has developed a process that will allow research subjects to register complaints or concerns regarding their participation in a research project through an alternative source to the Principal Investigator and his/her staff.

9.2. Complaints and/or allegations of noncompliance received from research subjects in human research conducted at the Jesse Brown VA Medical Center will be referred to the affiliated IRB. The IRB will handle the complaint according to UIC policy.

- 9.3. It is generally felt that guidance provided in 45 CFR 46.116(a)(7) under the “General requirements for informed consent” are meant to include a provision that will allow the research subject a means to contact a source at the JBVAMC to file a complaint. Information is included in the informed consent document so the research subject will know who to contact regarding research related issues. The subject may contact OPRS through a toll-free number (1-866-789-6215; contact the JBVAMC Patient Advocate at 312-569-6146; 312-469-3095; or the JBVAMC R&D Office at 312-569-6166 during normal office hours (Monday through Friday).
- 9.4. If a complaint involves an issue, department or employee and is unrelated to human subject research, the complaint will be handled according to the appropriate VA regulations and departmental policies.
- 9.5. Remedial action for and consequences of findings of noncompliance will be established for each incident by the IRB. The R&D Committee, VA Medical Center Director or other VA divisions, may require additional actions. These include but are not limited to compliance audits, letters of reprimand, suspension and/or termination of research protocol, and restrictions on serving as an investigator on human subject protocols.
- 9.6. Findings and actions taken by the IRB will be reported to the JBVAMC ACOS R&D. Findings and actions taken by the R&D Committee will be reported to the VA Medical Center Director, the IRB and all other appropriate parties and authorities as described in Section 10.

10. PROCEDURES FOR REPORTING TO REGULATORY AGENCIES:

- 10.1. The JBVAMC ACOS R&D and Medical Center Director are responsible for submitting all reports of non-compliance received from the IRB to the appropriate VA regulatory agencies.
- 10.2. The R&D Office will prepare a letter to regulatory agencies with the following information:
- 10.2.1. Copy of the IRB letter to the JBVAMC.
- 10.2.2. A letter from the ACOS R&D that documents the following:
- Nature of the event (unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research).
 - Name of the institution conducting the research.
 - Title of the research project or grant proposal in which the problem occurred.
 - Name of the principal investigator on a protocol.
 - Identification number of the research project as assigned by the IRB and the identification number of any applicable federal award(s), grant, contract, or cooperative agreement).
 - A detailed description of the problem including the findings of the organization and the reasons for the IRB's decision.
 - Actions that the IRB has taken or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, and increase

monitoring of subjects).

- Additional actions VA has taken or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, and increase monitoring of subjects).
- Plans, if any, for the IRB to send a follow-up or final report by the earlier of (a) a specific date, or (b) when an investigation has been completed or a corrective action plan has been implemented.
- Plans, if any, for the VA to send an additional follow-up or final report by the earlier of (a) a specific date, or (b) when an investigation has been completed or a corrective action plan has been implemented.

10.2.3. At a minimum the following VA agencies will be notified:

- Chief Executive Officer, Veterans Integrated Service Network 12.
- Regional VA Office of Research Oversight (ORO).
- VA Office of Research and Development.
- Privacy Officer of an organization, if the report involves unauthorized use, loss, or disclosure of individually-identifiable patient information from that covered entity.
- Information Security Officer of an organization, if the report involves violations of information security requirements of that organization.
- Foundation Director, if applicable.
- VA Service Line Director responsible for the investigator.

11. References

General requirements for informed consent:

- 45 CFR 46.116(a)(7)
- 38 CFR 16.103(b)(5);
- 38 CFR 16.116 (a) (7);
- 45 CFR 46.103 (b) (5);
- 21 CFR 50.25 (a) (7)

VHA Handbook 1200.5 "Requirements for the Protection of Human Subjects in Research" dated July 15, 2003.

"What to Report to ORO: Action" Memorandum dated September 8, 2005.

Schedule of QA/QI Projects for R&D Committee Evaluation

A) Monthly QA/QI Programs

- Review of IRB Meeting Minutes
- Review of R&D Committee meeting Minutes
- Review of Animal Care and Use Subcommittee Meeting Minutes
- Review of Research Safety and Common Resources Subcommittee (Alternate Month)

- Review of Space Subcommittee Meeting Minutes (PRN)
- Review of WOC Application

B) Quarterly QA/QI Programs

- Review of Quarterly Feedback Questionnaire from VA Representatives in the IRB
- Review of Quarterly Patient Informed Consent Questionnaire Telephone Audit Report
- Review of VA Pharmacy Quarterly Feedback Report
- Review of Quarterly CPRS Report
- Review of Quarterly Report for Continuing Review Expiration Protocols.

C) Annual QA/QI Programs

- Annual Review of IRB Structure and Performance
- Investigator(s) Compliance with HRPP: Annual Evaluation By R&D Committee
- R&D Committee Compliance to R&D Policy:

D) Non-Compliance Quarterly Report

- Report of subjects enrolled in research studies but not flagged in CPRS
- Investigators who are non-compliant with VA Training requirements
- R&D Committee members with Expired GCP / HSRP and VA Privacy Training
- VA Representatives in IRB with Expired GCP / HSRP and VA Privacy Training

Sponsored Research Policy & Procedures at the Jesse Brown VA Medical Center (JBVAMC)

1. PURPOSE:

To clarify policies and procedures for conducting a clinical research trial sponsored by a commercial company (Sponsor) who owns an investigational new drug or device, designs the protocol, and/or funds the project.

2. POLICY:

Research conducted in collaboration with a commercial company will be subject to Veterans Health Administration (VHA) policies, especially VHA Handbook 1200.5; the procedures related to Clinical Trial Cooperative Research and Development Agreements (CT-CRADAs); Jesse Brown VAMC (JBVAMC) policies and guidelines for conducting research; and the IRB Agreement entered into with the University of Illinois at Chicago (UIC), and Northwestern University (NU) ("University affiliates"). Sponsored Research utilizing VA resources and/or involving Intellectual Property may not be undertaken without prior review and approval of the responsible committees and officials.

3. RESPONSIBILITIES:

a. The Hospital Director is the responsible Institutional Official who has overall responsibility for all research at JBVAMC, including sponsored research.

b. The Associate Chief of Staff for Research and Development (ACOS) is responsible for the management of the research program.

c. Research and Development (R&D) Committee is responsible, through the Chief of Staff (COS) to the Medical Center Director, with the assistance of the ACOS, for the oversight of the research program. The R&D committee will review all research conducted at JBVAMC to ensure the scientific and ethical quality of VA research projects, the protection of human subjects in research, the safety of personnel engaged in research, the welfare of laboratory animals, security of VA data, and the security of VHA research laboratories.

d. The Human Subject Research Coordinators (HSRC) are responsible for reviewing compliance with the Human Research Protection Program (HRPP). HSRC will conduct quality assurance audits and notify the ACOS and R&D Committee of any signs of non-compliance that appear to pose a risk to human participants.

e. Regional Counsel is responsible for reviewing and approving sponsored research agreements as well as any related legal documents such as the Conflict of Interest survey.

4. PROCEDURES:

- a. The Human Research Protection Program and JBVAMC's research policies will apply to sponsored research. There will be a case-by-case review of the agreement to determine if it addresses protections of human research subjects, can proceed within JBVAMC or its satellite clinics, and can utilize VA resources.
- b. Agreements with Sponsors, including those involving the University affiliates, will comply with the policies noted in this memorandum.
- c. Agreements shall address, but are not limited to, the following: protections of human research subjects; medical care for research participants who sustain a research related injury; and prompt reporting to JBVAMC and IRB committee of any findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the status of the protocol at the IRB level.
- d. If participant safety or medical care could be directly affected by study results, JBVAMC and, if required, University affiliates will notify the Sponsor of its concerns and address how the results will be communicated to study participants.

REFERENCES:

- a. VHA Handbook 1200.5, Requirement for the Protection of Human Subjects in Research, Department of Veterans Affairs, Veterans Health Administration, Washington, DC.
- b. Cooperative Trials Agreements and Clinical Trials Cooperative Research and Development Agreement
- c. Conflict of Interest Survey

BILLING FOR CLINICAL STUDIES POLICY & PROCEDURES AT THE JESSE BROWN VA MEDICAL CENTER

1. PURPOSE:

To establish procedures for reimbursement to the Jesse Brown VA Medical Center for services rendered to patients taking part in approved medical research, where the cost of such services exceeds ordinary care for existing conditions of the patient.

2. POLICY:

a. Research Service will serve the Department of Veterans Administration (VA) and the general public through facilitation of medical research and investigation. Because the JBVAMC and Research Service possess valuable skills, knowledge, expertise, and resources relating to such research, it is incumbent that these services and facilities be made available when appropriate to other affiliated research entities. However, reimbursement should be made for all research and/or clinical studies that will result in expenses to the JBVAMC over and above the normal required standard of care for patients. Therefore, the procedures will be used to ensure appropriate and reasonable compensation is made for research and/or clinical studies involving VA patients, facilities, or services.

b. The Research and Development (R&D) Committee must approve, prior to initiation, all research and clinical studies involving VA patients, VA facilities, or VA staff. Research Service will provide a mechanism for the tracking and billing of clinical studies, or other protocols, that generate costs to the JBVAMC.

3. PROCEDURE:

a. Investigators desiring to participate in research or clinical studies that involve VA patients, staff, or facilities must obtain prior approval for such studies from the R&D Committee. The required forms for approval may be obtained from the Research Service Office. The R&D Committee will determine if the study will incur costs that are in excess of the normal standard of care, and will ensure the principal investigator has made provisions with the grantee to provide for reimbursement to the JBVAMC of any such expenses.

b. Research Service will assign the approved protocol a tracking number. The affected VA service or department, and the protocol administrator, will be notified by the Research Service of the approval to conduct the clinical trial and of the tracking number to use for billing purposes.

c. The service or department within the VA hospital that provides the service or supplies for the protocol will notify the Research Service Administrative Officer (AO/R&D) of the total costs incurred for the particular protocol.

(1) If the funding for the protocol is administered outside the local VA, the Research Service will then generate a Bill of Collection for this cost and send it to the protocol administrator for payment, with a copy also sent to Fiscal Service. Money received for clinical research studies will be deposited in the hospital Medical Care Appropriation.

(2) If the funding for the protocol is administered by the local VA, the AO/R&D will transfer funds to the appropriate control point to compensate for the billed services.

d. Research Service will maintain records of approvals and billing for research or clinical protocols with affiliated research entities.

Department of Veterans Affairs
Jesse Brown VA Medical Center
820 S. Damen Avenue
Chicago, IL. 60612

R&D 537/151
March 10, 2008
Revised Version 1.1

Research & Development Committee at the Jesse Brown VA Medical Center
Scientific Review Check List

Initial, Amendment, and Continuing Review Guide for R&D Committee
Members

IRB Protocol #

Review Date:

Protocol Title:

Principal Investigator:

Scientific Evaluation of Proposal (Check that apply)

- | | | | | |
|----|---|----|-----|----------|
| 1. | Testable Hypotheses/Questions? | | | Comments |
| | YES | NO | N/A | |
| 2. | Specific Objectives /Aims? | | | Comments |
| | YES | NO | N/A | |
| 3. | Relevant for VA Healthcare | | | Comments |
| | YES | NO | N/A | |
| 4. | Specification of Subjects? | | | Comments |
| | YES | NO | N/A | |
| 5. | Adequacy of Design Methods/Procedures? | | | Comments |
| | YES | NO | N/A | |
| 6. | Significance of Potential New Findings? | | | Comments |
| | YES | NO | N/A | |
| 7. | Availability of Resources to Conduct Study? | | | Comments |
| | YES | NO | N/A | |
| 8. | Ethical Concerns? | | | Comments |
| | YES | NO | N/A | |

9. Adequate Resources Available to Ensure Human Research Protections?

a. Adequate members of qualified staff?

YES NO N/A

b. Adequate facilities?

YES NO N/A

c. Access to a population which allows recruitment of the required number of participants?

YES NO N/A

d. Availability of medical or psychological resources that participants might require as a consequence of the research.

YES NO N/A

e. Sufficient time to conduct and complete the research.

YES NO N/A

f. Adequate preparation of persons assisting with the research to perform research-related duties and functions?

YES NO N/A

10. Does the consent contain the appropriate template medical treatment/injury statements from the VA consent template?

"If you are injured or harmed from taking part in this research study, medical care (emergency or immediate non-emergency) for the injury will be provided to you at no cost by the V A. The V A has not set aside funds for other payments if research subjects are injured or harmed. You have not given up any legal rights or released the V A or its agents from liability for negligence by signing this form. In the event of a research-related injury or if you experience an adverse event, please immediately contact Dr. (insert name) at (XXX) XXX-XXXX) during the day and (XXX) XXX-XXXX) after business hours. If you need emergency hospitalization in a private hospital because you are unable to come to the V A, have a family member or friend contact Dr. (insert name) so that the V A can coordinate your care and any related costs with the private hospital. The V A will pay the costs of any emergency hospitalization related to the research."

Yes NO N/A

11. Does the consent have signature lines for the subject and/or the subject's legally authorized representative, a witness whose role it is to witness the subjects (or legally authorized representative's) signature, and the person obtaining the informed consent?

Yes

NO

N/A

12. VA Consent form has statement to provide participants with contact information for a person independent of the research team to contact when:

- a. The research staff can not be reached.
- b. They wish to talk to someone other than the research staff.
- c. They wish to voice concerns or complaints about the research.

Yes

NO

N/A

13. If the research involves banking, is this a VA approved banking facility?

Yes

NO

N/A

Reviewer Recommendation:

Table []

Disapprove []

Approve []

Approve Pending []

Reviewer Name _____

Reviewer Signature _____

Department of Veterans Affairs
Jesse Brown VA Medical Center
820 S. Damen Avenue
Chicago, IL. 60612

R&D 537/151
March 10, 2008
Revised Version 1.1

**Outreach Program for Human Research Participants
at the Jesse Brown VA Medical Center (JBVAMC)**

PURPOSE: To describe responsibilities and procedures for active involvements of research participants in protocols and conduct of outreach activities to human research participants and their communities.

POLICY: To comply with the ethical principal of respect for persons participating in research and maximize their involvement in the research process, including proactive outreach activities.

RESPONSIBILITIES:

- a. The Hospital Director is responsible for oversight of all aspects of the Research Program at Jesse Brown VA Medical Center.
- b. The Associate Chief of Staff for Research and Development (ACOS/R&D) is responsible to ensure respect for human participants, involvement in protocols, and outreach of communities.
- c. The Human Subject Research Specialist are responsible for day –to-day assurance of compliance with all aspects of the Human Research Protection Program (HRPP), including participants outreach activities.
- d. Investigators involved in human research protocols are responsible for maintaining respectful interactions with participants, involving research participants at every stage, enhancing appropriate safeguards, and answering questions in a complete and sensitive manner, and participating in outreach and educational activities to participants and their communities.

PROCEDURES:

- a. The VA consent form for each protocol has been reviewed by the Institutional Review Board (IRB), VA representatives in IRB, and the R&D Committee to ensure that procedures are in place to facilitate the ability of research participants to ask questions, express concerns, or voice complaints to the investigator.
- b. The human study research coordinators are distributing pamphlet which provides information regarding a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives or their community to discuss concerns, raise questions, obtain information, complaint about the research or questions about rights as

- a research participant or input from potential participants help to design future studies. The pamphlet is disseminated by investigators to all persons who are going to participate in the human research protocol. In addition, this pamphlet is posted on our website www.chicago.med.va.gov and click Research for detail.
- c. The Jesse Brown VA Medical Center is celebrating VA Research Week each year during 2nd week of May. The R&D office invites all VA researchers to bring their research posters or abstracts for display in the atrium at JBVA highlighting our VA research projects and accomplishments as a part of outreach activities for current, prospective, or past research participants or their designated representatives or their community. The investigators and their staff are also available to response any research related questions.
 - d. The Jesse Brown VA Medical Center is having a Complaints and /or Allegations of Non-Compliance in Human Research Studies policy and procedures to implement participant outreach program.
 - e. The Research and Development Committee is reviewing quarterly feedback telephone audit questionnaire related to VA consent process. The R&D Committee is responsible for evaluating the adequacy of the outreach activities annually in July each year and recommending changes as may be indicated.

Tissue Banking Procedures at the Jesse Brown VA Medical Center

All new applications for VA approved tissue banks must be submitted to ORD by the Associate Chief of Staff for Research at the VA Medical Center on behalf of the principal investigator/project director. Applications cannot be submitted by non-VA investigators.

a. All new applications for VA approved tissue banks must clearly address the following points in the submitted memo:

1. The justification for establishing a tissue bank or for banking specimens at a non-VA repository.
2. The benefits of the tissue bank to veterans, the VA investigator(s)' research program and the VA Medical Center.
3. A description of the system used by the bank for the protection of veterans' privacy and confidentiality including protection of all clinical and personal data, the location and accessibility of the data, coding system utilized, and other important regulations.
4. An assurance that the specimens cannot be linked to the veteran's social security number or name and that the code used to identify the specimen is maintained at the VA facility. (Under very rare circumstances, ORD may waive this requirement).
5. A statement indicating whether the PI will transfer to the tissue bank any information from the patient's medical record and if such, an exact outline of the information.
6. A statement indicating that all future uses of VA samples will be done through VA-approved protocols. If this can not be assured, a clear description of the reasons and the mechanisms
7. Used by the bank to distribute specimens to researchers, including a description of the oversight mechanisms protecting these specimens.

8. A written assurance indicating that upon termination/closing of the bank, all veterans' biological specimens shall be destroyed or returned to the originating VA.
 9. A written assurance indicating that the specimens and all links to clinical and personal data can be destroyed upon the request of the donating human subject.
- b. The front page of the application must state the name of the PI, the name, number and address of the VA Medical Center, the title of the project collecting/banking specimens, and the name, address and contact information of the tissue repository.
 - c. The biographical Sketch of the PI shall be appended after the memo.
 - d. A copy of the research protocol, the recent IRB and R&D committees' approval letters must be appended to the application after the biographical sketch section. In addition, the application must also include the IRB approved and stamped consent form.
 - e. A copy of the manual for the tissue bank. This manual should provide sufficient information regarding the bank's policy, mechanisms of tissue acquisition and redistribution, and all oversight mechanisms in place.
 - f. The informed consent under which specimens are collected must meet all the requirements stated in VHA Handbook 1200.5 "Requirements for the Protection of Human Subjects in Research". In addition, the consent form must clearly address the following points:
 1. Will the collected specimen be used for future research and if so, what choice of research (research specified in the consent form; research conducted by the PI only; research conducted by other investigators; research related to specific diseases; etc.).
 2. Will the specimen be used to generate a cell line or for genetic testing.
 3. Will the specimen be stored without any identifier (de-identified) and if so, will it be linked specimen or unlinked specimen.
 4. Will the research results be conveyed to the subject and/or health care provider?
 5. Will the human subject be contacted after the completion of the original study?
 6. Will the specimens and all links to clinical data be destroyed or removed from the bank upon the subject's request.
 7. The disposition of the specimen after completion of the study or at the end of the banking period.

8. Any potential conflict of interest or financial gains for the investigators or the participating institution.

Please mail your application to:
Attn.: James Free
Tissue Banking Program
Medical Research Service
1400 I Street, Suite # 400
Washington, DC 20005

**TISSUE BANKING APPLICATION
STATION # 537/151
Jesse Brown VA Medical Center
820 S. Damen Avenue
Chicago, IL 60612
Tel. # 312-569-7441
Fax # 312-569-8114**

Principal Investigator

Last Name _____ **First Name** _____

IRB Protocol # _____

Project Title:

CONTACT INFORMATION OF THE TISSUE REPOSITORY

Last Name _____ **First Name** _____

Full Address:

Telephone #:

Fax:

E-Mail Address _____

Principal Investigator's Signature

Date:

Management of VA Pharmacy at the Jesse Brown VA Medical Center

Flowchart

**Investigational Drugs and Investigational Device Protocol Procedures
IRB / R&D Approved IND / I D New Protocol**



**P.I. will Prepare R&D Committee Review Packet with IRB application
After IRB approval the R&D will Review and give Final approval/ approval pending
clarification/ disapprove / table**



R&D Committee will review and give final approval



**R&D approval letter, R&D approve stamp VA Consent, 10-1223 form. P.I. will
forward VA IND Form 10-9012 with signature to the R&D Office**



**The R&D office will forward 10-9012 form to the IRB for the IRB chair signature.
After IRB Chair signature 10-9012 form will be forwarded for the R&D Committee
Chair signature.**



.....R&D Office



**R&D office will call P.I. to report final approval
following
IRB approval, R&D Committee approval, Stamp
VA Consent Form, a copy of 10-1223 form,
R&D and a copy of VA form 10-9012
Stamped VA Consent Form,**

**R&D office will forward the
documents to VA Pharmacy.
IRB approval, IRB application,
approval,**

10-1223 VA Form and 10-9012 VA

Form,

and protocol



Continuing Review & Amendment



IRB approved Continuing Review and Amendment forwarded to the R&D office for review and approval

R&D Office



Call P.I. to forward R&D and IRB approvals, and VA Forward R&D and IRB approvals and VA

Stamped VA Consent Form to continuing study Stamped VA Consent Form to the VA

Pharmacy for their records

*** The VA research pharmacy will report to the R&D Committee quarterly regarding protocol deficiency at pharmacy for quality purpose. The R&D office will feed required documents to the VA pharmacy.**

Policy for Flagging Medical Records

1. PURPOSE:

To describe the policy and procedures for the flagging of research subjects' medical records to indicate participation in a research study at the JBVAMC.

2. POLICY:

VA regulations require that the records of all research subjects enrolled in research at a VA facility have a flag placed on the medical record (electronic or paper) unless the requirement is waived by the R&D Committee.

3. RESPONSIBILITIES:

- a. The JBVAMC R&D Committee must review each human subject research protocol to determine if subjects' medical records must be flagged to meet compliance requirements of VA Policy 1200.5 Appendix C 3.c.
- b. The Principal Investigator, or designated research team member, must enter the term "Clinical Warning/Research Protocol" to document research related issues (not general medical care), into the record of each enrolled subject in the Computerized Patient Record System (CPRS).
- c. The Principal Investigator must provide a list of newly enrolled research subjects to the R&D Office every six months from the date of initial R&D approval of the research.
- d. The R&D Office Human Subjects Research Coordinators conduct quarterly audits of the CPRS and telephone surveys of research participants. The results of these audits are reported to the Research and Development Committee.

4. PROCEDURES:

- a. The R&D Committee will determine if the patient's medical record (electronic or paper) 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.
- b. The R&D Committee will make a flagging determination at the time of initial protocol review. All research study protocols that are determined to be greater than minimal risk and/or place the subject at greater than minimal risk will be reviewed to determine if flagging of the medical record is required.
- c. The R&D Committee may determine that the medical record does not require flagging if:
 - i. 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
 - ii. 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.
- d. The R&D Committee's determination for flagging of the medical record must be documented in the R&D Committee meeting minutes for each human subject protocol reviewed.
- e. The R&D Committee approval letter will state whether the protocol needs to be flagged in the medical record.
- f. The R&D Committee have established the following criteria to fulfill the CPRS requirement:
 - i. All active human research studies with a VA consent form that are actively enrolling patients must post the CPRS clinical warning.
 - ii. All active drug studies either closed for accrual but open for follow-up or actively enrolling patients must post the CPRS clinical warning.
 - iii. All active human studies closed for accrual but collecting new data must post the CPRS clinical warning.
 - iv. All active behavioral drug abuse studies, observational studies, and/or rehabilitation studies collecting new data must post the CPRS clinical warning.
 - v. All active human studies closed for accrual but open for data analysis do not need to post the CPRS clinical warning.

- g. The Principal Investigator, or designated member of the research team, must enter the protocol information into CPRS no later than three (3) days after the subject has signed the informed consent document.
- h. If the research protocol is flagged, the Principal Investigator must report the following information to the R&D office twice a year on June 1 and December 1.
 - ii) Full name of the research subject(s) including middle initial
 - iii) Last four digits of the SS#
 - iv) Last page of each signed consent form
 - v) Home telephone number(s) of the research subject
 - vi) The total number of research subjects enrolled as of the requested date
 - vii) Last page of each signed HIPAA document.
- i. The R&D Office Human Subjects Research Coordinators will conduct a telephone audit to ensure that the research is being conducted according to protocol. Randomly selected subjects will be contacted and asked specific questions to ensure that:
 - i. they understand the nature of the research
 - ii. an explanation of an alternate treatment plan was provided to them
 - iii. their participation is voluntary
 - iv. they signed a consent document prior to participation in the research

Telephone audits will be conducted quarterly and the results will be reported to the R&D Committee to meet VA compliance requirements.

- j. Failure to comply with flagging and reporting procedures will be considered non-compliance with VA regulations and may cause suspension of the protocol by the R&D Committee.

5. REFERENCES:

VHA Handbook 1200.5, Requirement for the Protection of Human Subjects in Research, Department of Veterans Affairs, Veterans Health Administration, Washington, DC.

Department of Veterans Affairs
Jesse Brown VA Medical Center
820 S. Damen Avenue
Chicago, IL 60612

R&D 537/151
March 10, 2008
Version 1.1

**Principal Investigator Assurance Conducting Research
at the JBVAMC Check List Regarding Adequate Resources
and Facilities to Protect Human Research Participants**

IRB Protocol #

Protocol Title:

Principal Investigator Name:

Resources Allocated to the Human Research Protection Program

- 1. Available research staff needed for the number of research subjects to be enrolled.**

Adequate	Inadequate	Comments
-----------------	-------------------	-----------------

- 2. Research Office Space enough to accommodate computers and office equipment.**

Adequate	Inadequate	Comments
-----------------	-------------------	-----------------

- 3. Secure storing available for research records.**

Adequate	Inadequate	Comments
-----------------	-------------------	-----------------

- 4. The Investigator will obtain enough funding to bear the cost of staff and research equipment.**

Adequate	Inadequate	Comments
-----------------	-------------------	-----------------

I assure the Research and Development Committee that are available adequate resources and

facilities to Conduct Research at JBVAMC and will provide adequate protection to human

research participants

Principal Investigator Signature

Print Name:

Date: