

# Human Research Protection Program (HRPP) Investigator Handbook

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Research and Development  
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Chicago Illinois

<http://www.chicago.med.va.gov>

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# **Investigator Handbook**

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Jesse Brown VA Medical Center  
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820 S. Damen Avenue  
Chicago, IL. 60612

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Welcome to the Research and Development's (R&D) Human Research Protection Program (HRPP) Handbook! Here at the Jesse Brown VA Medical Center, we strive to be on the forefront for the advancement of protections for human participants in research. We have an excellent record of compliance with human research protection rules, regulations, and policies, and we are working to continually improve in this area. This handbook has been prepared to aid you in your work as a researcher. It should be a reference that will help fulfill your obligations regarding human participant protections. This handbook is a testament of R&D's strong commitment to develop a community of researchers that are exceptional with regard to implementing human research protections. Please know that the R&D staff is here to assist you when needed. Thank you for your commitment to research and to the protection of human participants.

## **RESEARCH AND DEVELOPMENT VISION AND MISSION STATEMENT**

### **OUR VISION**

To advance the care of veterans through high quality scientific research

### **OUR MISSION**

Research services serve the VHA mission in three ways.

- a) Development of new knowledge, new technique, and / or products that lead to improved prevention, diagnosis, treatment, and control of disease.
- b) Attraction and retention of the highest quality professional staff that improves care for veterans.
- c) Cultivation of a stimulant intellectual environment that is beneficial for both patient care and educational programs.

## HRPP Overview and Purpose

In conformance with the Belmont Report, the document, which codifies the United States' ethical principles underlying modern concepts of human subject protection, there are three key principles governing the use of humans in research at the JBVAMC. These are **Respect for Persons, Beneficence** and **Justice**.

The purpose of the HRPP is to assure appropriate protections for human research participants and to maintain compliance with all applicable policies, regulations, and laws. The Medical Center Director is the Institutional Officer for the HRPP. The Director is ultimately responsible for the overall conduct of the R&D program, including the welfare of human research participants; the Director also is the signatory / institutional official for all Assurances. The Director is responsible for assuring that adequate resources and facilities are provided for the HRPP and for appointing members of the R&D Committee. The JBVAMC is committed to conducting its HRPP with the highest regard for the welfare of human participants and in compliance with the ethical principals of the Belmont Report and the regulatory requirement of the Common Rule. The HRPP is a multi-tiered program involving the Hospital Director, Chief of Staff, Associate Chief of Staff for R&D, Administrative Officer for R&D, Human Subjects Research Specialist, IRB(s), Research Administrative Staff (IRBs), Investigators, and research team members.

### What is HRPP?

At the national level, the Veterans Health Administration (VHA) is committed to being at the forefront of strategies for the protection of human participants in research programs. One of the responsibilities of the R&D Committee is ensuring the welfare of all human subjects. Therefore, the Research Office at the JBVAMC has designated a Human Study Research Specialist (HSRS), who oversees all aspects of the VA human research portfolio. HSRS oversight includes ensuring proper credentialing, educational verification, and training for human researchers. There is close interaction with the affiliate IRB, the JBVAMC/ Northwestern University/ University of Illinois at Chicago (UIC) Collaborative IRB (i.e., UIC IRB #4).

The continual pursuit of knowledge that can help not only V A patients, but also other healthcare consumers is highly valued and supported throughout the VA system, and at the Jesse Brown VA Medical Center. One of the most important qualities of a researcher is the "intention to do careful, ethical work" (Parker & Katz, 1998\*). Protecting the welfare of our patients who accept, or decline, to participate in research must be the primary concern of every research protocol involving human participants. All health science professions have ethical principles and guidelines that guide the behavior of those practicing in that profession. There are also principles (like those in the Belmont Report) and regulations (such as the Common Rule) that guide the ethical behavior of those conducting human participants research.

## **Elements of the JBVAMC Human Research Protection Program (HRPP)**

The HRPP at JBVAMC comprises three arms. These are:

**A. Institutional review**, initial, amendment, and continuing review of all research involving human subjects - This responsibility is accomplished through IRB and Research and Development (R&D) Committee review and oversight. The R&D Committee review is supported by various designated subcommittees; the JBVAMC uses UICIRB #4.

**B. Education** - There is a program ensuring that investigators, research staff, IRB members and other individuals with responsibility for human subject protection have completed required training in human subject use and protection. Instructional methods and materials include web based tutorials and information, VA and UIC manuals, handbooks and policy documents, ongoing educational conferences and internal and external training activities.

**C. Compliance and Quality Improvement** - There is an ongoing program evaluating HRPP effectiveness, including quality improvement activities. Evaluation and improvement include measuring, assessing and improving compliance with institutional HRPP policies, assurances and other requirements for the protection of human subjects in research.

### **Who are the staffs responsible for the HRPP?**

#### **A. Medical Center Director:**

JBVAMC, under the direction of the Director, will: Apply for, receive, and maintain an Assurance of Compliance with DHHS, OHRP, and ORO. The Director is the VA's Federal wide Assurance Signatory Official and is ultimately responsible for oversight of human subject protection for JBVAMC. Such oversight is accomplished through membership on the Research and Development Committee, regular communication with the Chief of Staff and ACOS for Research and Development, and ongoing communication with members of the research community and academic affiliates. Arranges for securing the services of the UIC IRB #4. This arrangement is legally documented in an MOU that includes at a minimum specific requirements for the membership and operation of the IRB to review VA research in compliance with VA regulations, the respective responsibilities of the institution and the designated IRB for human subject protection, the scope of activities delegated to the IRB, the method, frequency and nature of reporting to the R&D Committee, the process by which the institution evaluates the IRB's performance, the remedies, including revocation of the Formal IRB Agreement, and available to the institution if the designated IRB does not fulfill its obligations.

Apply for, receive, and maintain accreditation of its HRPP, including those elements supported by the University of Illinois at Chicago and Northwestern University, by an organization contracted by VHA to perform this function. Provide sufficient resources for the HRPP, including the R&D Committee and the IRBs. Engage in a systematic budgeting process for the HRPP resources including personnel, materials, space, equipment, training and education. Budgeting includes consideration of the following factors:

- a. Analysis of the volume of research to be reviewed.
- b. Feedback from accrediting and oversight bodies, IRB members and staff.

#### **B. Chief of Staff:**

The Chief of Staff has overall responsibility for all clinical and academic activities of JBVAMC, including research.

#### **C. Associate Chief of Staff for Research and Development**

The ACOS for R&D, , is responsible for daily operation of the Research Service, providing administrative support to and implementing the decisions of the R&D Committee and the affiliate IRB. The ACOS / R&D ensures that the administrative infrastructure exists to effectively implement the research mission of the JBVAMC in compliance with all applicable federal regulations. The ACOS/ R&D provides advice and assistance to the R&D Committee and the affiliate IRB on administrative and regulatory matters, and to investigators on both scientific and administrative matters, including the requirements for conducting research involving human subjects. The ACOS /R&D is also responsible for management and oversight of the research enterprise of the JBVAMC. As such, this person is charged with implementation of the HRPP policy to include the designation of a Medical Administration Specialist to review and evaluation of the reports and results of compliance assessment and quality improvement activities, implementation of needed improvements and follow-up on actions as appropriate monitoring changes in VA and other federal regulations and policies that relate to human research protections, serving as the individual to whom research subjects and others may ask questions or voice research-related concerns or complaints. All concerns or complaints will receive a response including investigation and appropriate remedial action if necessary.

#### **D. Administrative Officer for R&D**

The AO/R&D supervises the day –to-day operations of the Research Office and organizes staff support to efficiently operate the R&D Committee. The AO/R&D maintains up-to-date knowledge of federal – wide requirements provided in both regulations and interpretations for conducting VA human studies research. The AO/R&D uses this knowledge to advise the ACOS/R&D, affiliates IRB, and investigators concerning relevant regulations and polices. The AO/R&D is also responsible for the deployment of resources as required to maintain compliance with HRPP activities.

## **E. Human Subject Research Specialist**

He/ She is responsible for fulfilling all **educational** requirements mandated by VA ORD and OHRP, ensuring communication among investigators, the IRB, and other staff involved in research, arranging access to the facility's FWA, applicable VA policies, and other related federal regulations, as well as human subject protection policies and procedures, maintaining accurate, up-to-date records regarding the mandatory training and certification of investigators and other appropriate research staff in the protection of human research subjects as required by the ORD, VACO, serving as the institutional staff member who receives communication from federal agencies such as FDA or OHRP. These communications must be forwarded to the Associate Chief of Staff for Research and Development (ACOS/R&D) and the Medical Center Director.

## **F. R&D Committee**

The R&D Committee at JBVAMC is governed by the Federal Policy codified by VHA handbook 1200.1 STANDARDS for all research activity within the JBVAMC. The standards include those concerning the scientific quality of research & development projects, protection of human rights, laboratory safety, and welfare of animal subjects used in research and development and financial oversight of Research Service. The R&D Committee provides the overall direction and oversight for the R&D Program. The primary FUNCTION of the Research and Development Committee is to assure continuing high quality Research and Development (R&D) Programs by critically evaluating the quality, design, desirability, and feasibility of each new and continuing research and development application. All research and development activities, whether funded or unfunded by the VA or other sources, are within its purview. The R&D is providing oversight of programs and reporting activities to assure maintenance of high scientific standards, protection of human subjects, adequate safety measures, proper use of animals and fiscal responsibility, planning and developing broad objectives of the R&D so that it supports the patient care mission of the facility, recommending policies on the recruitment and development of personnel supported by R&D fund, determining the extent to which the R&D Programs have met its objectives, advising the ACOS, COS, and the Director on professional and administrative aspects of the Research and Development Program. All R&D committee members, VA representatives in IRBs, Investigators, and research team must complete annual training in CITI Course in the Human Research Subjects, VHA Privacy Policy Training, VA Cyber Security Awareness, and VA Research Data Security and Privacy. All R&D committee members, chairman, and ACOS are required to sign a statement of confidentiality. An 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 on a protocol if a conflict exists. The R&D Committee will serve as a privacy board for research related activities for the JBVAMC. The R&D Committee APPROVAL, conditional or otherwise, must be obtained in

writing prior to the start of any research project. The R&D committee will evaluate the productivity of the members of the Research and Development Service by reviewing peer reviewed publications at least every year. This evaluation can be accomplished during review of each investigator's current curriculum vitae. The R&D committee is responsible to maintain overall functions and activities of each subcommittee. The R&D committee reviews resources of HRPP which include but are not limited to personnel, materials and supplies, space, capital equipment, training and education. All Subcommittees will work under supervision of the R&D committee which are as follows:

1. Animal Care and Use Subcommittee (ACUS)
2. Research Safety & Common Resources Subcommittee
3. Laboratory & Office Allocation Space Subcommittee

All studies involving the use of VA human subjects will be reviewed by the Collaborative IRB (UIC IRB #4) and then by the R&D Committee. Approved non-exempt VA studies will be reviewed at least annually by the appropriate IRB and R&D Committee. Exempt studies are reviewed annually only by the R&D Committee. All modifications and amendments of proposals must be reviewed by the IRB and the R&D committee for final approval. The R&D Committee will review the structure and performance of the IRB every year in July. Research Progress Note Titles and Templates Used in Computerized Patient Record System (CPRS) Graphical Use of Interface(GUI): Investigators are responsible to include a clinical warning in the electronic patient medical record in CPRS GUI system to document research related issues for Veterans participating in research study. The R&D Committee will determine protocols to be flagged in CPRS. The R&D committee will handle all Allegations of noncompliance related to VA investigators are referred to the Collaborative IRB, is as described in the UIC HSPP policy, *Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations*. The findings of the IRB are sent to the R&D Committee for review. The R&D Committee reviews Individuals whose willingness to volunteer in a research study may be unduly influenced or coerced and individuals with limited autonomy. These individuals may include, but are not limited to, children, prisoners, pregnant women, mentally disabled, or economically or educationally disadvantaged persons. The R&D Committee regularly evaluates human subject research protection through QA/QI reports prepared by the human subject research coordinators. The R&D Committee review monthly IRB meeting minutes, R&D Committee meeting minutes, Animal Care and Use Subcommittee meeting minutes, Research Safety and Common Resources Subcommittee (Alternate Month), Space Subcommittee Meeting Minutes (PRN), and WOC Application list. The R&D Committee evaluates quarterly review of Quarterly Feedback Questionnaire from VA Representatives on the IRB, Quarterly Patient Informed Consent Questionnaire Telephone Audit Report, VA Pharmacy Quarterly Feedback Report, Quarterly CPRS Report (JBVAMC), and Resources Allocated to the Human Research Protection Program, including staff, equipment, finances,

accommodate computers, office equipment, conference room, and space to securely store records. The R&D Committee also reviews non-compliance quarterly reports regarding patients enrolled but not in CPRS.

### **Key Staff Members**

1. James S. Jones, Medical Center Director, JBVAMC 312-569-6101
2. Wendy Weinstock Brown, MD, MPH, Chief Of Staff, JBVAMC 312-569-6102
3. Israel Rubinstein, MD ACOS / R&D JBVAMC 312-908-8163
4. Karen Lenehan, BS, Acting AO/ R&D JBVAMC 312-569-6343
5. Salar Khan, MD., MBA. Medical Administration Specialist, 312-569-7426
6. Carol Lane, BA, Medical Administration Specialist 312-569-7441
7. Doreene Weirzgacz, Program Support Assistant 312-569-7440
8. Peter Sporn, M.D. and Donald Lavelle, M.D. , co-Chairs R&D Committee

### **Accreditation History**

The JBVAMC was audited by the National Committee on Quality Assurance (NCQA) in October 2005. The JBVAMC (Westside) obtained 100% score (passed) and JBVAMC (Lakeside) obtained 82.8 % (passed). Our status was pending University of Illinois at Chicago and Northwestern University to be accredited by the NCQA within 12 months from November 2005. The NCQA contract with Central Office expired in December 2005.

### **Types of Human Research Conducted**

The types of human studies reviewed by IRB are Hematology & Oncology Studies, investigational drugs/ marketed drugs studies, social and behavioral studies, bio-medical studies, retrospective studies (data collection/ screening studies), Eye/ Limbs rehabilitation studies, and using human cell line . The Research Office through its HRPP conducts activities intended to improve and promote a solid foundation for human research at the JBVAMC. Actions include the development of appropriate policies and procedures for the R&D and to provide ongoing education and training.

### **Unique Characteristic of Organization**

The JBVAMC collaborates with its two academic affiliates, the University of Illinois at Chicago and the Northwestern University to provide human research protection program at the Jesse Brown VA MC through the JBVAMC/NU/UIC Collaborative IRB.

**Affiliate # 1: University of Illinois at Chicago:** The Jesse Brown VA Medical Center is affiliated through their FWA with the UIC-IRB # 1, # 3 and # 4. The JBVAMC has two VA representatives on the UIC-IRB #1, three on the UIC-IRB #3 and four on UIC IRB #4.

The IRB #1 reviews biomedical research and IRBs # 3 and # 4 review both biomedical and social/ behavioral research. Each IRB meets twice y each month.

**Affiliate # 2: Northwestern University:** The Jesse Brown VA Medical Center is academically affiliated with the NU-IRB Panels C, D, and Q. The JBVAMC has two VA representatives in each NU-IRB Panels C and D. The Panel Q has only one VA representative.

The NU –IRB Panel C is met once in a month reviews biomedical. The NU –IRB Panel D is met once in a month reviews social. The NU-IRB Panel Q is met every week reviews behavioral research.

UIC IRB #4 is the only IRB reviewing new and continuing review submission for research being performed at the JBVAMC. Protocols from the other NU and UIC IRBs are transferred to UIC IRB # 4 at the time of their next continuing review. After June, 2009, UIC IRB # 4 will serve as the sole IRB for JBVAMC.

### **What are the responsibilities of the Principal Investigator in relation to the HRPP?**

The PI maintains the responsibility for ensuring the protection of all human participants involved in VA-approved research, and is expected to abide by the highest ethical standards. The PI's responsibilities in relation to protecting human participants include:

1. Developing and executing research that incorporates the principles of the Belmont Report.
2. Conducting research in accordance with an approved protocol.
3. Overseeing all aspects of the research, including supervision of the research team members, fellows, residents, and other staff involved in conducting human research.
4. Ensuring that the informed consent process approved by the Research and Development Committee and IRB is followed.
5. Establishing and maintaining open lines of communication with his/her research participants throughout their research participation.
6. Complying with institutional policies and administrative requirements, including requirements of the IRB (e.g., submitting amendments, continuing reviews, serious adverse events, unanticipated problems) for conducting research.
7. Acknowledging contributions of the VA when presenting results of studies in publications, presentations, media interviews, and other public activities as outlined in VHA Handbook 1200.9.
8. Maintaining appropriate oversight of their research protocols, research staff, research conduct, and selection of study participants including recruitment.

### **Role of Principal Investigator in HRPP**

The Principal Investigator is the person with ultimate responsibility for the safety and welfare of research subjects. The P.I. is responsible for designing studies that are scientifically sound and minimize risks to subjects while maximizing research benefits, assuring that the research is conducted responsibly and in accordance with the IRB requirements, assuring that research personnel are adequately trained and supervised, disclosing potential conflict of interest, reporting serious adverse events and unanticipated problems, ensuring adequacy of the informed consent process, maintaining initial and ongoing approval for the research, and meeting education requirements for self and staff. The use of drugs in research must be carried out in a responsible manner. The storage and security procedures for drugs used in research shall follow all federal rules, regulations, and laws regarding controls and safety that pertain in ordinary clinical situations. All drugs used in research will be in accordance with VHA Handbook 1200.5. An investigational drug for clinical research use is one for which a sponsor has filed an Investigational New Drug (IND) application (21 CFR Part 312).

Pursuant to these regulations an IND application goes into effect 30 days after FDA receives the application (unless the investigations described in the IND application are subject to clinical hold) or earlier if notified by FDA that the clinical investigation may begin (21 CFR 312.40). The investigator is responsible for informing the Pharmacy Service that IRB and R&D Committee approval has been obtained. A copy of VA Form 10-1086, VA Research Consent Form, must be sent to Pharmacy Service to document the subject's consent to participate in the study. The PI must inform the Chief, Pharmacy Service, the IRB, and the R&D Committee when a study involving investigational drugs has been terminated. All applicable requirements in M-2, Part VII, Chapter 6, Investigational Drugs or superseding document must be met. An investigational device, as defined by the FDA, is a medical device, which is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. Use of investigational device in a clinical trial to obtain safety and effectiveness data must be conducted according to FDA's Investigational Device Exemption (IDE) regulations, 21 CFR part 812 and other applicable FDA regulations. The IRB reviewing investigational medical device protocols must have written procedures for: conducting the reviews, determining if the device represents a "significant risk," and reporting findings to the investigator. If the study of the device is not exempt (21CFR 812.2 ©, the device must be characterized as "significant risk" (SR) or non-significant risk" (NSR). The IRB must determine and document if the device represents SR or NSR. SR device studies must be conducted in accordance with the full IDE requirements (21 CFR Part 812).

### **How Can HRPP Questions, Suggestions, or Concerns be Addressed?**

Any person listed as a Key staff member responsible for the HRPP is available to answer questions, accept suggestions, or consider concerns voiced by investigators or their team members. In addition, the UIC Office for the Protection of Research Subjects 312-996-1711, 1-866-789-6215 (toll-free) or e-mail: uicirb@uic.edu) is available to answer questions, accept suggestions, or

address concerns voiced by investigators, research staff or research participants.

## **R&D Application**

What are the steps in the application process?

Completion of this packet is required for review of research projects by the Research and Development (R&D) Committee. Final approval will not be given until all required subcommittees of the R&D Committee (UIC-IRB or NU-IRB, Animal Care and Use Subcommittee, Research Safety Subcommittee, Space Subcommittee, and Radiation Safety Subcommittee) have also approved the protocol. Routing to the required subcommittees (except UIC-IRB and NU-IRB) will be handled internally by the Research Office.

Application includes

Research and Development Committee dates  
Request to Review Research Proposal / Project  
Funding Information  
Research protocol Narrative

VA Form 10-1223

VA Form 10-9012

FDA Form 1571

FDA Form 1572

VA Form Consent for Use of Picture and / or Voice 10-3203

Tissue Bank Application

Approved Human Research Protocol Radiation Dose Supplement (if applicable)

VA Authorization for the Release of Protected Health Information for Research Purposes

Request for Waiver of Authorization to Release Medical or Health Information (if applicable)

Approval or pending approval of IBC (if applicable)

JBVAMC PI Certification of Storage and Security of VA Research Information and Data Security Checklist for PIs

Use of biological specimens (if applicable)

Research Financial Conflict of Interest Statement

Statement of Disclosure

PI Assurance Application

All project staff who will access VA patients and/or data, or who will access VA space for research activities are required to hold VA appointments (Paid or Without Compensation [WOC]). Detailed information on the forms and procedures can be obtained in the Research Staff Section of the HRPP Handbook.

Submit the entire packet (including hardcopy of IRB application) to the VA R&D Office, Room 6209 or call at 312-569-7441.

### **Why must I also apply to the IRB?**

The IRB reviews all VA protocols involving human subject participants prior to initiation; and continually monitors ongoing research through periodic reviews, including the review of adverse events and amendments to the protocol. The IRB is charged with the responsibility of protecting the rights and welfare of all research participants in VA-approved research as required by the Common Rule and the Federal-Wide Assurance (FW A).

### **What if my project appears to be Exempt?**

All research involving human participants must be submitted to the IRB. Decisions regarding Exempt status can only be made by the IRB. Exempt protocols reviewed and approved by the IRB and R&D Committee are subsequently reviewed every 12 month by the R&D Committee. The investigator must submit an annual report for exempt protocols for the R&D Committee review and approval, per VA regulations.

### **How do I apply to the IRB?**

Application materials and instructions are available on the UIC and NU websites. The Collaborative IRB will not accept submissions for research to be performed at the JBVAMC without an IRB Protocol Submission Checklist signed by the R&D staff.

### **What is a Conflict of Interest (COI)?**

A Conflict of Interest is defined as any financial arrangement, personal obligation, or action of the investigator that exerts, or is perceived to exert, inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings.

Conflicts of interest arise because of:

1. Intellectual property involved in research and partnerships between industry and Academia.
2. Financial incentives by pharmaceutical or biotech companies for investigators conducting clinical trials or enrolling participants into a clinical trial
3. A particular role or relationship an investigator has within the administrative structure(s) of the institutions(s) with whom they are affiliated.

### **How do I disclose a CO I?**

Investigators must submit COI documentation with their IRB and R&D applications. This includes completion of the VA *RESEARCH FINANCIAL CONFLICT OF INTEREST STATEMENT* and the appropriate section on the NU or UIC application form.. The IRB will make final determination related to COI and Financial COI. The Jesse Brown VAMC will rely on IRB policy and procedures.

THE INVESTIGATOR IS RESPONSIBLE FOR DISCLOSING ANY COI. IF A COI DEVELOPS AFTER IRB APPROVAL, IT MUST BE REPORTED IMMEDIATELY. CONFLICTS OF INTEREST INVOLVING THE INVESTIGATOR'S SPOUSE OR DEPENDENT CHILDREN THAT REASONABLY APPEARS TO AFFECT THE

## RESEARCH MUST ALSO BE REPORTED.

IT IS THE INVESTIGATOR'S ETHICAL OBLIGATION TO CONSIDER THE POTENTIAL EFFECT THAT A FINANCIAL RELATIONSHIP OF ANY KIND MIGHT HAVE ON THEIR STUDY, INCLUDING INTERACTIONS WITH RESEARCH PARTICIPANTS.

Some examples of financial conflicts of interest:

1. Salary or payments for services (such as consulting fees or honoraria).
2. Compensation to the investigator(s) that is affected by the outcome of the study.
3. Stocks, stock options, or other ownership interests.
4. Patents, copyrights, or other intellectual property rights and any royalties from such rights. See R&D Conflict of Interest in Research Policy or VHA Handbook 1200.13 for more details.

### **Staff Appointments**

Who must acquire a VA staff appointment?

The JBVAMC to ensure that each member of the research team has the credentials, competencies, and qualifications to perform their assigned duties, all project staff who will access VA patients, and/or data, or who will access VA space for research activities must hold a V A appointment (Paid or Without Compensation [WOC]).

### **What are the procedures to receive a VA appointment?**

1. Notify the Research Secretary at 312-569-6166
2. The Principal Investigator(s) should complete the Request for Staff Appointment (JBVAMC).
3. The Principal Investigator should submit a Request for Functional Statement of Research Duties and Responsibilities. Note. Physicians and health care providers will have additional appointment requirements (e.g., submitting copies of licenses/certificates and/or following hospital credentialing requirements, as may apply).
4. The following documents should be submitted by the applicant: (a) Application for Federal Employment (OF612), (b) Questionnaire for Non-Sensitive Positions (SF85), (c) Declaration for Federal Employment (OF306), (d) VA Benefits Letter, and (e) Documentation of HIP AA Functional Classification. Note. The Questionnaire for Non-Sensitive Positions (SF85) is not required for appointments of less than six (6) months duration.
5. If the new Research staff member is not a U.S. citizen, submit a copy of the Visa.
6. Complete all required training activities; deliver certificates to Research Secretary or Human Study Research Coordinator.
7. Obtain key card for Research space after all required training is completed.

**What trainings need to be completed?  
What trainings will need to be completed annually after initial appointments?**

Please contact Carol Lane at 312-569-7441 for detail regarding trainings.

**Informed Consent**

How do I document informed consent?

The PI develops written informed consent documentation for participants to sign which must be approved by the IRB and the R&D committee prior to enrolling patients in a study.

The VA Research Consent Form template, available on the IRB website, must be used to produce informed consent documentation.

When informed consent is obtained, it is best practice to have the participant sign and date three (3) copies. One original should be placed in the participant's research file maintained by the PI. The one copy should be sent to the R&D Office and second copy placed in the participant's paper medical record. The participant must receive a signed and dated copy of the consent document. Informed consent documents are required to be retained for seven (7) years.

How do I document that a participant understands their rights in relation to the Health Insurance Portability and Accountability Act (HIPAA)?

Research participants must sign a "HIPAA Authorization" form. The HIPAA Authorization template is available on the IRB website. PIs can add their study's information to this template.

As with the informed consent document, it is best practice to have the participant sign and date three (3) copies of the HIPAA Form. One original should be placed in the participant's research file maintained by the PI; one should be forwarded to the R&D office. One copy should be placed in the participant's paper medical record; and one (signed and dated copy) provided to the participant.

**Continuing Review  
What is continuing review?**

The process of continuing review helps R&D and the IRB ensure that UIC, NU, and VA policies and procedures are being followed for each research study, and that each study is conducted according to the protocol approved by the IRB and the R&D Committee. Continuing review by the IRB is required for each approved non-exempt research proposal at least annually. The IRB will issue 90, 60, and 30 days notices to remind the the investigator to submit their continuing review for the IRB review and

approval . After IRB approval the R&D Committee will review and issue approval letter to the investigator. The investigator is referred to the UIC HSPP policies, *Continuing Review and Study Closure, Lapse in IRB Approval and Withdrawal of Research*, for further details.

### **Pharmacy**

#### **What information is maintained in the pharmacy regarding my research study?**

The Pharmacy maintains a protocol file for each study, which includes:

1. A copy of the IRB and R&D approved Consent Form (VA Form 10-1086) that has been signed by the participant.
2. A copy of the Investigational Drug Information Record (VA Form 10-9012).
3. A copy of the Report of Subcommittee on Human Studies (VA Form 10-1223).
4. A copy of the approved research protocol and any amendments.
5. A copy of the Investigator Brochure for the study.

#### **What information must be obtained for my study's Investigational Drug/Device Dispensing Log?**

The following information is included in an Investigational Drug Dispensing Log:

- Participant's name
- Social Security number
- Name of drug
- Dosage form
- Strength
- Source of the drug (manufacturer, sponsor)
- IRB number and approval/review dates
- Inventory notes
- Amount and date of drug received
- Expiration date of prescription
- Lot/control number
- Date of authority to use
- Serial number and date of prescription dispensed
- Pharmacist's verification signature
- Inventory balance
- Name of prescriber
- Initials of dispensing pharmacist

#### **The following information is included in an Investigational Device Log:**

- Name and identification number of the patient
- Device name
- Serial number
- Model number
- Manufacturer
- Name of issuing
- Inventory balances
- Other relevant details specific to the appropriate use and dispensing of the device

## **Adverse Event Report**

Investigators must comply with the requirements of the IRB and R&D for the problems that require prompt reporting to the IRB. Events requiring prompt reporting and the process for prompt reporting is described in the UIC HSPP policy, *Unanticipated Problems and Other Events Requiring Prompt Reporting*.

### **How is my study continually monitored by the IRB and the R&D Committee?**

The IRB and the R&D Committee reviews all non-exempt studies at least annually. The R&D Committee reviews exempt studies annually.

**FAILURE TO SUBMIT CONTINUING REVIEW REPORTS IN A TIMELY FASHION WILL RESULT IN EXPIRATION OF THE STUDY. A NEW IRB APPLICATION MAY HAVE TO BE SUBMITTED AND THE STUDY WOULD START OVER.**

### **What is required when I complete a study?**

When all data analysis and patient interaction is complete, follow IRB policies and procedures for submitting a final report, *Study Closure, Lapse in IRB Approval and Withdrawal of Research*,

### **What if an investigator does not comply or there is an allegation of non-compliance with IRB and VA policies or approved research protocol?**

All complaints or allegations of non-compliance are handled according to IRB policies and procedures, *Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations*. Possible consequences of noncompliance include: Termination of protocol(s) restrictions on privileges to conduct research, and potential disciplinary action.

## **Accreditation**

### **What is the Association for the Accreditation of Human Research Protections Programs, Inc. (AAHRPP) and how is it related to the JBVAMC'S HRPP?**

AAHRPP is a not-for-profit organization, and its mission is to protect the rights and welfare of research participants. The U.S. Department of Veterans Affairs (V A) has awarded a contract to AAHRPP to operate an accreditation program to ensure that VA medical centers are in compliance with V A and other relevant federal regulations designed to protect human research participants.

## **Additional Investigator Responsibilities For Research Activities Conducted At The Jesse Brown VA Medical Center (JBVAMC)**

**GUIDELINES FOR INVESTIGATORS CONDUCTING RESEARCH AT JESSE  
BROWN VAMC**

Version 2.5: October 1, 2008

The Research and Development Committee (R&D) of the Jesse Brown VA Medical Center (JBVAMC) must approve all research activities that engage the JBVAMC before the research may begin at the JBVAMC. This includes research studies that recruit JBVAMC subjects (staff, patients, volunteers), use JBVAMC resources (funds, facilities, space, personnel), or wish to post advertisements for the recruitment of subjects on JBVAMC property.

1. **Research involving the JBVAMC as a performance site.** Research may not be initiated at the JBVAMC until after you have received notice of JBVAMC R&D Committee approval. With the written approval from the JBVAMC R&D you will receive copies of the informed consent document(s), HIPAA authorization(s) and any recruitment, including advertising, or enrollment materials that have been approved by both the IRB and R&D for use at the JBVAMC.
2. The JBVAMC has appointed the Collaborative JBVAMC/Northwestern University (NU)/University of Illinois at Chicago (UIC) IRB as the IRB of record for reviewing biomedical and behavioral research that utilizes the JBVAMC as a recruitment or performance site. Review and approval by the Collaborative IRB is required for all applicable VA Research involving human subjects or human biological specimens prior to its initiation either through convened or expedited review or a determination that the research is exempt from IRB review or is not human subject research or human biological specimens.
3. **IRB Pre-Submission Process.** **The R&D Office must review the IRB and R&D applications for completeness before the investigator may submit the application to the Collaborative IRB.** Please bring two (2) copies of the completed applications and any relevant forms/ appendices. The ***IRB Protocol Submission Checklist*** lists the required documents for submission. Your submission for IRB review will not be accepted without a signature from the R&D Office on the checklist.
4. **HIPAA Authorizations for Research.** The IRB evaluates the VA HIPAA Authorizations or request for a waiver as part of their review of the protocol application and recruitment materials. However, the IRB does not serve as the privacy board for the JBVAMC. Final review and approval of HIPAA Authorizations or waivers must be conducted by the JBVAMC R&D.
5. **Amendments.** Any amendment including changes to the research protocol, research personnel, recruitment procedures, VA consent form(s) or HIPAA Authorization document(s), or that adds the JBVAMC as a performance site, must have R&D approval before implementation. A copy of the IRB approval letter along with any consent documents, HIPAA Authorizations, and/or recruitment materials for use at the VA will be forwarded by the IRB office directly to the JBVAMC R&D.

6. **Advertisement for and Recruitment of VA Subjects.** Any advertisements to be posted at the VA must have prior R&D Committee approval. This includes recruitment of subjects from the patient population within the JBVAMC facilities and advertisements for subjects that will be posted on any JBVAMC property. These documents will be stamped "R&D Approved" and cannot be posted at the JBVAMC without this stamp. Subjects may be recruited at the JBVAMC by UIC or NU investigators through advertisements, flyers, or physician referral only with prior VA R&D approval. Even if it is determined that a full R&D proposal may not need to be submitted to the R&D Committee, all recruitment materials/scripts/letters should be submitted to the VA R&D for review and "R&D Approved" stamping prior to use. Please call the JBVAMC R&D Office at 312-569-7441 for more information.

**NOTE:** Non-R&D stamped documents used or posted without appropriate R&D approval will be considered a protocol violation and could result in suspension of the research at the JBVAMC.

7. **Continuing Review.** The JBVAMC R&D must review and approve all IRB-approved research protocols at least annually. Applications for continuing review should be submitted to the IRB in a timely manner so that they may be reviewed and approved prior to the expiration of VA approval. Once IRB approval for continuing review has been received, the IRB will forward a notice to the JBVAMC R&D Committee. Consent documents re-approved through the continuing review process must also receive R&D re-approval before being used in the new approval period.
8. **Exempt Research.** VA regulations require an annual review of all research including those protocols that have been determined to be exempt. If your research protocol has been determined to be exempt, the JBVAMC R&D requires that you submit an annual report of research activities for your protocol. This report should be sent directly to the R&D. Please contact the R&D Office at 312-569-7441 for further information.
9. **Events Requiring Prompt Reporting to the IRB. Unanticipated** problems involving risks to subjects or others (unanticipated problems), adverse events, protocol violation, breaches of confidentiality, subject complaints and other events meeting the requirements for prompt reporting (see Collaborative IRB policy, "*Unanticipated Problems Involving Risks to Subjects and Others*") must be reported promptly to the IRB. The event should be reported to the NU or UIC OPRS using the *Prompt Reporting to the IRB* form within:
- 5 working days of becoming aware of a serious adverse event or change made to eliminate apparent immediate harm to subjects at JBVAMC, or
  - 10 days for other incidents requiring prompt reporting.

When different investigators exist, the VA investigator and UIC/NU investigator should both sign the report prior to submission to the IRB. This will ensure that the PIs at each institution are aware of reportable events. Please contact the appropriate office for details on reporting requirements: UIC (312) 996-1711 or NU (312) 503-6011.

10. **Final Reports.** When the research study is completed a final report must be submitted to the appropriate IRB. Prior to IRB submission, the final report should be submitted to the JBVAMC R&D Office for review and signature of the *IRB Protocol Submission Checklist*.
11. **Non-Compliance.** Any instances of observed or apparent non-compliance with the requirements of the IRB or VA are required to be promptly reported to the Collaborative IRB and the JBVAMC R&D Committee. Please contact the appropriate office for details on reporting requirements: UIC (312) 996-1711; NU (312) 503-6011 or JBVAMC (312) 569-7426.
12. **Audits, On-Site Evaluations, FDA Inspections, Reports to Sponsors or Federal Agencies.** These events and/or reports should be reported simultaneously to the IRB and JBVAMC R&D Committee.
13. **New Facility Human Protections Program (FHPP) Policy: Allocation of Funds for WISE Foundation or General Post Fund (GPF) for JBVAMC.** The VA Central Office has instituted a new facility human protections program (FHPP) policy to help VA Medical Centers defray the costs of protecting veterans that participate in industry-sponsored studies. VA directive 2003-031 ([www.va.gov/resdev](http://www.va.gov/resdev)) became effective July 1, 2003, and applies only to new, VA-approved studies funded by industry that involve human subjects. VA investigators are required to administer Non-Federal Research Funding through either WISE or GPF. Please contact the R&D Office for additional information (312) 569-6343.
14. **Tissue Banking Guidelines.** If a human subject research study involves the collection and/or storage of tissue, the tissue may only be stored at either a VA site or a VA approved off-site tissue bank. Please refer to the following Tissue Banking FAQ for further information: [http://www.research.va.gov/programs/tissue\\_banking/Tissue-Banking-FAQ.pdf](http://www.research.va.gov/programs/tissue_banking/Tissue-Banking-FAQ.pdf) For a list of VA approved off-site tissue banks, please refer to [http://www.research.va.gov/programs/tissue\\_banking/ApprovedTissueBanks.pdf](http://www.research.va.gov/programs/tissue_banking/ApprovedTissueBanks.pdf) Note that specific language must be in the informed consent if the study involves tissue banking: [http://www.research.va.gov/programs/tissue\\_banking/InformedConsent.pdf](http://www.research.va.gov/programs/tissue_banking/InformedConsent.pdf) A research protocol application that involves the use of tissue stored in a VA approved tissue bank must be submitted to Office of Research and Development (ORD) by the Associate Chief of Staff for Research at the JBVAMC on behalf of the Principal Investigator/Project Director. Applications cannot be submitted by non-VA investigators. Please contact the R&D Office for additional information (312) 569-7441 on the procedures for preparing a tissue bank application.
15. **VA Research Pharmacy Charge Form for Pharmaceutical Drug Proposals.** All Investigators' must submit information to the VA Pharmacy Service to allow for the calculation of estimated charges for each new investigational drug protocol. VA regulations require that Pharmacy Service receive, store, and dispense all drugs used under investigative protocols or in clinical stages of evaluation. A **one-time administration fee** will be assessed at the initial review of the protocol. If a protocol requires the use of VA stock medication(s) that is not on the drug formulary or does not have FDA approval for the indication used in the protocol, the principal investigator will be responsible for the

reimbursement cost of the drug. **These fees will be billed to the investigator or the department handling funding upon receipt of drug (s) in the pharmacy.** In addition, all required documentation (i.e. dated IRB approval letter dated and signed subject consent documents, study drug protocol, 10-1223, and 10-9012 forms) must be received by pharmacy prior to drug dispensing. If you have any questions or need further assistance, please call the clinical research pharmacist at (312) 569-7075.

16. **Flagging of Medical Records for Research Participants at JBVAMC.** The R&D Committee at the time of initial review determines if subjects' medical records must be flagged to meet the requirements of VA Handbook 1200.05 Appendix C 3.c. This determination is made on a protocol specific basis, taking into consideration the relative risks to the subjects of flagging the records. The investigator is notified of the determination for flagging with the R&D approval notice. When required by the R&D committee, research investigators must include a clinical warning in the electronic patient medical record in the Computerized Patient Record System (CPRS) Graphical User of Interface (GUI) system to document research-related issues for veterans participating in research studies. The following research titles are to be used by Principal Investigators/ Research Coordinators or Research Assistants when entering data into CPRS GUI: a) "Clinical warning / Research protocol;" and when the study is completed; b) "Research protocol Completed." **Investigators failing to comply with an R&D determination for this requirement will face suspension of research activities.** If you have any questions about progress note documentation or training on how to use CPRS, please page the CPRS Clinical Coordinators at 312-389-3644.
17. **Use of Radiation in Human Research Subjects.** For human subject research involving ionizing radiation or administration of radioactive substances, protocols must be approved by the JBVAMC Radiation Safety Officer before submission to the IRB. Submit a copy of your IRB application form, protocol, consent form, and a completed *Human Research Protocol Radiation Exposure Supplement* to the RSO as soon as possible. If you are having difficulty with the radiation supplement, the RSO will provide assistance. The RSO is David Derenzo and he can be contacted at: 312-569-6596 / Page: 312-389-3674 / e-mail: [david.derenzo@med.va.gov](mailto:david.derenzo@med.va.gov).
18. **Procedures for Use of Protected Health Information for Subject Recruitment.** Investigators intending to use protected health information from medical records to identify and contact potential participants (including their own patients) for recruitment for research must request a waiver of informed consent and authorization from the IRB for this purpose.
19. **Researcher Contacts with Veterans.**
  - During the recruitment process, researchers must make initial contact with the patient in person and/or through a letter prior to any phone contact and provide a telephone number or other means that veterans can use to verify the validity of the study;
  - Phone and other contacts with veterans are restricted to only those procedures and data elements outlined in the IRB-approved protocol application, and, in these contacts, research staff must not request social security numbers; and

- The informed consent document includes information about where and how a veteran can verify the validity of a study and authorized contacts.

## 20. **Special Populations**

- **Prisoners:** The inclusion of prisoners in VA research requires a waiver from the Chief of Research and Development Officer (CRADO) in VA Central Office. If the waiver is granted, the research must be conducted in accordance with applicable Federal regulations pertaining to prisoners as research subjects (45CFR46, subpart C). Currently the Collaborative IRB is not eligible to review prisoner research.
- **Children:** The inclusion of children in VA research requires a waiver from the Chief of Research and Development Officer (CRADO) in VA Central Office. If the waiver is granted, the research must pose no greater than minimal risk and be conducted in accordance with applicable Federal regulations pertaining to prisoners as research subjects (45CFR46, subpart D).
- **Pregnant Women:** The inclusion of pregnant women in VA research requires that the research meets the requirements outlined in VHA Handbook 1200.05, Appendix D, 4.a-4. Also, adequate provisions must be made to monitor risk and adequate considerations given to subject selection and monitoring of the informed consent process.
- **Mentally Disabled Persons or those Persons with Impaired Decision Making Capacity:** The inclusion of mentally disabled persons or persons with impaired decision make capacity in VA research requires that the investigator demonstrate to the IRB that the conditions for inclusion of this vulnerable group as specified in VHA Handbook 1200.05, 11.a.(1)-(2) is met. Incompetence to provide consent must be determined in accordance with the requirements provided in VHA Handbook 1200.05, 11.a.(3) or as established by a legal determination. The list of individuals who may provide surrogate consent is provided in VHA Handbook 1200.05, 11.a.(2).

21. **Data Privacy and Cyber Security Training.** Anyone performing duties for the VA including Principal Investigators, Research Coordinators, Research Assistants, students, contractors, Without Compensation employees (WOCs) are required to take Privacy and Cyber Security Training. Research personnel are also required to sign a Statement of Commitment and Understanding.

22. **Research Record Keeping.** VA regulations require that investigator's research records 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. For research involving investigational drugs, the FDA requires the investigator to retain the records for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and the FDA is notified. For investigational devices, the FDA requires retaining records for the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol. Because of the difficulty in ascertaining

these dates and varying sponsor requirements, the investigator is strongly advised to consult their research/funding source prior to destroying any records.

