



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

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**SOP: Assurance of Compliance  
and Quality Improvement for the  
Human Research Protection  
Program  
At Jesse Brown VA Medical Center**

**PURPOSE**

To establish policies and procedures for evaluating the effectiveness and compliance of the Jesse Brown VA Medical Center (JBVAMC) Human Subjects Protection Program (HSPP)

To describe the Research and Development (R&D) responsibilities and procedures for monitoring all compliance requirements of the Human Subjects Protection Program (HSPP) at the JBVAMC

To describe procedures for conducting quality improvement activities in the JBVAMC HSPP

**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.

**RESPONSIBILITIES**

The responsibilities for ensuring compliance and for implementing quality improvement activities for the JBVAMC HSPP are as follows:

- A. **Medical Center Director.** The Medical Center Director is responsible for the overall assurance of protections for human research subjects 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 subjects.
- B. **Associate Chief of Staff for Research and Development (ACOS R&D):** The ACOS R&D is delegated the responsibility for the implementation, conceptual oversight, and administrative leadership of the HSPP with regard to ensuring compliance and quality improvement.
- C. **Human Subject Research Specialist (HSRS):** The HSRS is responsible for the day-to-day monitoring of the HSPP, 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.
- D. **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 HSPP activities, including the conduct of human subject research compliance audits.
- E. **RESPONSIBILITIES AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OR REPORTS OF NONCOMPLIANCE WITH HSPP REQUIREMENTS:**

Refer to: 1). JBVAMC SOP: Complaints and/or Allegations Of Noncompliance in Human Research Studies Policy & Procedures, 2). Operating and Coordinating Policy for the Administration of the Collaborative JBVAMC/NU/UIC IRB and UIC HSPP Policy: Handling Complaints and Allegations of Potential Non- Compliance with Human Subject Protection Regulations.

**F. COMPLIANCE WITH CHANGES IN HSPP POLICIES AND REGULATIONS:**

- (1) Officials delegated as responsible for the HSPP (i.e., ACOS/ R&D, Medical Administration Specialist, AO/ R&D) will closely monitor all policies and regulations which pertain to HSPP compliance requirements. Strategies for effective monitoring will be as follows:
  - a. The Medical Administration Specialist and other officials, as appropriate, will participate in recurring training in order to remain cognizant of all changes in HSPP 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 HSPP Handbook and through ongoing educational activities.
  - b. 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 HSPP policies and regulations so that compliance can be maintained.

#### **G. COMPLIANCE AUDIT AND MONITORING:**

- (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:
  - a. Identify areas that need improvement
  - b. Recommendations made and actions taken to implement improvements
  - c. Results of QI activities including pre- and post- evaluation measurements
- (2) On a quarterly basis the R&D Office performs telephone audits to actively seek feedback from current research subjects
- (3) The R&D Office evaluates HSPP effectiveness and conducts quality improvement activities. Evaluation includes measuring, assessing, and improving compliance with institutional HSPP policies, assurances and other requirements for the protection of human subjects in research. This is done through routine review of HSPP procedures and weekly staff meetings to discuss and evaluate any findings. The Research Compliance Officer monitors the performance of investigators to ensure compliance with HSPP and IRB requirements by evaluating the following:
  - a. Using only IRB-approved advertisements and subject recruitment materials
  - b. Using only IRB-approved consent forms
  - c. Signing and dating the consent form
  - d. Documenting consent in the case history, if subject is a VA patient
  - e. Obtaining IRB approval prior to initiating changes to the protocol or consent form, except where necessary to eliminate apparent immediate hazards to subjects
  - f. Reporting all unanticipated problems involving risks to human subjects
  - g. Reporting all protocol deviations
  - h. Adherence to HSPP policies
  - i. Adherence to IRB approved protocols and conditions
- (4) The R&D monitors performance of investigators in implementing informed consent requirements. The institution evaluates the following:
  - a. Obtaining consent prior to initiating any research related procedures
  - b. Using only IRB-approved consent forms
  - c. Signing and dating the consent form
  - d. Documenting consent in the case history, if subject is a VA patient
  - e. Providing a copy of the consent form to the subject or legally authorized representative
- (5) The R&D also monitors its responsiveness to questions, concerns and complaints by:
  - a. Timeliness of response to questions and complaints
  - b. Satisfaction with responses
- (6) 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) Compliance audits for the HSPP are conducted as follows by the R&D Program Support Assistant:

- a. 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.
- b. Compliance Audit of Informed Consent Documentation. A minimum of five (5) medical records of human subjects 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 subject. 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.
- c. 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.
- d. 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.
- e. If gaps in performance were identified and corrective action implemented, the institution will reassess performance to the effectiveness of the action taken.
- f. Results of compliance audit activities pertaining to the HSPP will be maintained on file in the R&D Office for a minimum of seven (7) years.

#### **H. OVERSIGHT OF THE IRB:**

(1) A key activity for ensuring compliance and quality improvement for the HSPP is careful oversight of IRB activities. Specific oversight is accomplished as follows:

- a. 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.
- b. The minutes of all IRB meetings are reviewed by the R&D Committee monthly at the R&D Committee meeting, as documented in the minutes of said meeting for consideration of VA-specific

issues including the following.

1. protection of VA research subjects
  2. presence of at least one VA representative during IRB review.
  3. content and accuracy of informed consents
  4. IRB analysis of risks and benefits including designation of minimal risks
  5. special considerations and protections for vulnerable or potentially vulnerable populations
  6. consideration of privacy and confidentiality protections
  7. continuing review of previously approved research (i.e., amendments, adverse events)
  8. use of expedited review or other procedures requiring review of less than the full IRB
  9. granting exemption from Federal requirements for IRB review
  10. granting waivers for documentation of informed consent
  11. granting waivers of any elements of informed consent
  12. the contents and accuracy of the VA HIPAA authorization and/or granting a waiver of HIPAA authorization documents.
- (2) 2. 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. The R&D Committee reviews the structure and performance of the IRB yearly, as documented in the R&D minutes. Review of the adequacy of IRB policies/procedures, monitoring of adverse events and the review process is accomplished by the monthly meeting attended by administrative staff from the Collaborative IRB, Northwestern University IRB, and JBVAMC Research and Development Staff. The minutes of this monthly meeting are presented to the R&DC for review and acceptance. In addition, the Executive Committee of IRB #4 is meeting on a quarterly basis to discuss overall policy, with minutes transcribed and presented for review. The R&D Office submits a HSPP IRB Performance and Oversight report annually to the R&D Committee for review. The report includes activities of the IRB (number of protocols reviewed, training etc). 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 HSPP requirements.

#### **I. Handling Research Subject Complaints:**

- (1) The JBVAMC recognizes that it must be responsive to the concerns of research subjects. 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.
- (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 Collaborative IRB. The IRB will handle the complaint according to UIC policy and procedure, **Handling Complaints and Allegations of Potential Non- Compliance with Human Subject Protection Regulations (Version 6.3, 1/25/2011)**..

- (3) 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).
- (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.
- (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.
- (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.

#### **J. PROCEDURES FOR REPORTING TO REGULATORY AGENCIES:**

- (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 in accordance with Handbook 1058.01,
- (2) The R&D Office will follow VA procedure and coordinate with the UIC OPRS as to reporting matters as described in the **Operating and Coordinating Policy for the Administration of the Collaborative JBVAMC/NU/UIC IRB**.

#### **REFERENCES**

General requirements for informed consent: 45 CFR 46.116(a) (7), 38 CFR16. 103(b) (5), 38 CFR16.116 (a) (7), 45 CFR 46.103 (b) (5), 21 CFR 50.25 (a) (7)

VHA Handbook 1200.05 "Requirements for the Protection of Human Subjects in Research" dated July 15, 2003.

"This has been replaced by Handbook 1058.01

VHA Handbook 1058.01 REQUIREMENTS FOR REPORTING RESEARCH EVENTS TO FACILITY OVERSIGHT COMMITTEES AND THE OFFICE OF RESEARCH OVERSIGHT

UIC IRB SOP "Reporting of Unanticipated Problems, Suspensions,

## **SCHEDULE OF QA/QI PROJECTS FOR R&D COMMITTEE EVALUATION**

### 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

### 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.

### Annual QA/QI Programs

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

### 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

### REVISION LOG:

#### **SOP: Assurance of Compliance and Quality Improvement for the Human Research Protection Program at Jesse Brown VA Medical Center**

<b>Version (#, date)</b>	<b>Replaces (#, date)</b>	<b>Summary of changes</b>
1.4; April 6, 2011	1.3; November 25, 2009	