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

Version 4.1: October 26, 2011

- Part I: PI informational material and instructions & VA Training Requirements!
- Part II: Checklist: PIs-go directly to Page 3 for signature (do not complete the checklist)
- Part III: Forms to be completed
- Part IV: Additional forms that may pertain to your research

Part I:

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 be initiated 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 written notice from the JBVAMC ACOS for R&D. The IRB will also receive a copy of this written notice. Once the IRB receives this written notice, the IRB will release 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 Information Security Officer (ISO), Privacy Officer, and 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. Please allow a **minimum of one (1) week** for review by the R&D Office, ISO, and Privacy Officer. The R&D Office will contact you when the reviews are complete and the checklist and submission are available for pick-up. Your submission for IRB review will not be accepted without a signature from the R&D Office on the checklist.
4. **Protocol Requirements.** The elements required in a research protocol to be performed at JBVAMC are described in the **JBVAMC investigator manual.**
5. **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. Final review of HIPAA Authorizations and approval of waivers are completed by the IRB with consultation from the JBVAMC Privacy Officer.
6. **Amendments.** Any amendment that adds the JBVAMC as a performance site must receive written notice from the ACOS for R&D before implementation.
7. **Advertisement for and Recruitment of VA Subjects.** Any advertisements to be posted at the VA must have Collaborative IRB 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 with an IRB approval stamp and cannot be posted at the JBVAMC without this stamp. Subjects may be recruited at the JBVAMC by VA investigators who may or may not be collaborating with UIC or NU investigators through advertisements, flyers, or physician referral only with prior approval.

NOTE: Any documents used or posted without an approval will be considered a protocol violation and could result in suspension of the research at the JBVAMC.
8. **Continuing Review.** The IRB must review and approve all non-exempt 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 IRB approval. The IRB highly recommends that continuing reviews are submitted 60 days prior to expiration to avoid lapses in IRB approval.

9. **Exempt Research.** VA regulations require an annual review of all exempt research. 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.

10. **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 UIC HSPP policy and procedure, *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:
 - If a problem (1) involves or suggests risks to VA research subjects OR (2) the problem involves or suggests risks to anyone else in VA research (e.g., family members, researchers, others), the investigator must report the problem to the IRB within 5 days, or
 - If a local adverse event occurs and the adverse event is serious as defined by the FDA, meaning that the adverse event resulted in (or needed medical or surgical intervention to prevent) death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, or jeopardy to any subject's rights, safety, or welfare, the investigator must report the problem to the IRB within 5 days.
 - If the problem does not involve the two categories above, then the investigator must follow the UIC HSPP policy and procedure *Unanticipated Problems Involving Risks to Subjects and Others*.

When different investigators exist between JBVAMC and the affiliate, 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.

11. **Final Reports.** When the research study is completed a final report must be submitted to the 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*.

12. **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) 569-7441.
13. **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.
14. **Facility Human Protections Program (FHPP) Policy: Allocation of Funds for WISE Foundation.** The VA Central Office has instituted a 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) 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 WISE. Please contact the WISE Office for additional information (312) 569-7765.
15. **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 VA Tissue Banking Program website for further information:
http://www.research.va.gov/programs/tissue_banking/default.cfm

NOTE: Specific language must be in the informed consent if the study involves tissue banking. Refer to the JBVAMC Consent template for more information.

A research protocol application that requests the use of tissue stored in an off-site 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.

16. **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.

17. **Flagging of Medical Records for Research Subjects at JBVAMC.** As of February 1 2009, the Collaborative IRB at the time of initial review, or during the review of an amendment to add the JBVAMC as a performance site determines if subjects' medical records must be flagged to meet the requirements of VA Handbook 1200.05 Paragraph 44. 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 IRB determination letter. For JBVAMC patient medical records that have been flagged by the Collaborative IRB, JBVAMC will have the responsibility of ensuring compliance with VHA Handbook 1907.01, Paragraph 6.t.(10) and other applicable sections of VHA Handbook with respect to such medical records by JBVAMC employees. When notified by the R&D Office of an IRB determination to flag the medical record, the research investigator 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:

- Informed Consent / Research
- Clinical warning / Research protocol;
- Research Progress note
- Research Protocol Completed

Investigators failing to comply with the collaborative IRBs requirements will be considered in noncompliance with IRB and VA policies and subject to appropriate corrective action and reporting. 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.

18. **Maintaining a Master List of All Subjects.** Investigators must maintain a master list of all subjects from whom informed consent has been obtained unless the IRB has waived this requirement. Refer to the JBVAMC Investigator Manual for more information.

19. **VHA Health Record for Research Subjects.** The criteria indicating when creation of a VHA Health Record for research subjects is necessary and the contents of the health record are described in the JBVAMC investigator manual.

20. **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.

21. **Procedures for Use of Protected Health Information for Subject Recruitment.** Investigators intending to use protected health information from medical records, schedules or other sources containing PHI to identify and contact potential subjects (including their own patients) for recruitment for research **must** request a waiver of informed consent and authorization from the IRB for this purpose.

22. **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; unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research (e.g., if the potential subject has diabetes, the subject may indicate a desire to be notified of any diabetes-related research studies).
- 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.
- **NOTE:** *One source of information about clinical trials that can be shared with potential subjects is the NIH clinical trials Web site (<http://www.clinicaltrials.gov>) where VA clinical trials are listed.*
- **Later Contact.** The research team should begin telephone calls to the subject by referring to previous contacts and, when applicable, the information provided in the informed consent form, and ensuring that the scope of telephone contacts with the subject is limited to topics outlined in IRB-approved protocols and informed consent forms.

23. **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, Paragraph 46. 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, Paragraph 49 is met. Incompetence to provide consent must be determined in accordance with the requirements provided in VHA Handbook 1200.05, Paragraph 49 or as established by a legal determination. The list of individuals who may provide surrogate consent is provided in VHA Handbook 1200.05, Paragraph 36c(1).

24. **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.

25. **Research Record Keeping.**

NOTE: Technical Correction to VHA Handbook 1200.05 Paragraph 7j,(04/24/09) states that required records must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1). VA regulations require that sensitive paper documents must be shredded in accordance with VA Directive 6371, Appendix A.

VA regulations require that investigator's research records be retained **indefinitely** 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.

26. **Security of Research Data.** Safeguarding the confidentiality, integrity and availability of research data is critically important to maintaining a successful research program. For specific information regarding research data security, please refer to the JBVAMC investigator manual.