



**Jesse Brown VA Medical Center
Department of Research and Development**

R&D Committee's Meeting Dates

***JBVAMC R&D Committee's Meeting Dates for your information
(Meetings are held on the 2nd Mondays and 4th Wednesdays of the
Month*)***

Deadline Dates	R&D Meeting Dates
October 3, 2008	October 10, 2008
October 15, 2008	October 22, 2008
November 3, 2008	November 10, 2008
November 26, 2008	December 3, 2008
December 15, 2008	December 22, 2008
January 5, 2009	January 12, 2009
January 21, 2009	January 28, 2009
February 2, 2009	February 9, 2009
February 18, 2009	February 25, 2009
March 2, 2009	March 9, 2009
March 18, 2009	March 25, 2009
April 6, 2009	April 13, 2009
April 15, 2009	April 22, 2009
May 4, 2009	May 11, 2009
May 20, 2009	May 27, 2009
June 1, 2009	June 8, 2009
June 17, 2009	June 24, 2009
July 6, 2009	July 13, 2009
July 15, 2009	July 22, 2009
August 3, 2009	August 10, 2009
August 19, 2009	August 26, 2009
September 7, 2009	September 14, 2009
September 16, 2009	September 23, 2009

*Please note that due to conflicts, meetings and/or deadline dates may be rescheduled.



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

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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) 569-7441.

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) 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 For a list of VA approved off-site tissue banks, please refer to 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 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.** As of February 1 2009, the Collaborative IRB 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 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.

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.

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.