



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

IRB Protocol Submission Checklist

Version 2.7, December 18, 2009

All investigators conducting human subject research are required to bring their new application, continuing review application, all amendments, prompt reports, and final reports to Carol Lane at the JBVAMC R&D Office for an initial screening of the IRB/VA documents. After the initial screening the VA investigator may submit the entire application to the IRB for review and approval.

Prerequisites:

- Principal Investigator (PI) has a JBVAMC salary appointment prior to conducting a human subject research study. The PI must include official documentation indicating the percentage of his/her VA salary appointment with JBVAMC.
- PAGE 18 (VA FORM 10-5368; INVESTIGATOR DATA FORM) NEW INVESTIGATORS ONLY
This form is used by Central Office to track investigators. This requirement is only for new investigators who have never completed such a form.

Collaborative IRB Documents

- IRB Application and Relevant Appendices for Initial Review of Research Protocol Form – Initial Review.
- Continuing Review Application
- Amendment to Previously Approved Research
- Final Report
- IRB Consent Form
- IRB HIPAA Authorization Form
- Research Protocol
- Recruitment Materials (Advertising, Recruitment Flyers, Informational Handouts)
- Prompt Reporting Form

Jesse Brown VAMC R&D Application Documents That Must Be Included with IRB Submission

- Approved *JBVAMC R&D IRB Protocol Submission Checklist*;
- JBVAMC RAF pages 3-10
- [VA consent documents on VA form 10-1086](#);
- VA Authorization for the Release of Protected Health Information for Research Purposes;
- JBVAMC Request for Waiver of Authorization to Release Medical or Health Information (if applicable)

- VA form 10-9012 when investigational drugs or devices are used in the research;
- Front page of VA Tissue Banking Application when the tissue bank is VA-approved plus when not, VA Form 10-0436 (Application for an Off-Site Tissue Banking Waiver), if banking of tissue is part of the protocol;
- Approval or pending approval of IBC (if applicable);
- VA Form 10-3203 consent for use of picture and/or voice is included (if applicable);
- JBVAMC PI Certification of Storage and Security of VA Research Information;
- Data Security Checklist for PIs;
- Approved Human Research Protocol Radiation Dose Supplement (if applicable);
- Use of biological specimens (if applicable) – Please note that this may require a determination by the IRB;
- Research Financial Conflict of Interest Statement;
- FDA Form 1571, if investigator initiated investigational drug study;
- Memo from sponsor that the investigational drug has FDA IND Number;
- FDA Form 1572 Statement of Investigator with current Curriculum Vitae

Jesse Brown VAMC R&D Application Only Documents

- VA Research Pharmacy Charge Form for Pharmaceutical Drug Proposals
- One hard copy of abstract and e-mail abstract carol.lane2@va.gov. Please include an abstract of the proposed work (<500 words) organized under the following headings: OBJECTIVE, RESEARCH PLAN, and METHODS (include CLINICAL RELEVANCE for basic science studies).
- Training Certificates for P.I., Research Coordinators/Assistants and all others attached to the project: Human Subject Protection, VHA Privacy Awareness Training; VA Cyber Security Awareness and Information Security 201 for Research and Development Professionals
- Statement of Disclosure
- PI Assurance Application

Please Note: Research may not be initiated at the Jesse Brown VA Medical Center until after receiving written notice by the Jesse Brown VA Medical Center ACOS for R&D. The R&D Committee's application packet can be obtained through the R&D Office located in Room #6215. Please contact the R&D Office at (312) 569-7441 for additional information.

I, hereby, agree to the commitment that neither I nor my research associates are allowed to initiate human subject research at the Jesse Brown VA Medical Center (JBVAMC) until after receiving written notice by the JBVAMC ACOS for R&D. Non-compliance may jeopardize my current and/or future research activities. Any non-compliance will be reported to all regulatory agencies (ORO-Office for Research Oversight, FDA-Food and Drug Administration, Network 12 Director, Sponsor, and IRB) as required.

VA Principal Investigator's Name: _____
(Print Name)

