

**JBVAMC Investigator Responsibilities
Poster**

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**Investigator Responsibilities for Performing Research Involving
Human Subjects at the Jesse Brown VAMC**

YOU, as a JBVAMC and NU or UIC investigator, are responsible for conducting research in an ethical and professional manner. This responsibility entails a positive obligation to know and act in accordance with federal regulations (both the general regulations pertaining to human subjects protection in 38 CFR 16, 45 CFR 46 and 21 CFR 50 & 56, Veterans Health Administration (VHA) Handbooks and any regulations that may be imposed by the federal agency funding the research), state and federal laws (HIPAA, the Health Insurance Portability and Accountability Act is a federal law relevant to all research involving medical records), and VHA, JBVAMC, NU and UIC policies and procedures.

CHECKLIST: Investigator Responsibilities

This checklist has been designed to serve only as an aide to investigators and should not be considered comprehensive. You are strongly encouraged to regularly consult these websites:

UIC OPRS (<http://tigger.uic.edu/depts/ovcr/research/>), JBVAMC (<http://www.chicago.va.gov/services/research.asp>), the VA (www.va.gov), ORO (<http://www.va.gov/oro/>), ORD (<http://www.research.va.gov/>), federal OHRP (www.hhs.gov/ohrp/), FDA (www.fda.gov), and the websites of your specific federal, state, foundation, and other agency funders for updated guidance regarding ethical research practices and the protection of human research subjects.

Section 1: Ready to go

- Research Protocol**
 - Is there a finalized research protocol in place that has been approved by the Collaborative JBVAMC/NU/UIC IRB and the funders/sponsors?
 - Is there a finalized clinical trial agreement, where appropriate, approved by JBVAMC, NU or UIC and the funders/sponsors?
 - If this is FDA-regulated research, are there adequate procedures in place for the control of the drugs, biological products, and/or devices under investigation?
 - If this is FDA-regulated research, are you knowledgeable of the investigator's responsibilities for conducting and supervising clinical trials under the FDA's Good Clinical Practice regulations?
 - Has the research been approved by the JBVAMC Research & Development (R&D) Committee as well as the IRB?

- Research Recruitment and Consent Processes and Documents**
 - Have all recruitment materials (posters, flyers, brochures, information letters, introduction and recruitment scripts, web ads, emails and listserv notices, newspaper/TV/radio ads, etc.) been approved and stamped by the Collaborative IRB?
 - Have all consent documents been approved and stamped by the Collaborative IRB?
 - Have all HIPAA authorization documents, where appropriate, been approved and stamped by the Collaborative IRB and approved by the JBVAMC Privacy Officer?

- Have waivers of consent, waivers of HIPAA authorization, and/or waivers of documentation (signed consent documents), where appropriate, been approved by the Collaborative IRB and JBVAMC Privacy Officer?
- If you intend to use protected health information from medical records to identify and contact potential subjects, have waivers of informed consent and authorization been obtained for this purpose?
- Is there an adequate plan in place to maintain secured files of signed consent and authorization documents for the required amount of time?

Note: VA regulations require that investigator's research records be 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 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.

Research Personnel

- Do all research personnel have sufficient professional training and experience, including professional licensure where appropriate, to perform their roles?
- Do all research personnel understand your specific research protocol and their role(s) in it?
- Has a delegation log delineating the responsibilities of research personnel been completed and reviewed with the staff?
- Have all research personnel completed appropriate human subjects training and is their training current?
 - **Note:** All research personnel accessing protected health information for research purposes, whether in medical records, data extraction forms, or a dataset, *must* complete annual VA HIPAA training.
 - Personnel engaged in JBVAMC-based research must complete all initial and annual VA education and training requirements, including VA privacy policy training, VA cyber security awareness, and VA research data security and privacy training.
- Do any research personnel have a financial or institutional conflict of interest? If research personnel have any conflict(s) of interest, a conflict management plan developed and reviewed by the relevant Conflict of Interest office (NU or UIC) must be in place before IRB approval can occur.

Research Contact with Veterans

- Are your research personnel aware that initial contact with subjects for recruitment purposes must occur in person or through a letter prior to any phone contact and they must provide a telephone number or other means that veterans can use to verify the validity of the study?
- Are your research personnel aware that phone and other contacts with veterans are restricted to only those procedures and data elements outlined in the IRB-approved protocol application, and they must not request social security numbers during these

contacts?

- Do informed consent documents include information about where and how a veteran can verify the validity of a study and authorized contacts?
- Are research investigators at JBVAMC, when flagging electronic medical record (CPRS-GUI) of enrolled human research subject as indicated by IRB and JBVAMC R&D Committee approval, incorporating a clinical warning in the record to document research-related issues for veterans participating in research studies?
- Has the informed consent document been scanned into the CPRS?
- Have arrangements been made to ensure the informational brochure *Volunteering in Research - Here are some things you need to know* is available to potential research participants in settings where participants may be recruited (e.g., clinic waiting areas), and provided to each prospective participant when that individual is approached to take part in a project?

Non-JBVAMC, NU or UIC (i.e., External) Research Sites

- Are collaborative agreements or sub-contracts approved by the appropriate parties?
- Has appropriate human subjects protection documentation from all external site(s) been submitted to, and approved by, the Collaborative IRB?

Note: Appropriate human subjects protection documentation may include an IRB approval from the external site, a finalized IRB Authorization Agreement between the Collaborative IRB and the non-UIC site, and/or a letter of support from an authorized executive at the external site. Please consult the staff of the Collaborative IRB regarding the documentation necessary for your research.

- For international research, has a local sponsor, host, or supervisor at the international site(s) been secured and, where appropriate, approved by the Collaborative IRB?

Section 2: Staying on Course

Continuing Review

- Have you noted the date on which the current approval of your protocol, and all of your recruitment and consent documents, expire?

Note: Unless you have received a determination of exemption, your IRB approval will expire in no more than 1 year and must be re-approved, via a continuing review, before expiration. This is a federal regulation and there are no exceptions, "extensions," or "grace periods." It is your responsibility to submit the continuing review report in a timely fashion to ensure a lapse in IRB approval does not occur.

- Do your research personnel understand that only recruitment or consent documents stamped by the IRB with the current approval dates may be used to recruit and enroll subjects?
- Have you submitted your continuing review application at least 60 days before the expiration date to ensure adequate time for IRB review and approval?
- Has your research been determined to be exempt? If so, although IRB continuing review is not required, an annual report of research activities must be submitted to the JBVAMC R&D Committee.
- Do your research personnel understand that all research activities - including subject recruitment, subject enrollment, data collection, and data analysis - must stop if your IRB approval expires? A lapse in IRB approval is non-compliance, and continuation of research activities after a lapse in IRB approval is serious non-compliance and reportable

to unit heads, institutional officials, federal regulatory authorities and sponsors.

- Are you aware that research interventions during a lapse in IRB approval may only continue if it is in the best interest of the subject and after submitting a *Protocol Exception* form to the IRB and receiving approval from the IRB Chair and Chief of Staff?

Making Changes

- Have you submitted an Amendment form and received IRB approval for *any* changes made to the research *before* implementing those changes?

Note: Changes include, but are not limited to:

- Research design, methodologies, and instruments
- Research funding, sponsors, contracts, sub-contracts, collaborative agreements, and clinical trial agreements
- Recruitment and consent processes and documents
- Research personnel
- Number or type of research subjects, particularly when vulnerable populations may be involved (for example, minors, prisoners, and/or the developmentally/decisionally impaired)
- Research sites
- Handling and control of drugs, biological products, and devices
- Data and research document security and storage, particularly regarding JBVAMC-based research

- Has the JBVAMC R&D Office, Privacy Officer, and Information Security Officer reviewed and signed off on the amendment application prior to submission to the IRB?

- You may not initiate any amendments or changes to the research without first obtaining IRB review and approval. The only exception is when it is necessary to avoid direct risks to subjects and the IRB should be immediately informed of this emergency change.

- Have you had to make an emergency change in order to prevent immediate danger or harm to a subject?

- **Note:** An emergency change to the research may be made without prior approval by the IRB only when necessary to prevent immediate danger or harm to a subject. An emergency change must be reported to the Collaborative IRB within 5 days.

Adverse Events and Unanticipated Problems

- Have you reviewed with your staff what events require prompt reporting to the Collaborative IRB? These include:

- Adverse events occurring locally that are unanticipated and related to the research;
- Adverse events occurring at external sites that are unanticipated, related, and increase risk of harm;
- Publication, interim analysis, safety monitoring report, or updated investigator's brochure that indicates an unexpected change to the risks or benefits of research;
- Change in FDA labeling or withdrawal from marketing of a drug, biologic or device used in the research;
- Subject complaints that indicate an unanticipated problem which cannot be resolved by the research staff;
- Changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects;
- Protocol violations that cause harm to subjects or others, place them at increased risk of harm, impact the scientific integrity, have the potential to recur or represent possible serious

- or continuing noncompliance;
- Unanticipated adverse device effects;
- Breach in confidentiality;
- Incarceration of a subject in a protocol not approved to enroll prisoners;
- Administrative hold by investigator or sponsor;
- Events requiring prompt reporting by the protocol or sponsor;
- Observed or apparent noncompliance

Please contact the NU or UIC OPRS for any questions regarding a possible unanticipated problem, adverse event or other incident requiring prompt reporting.

- Have events requiring prompt reporting been submitted to the Collaborative IRB via the *Prompt Reporting* form within the specified timeline?
Unanticipated events and problems may be identified by research personnel, subjects (including subject complaints), research collaborators, or sponsors, and may be reported via the investigator to the IRB or directly to the IRB
 - 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 event resulted in (or needed medical or surgical intervention to prevent) death, a life-threatening experience, inpatient 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.
 - Other incidents requiring prompt reporting must be submitted to the NU or UIC OPRS within 10 days of becoming aware of them.
- Have audits by external agencies, on-site evaluations, FDA inspections, and reports to sponsors and federal agencies been reported to the Collaborative IRB and JBVAMC R&D Committee?

Reporting and Record Keeping Requirements

- Are research investigators at JBVAMC maintaining the required master list of all subjects who have been enrolled in the research? The master list is required unless the IRB has determined otherwise.
- Has a signed consent document, unless a waiver of consent or a waiver of signed consent has been granted by the IRB, been obtained for each subject enrolled in the research?
Note: For subjects who are not legally able to consent for themselves (such as minors and the developmentally/decisionally impaired), has assent from the subject plus permission from their legally authorized representative been obtained, where applicable?
- Have you taken care not to enroll more than the total number of subjects approved by the Collaborative IRB?
- If the FDA or other funder/sponsor requires regular research reports, have you submitted a copy to the Collaborative IRB and JBVAMC R&D Committee (usually in the annual continuing review packet submitted to the IRB)?
- Have you maintained receipts and records of the use and disposition of all drugs, biological products, and/or devices?

Section 3: Crossing the Finish Line

Completing Your Research

- Has all data been stripped of both direct and indirect identifiers or destroyed?
 - **Note:** Fully de-identified data may be maintained after the closure or completion of the research. Please consult OHRP guidance regarding standards for the stripping of both direct and indirect identifiers from datasets.
 - Data should be de-identified or destroyed in strict accordance with the terms agreed to by subjects in the informed consent documents.
- Have you permanently closed or completed work on your research and submitted a final report to the Collaborative IRB?
 - **Note:** Research remains open until all analysis of directly or indirectly identifiable data, and all publications, reports, and presentations, are completed.
- Have all drugs, biological products, and/or devices been returned or destroyed in accordance with FDA standards and/or funder/sponsor agreements?
- Have adequate and appropriate provisions been made for the secure storage of all data and identifiable research-related documentation (such as consent documents)?

**JBVAMC and R&D specific questions? Call JBVAMC R&D office at 312-569-7441
or email carol.lane2@va.gov**