

JESSE BROWN VETERANS ADMINISTRATION MEDICAL CENTER
INVESTIGATOR MANUAL
Version 1.1, October 26, 2011

I. INTRODUCTION

Researchers and research staff at Jesse Brown Veterans Administration Medical Center (JBVAMC) protect the rights and welfare of human research subjects by conducting research in a competent, ethical, informed, compassionate, and responsible manner. This manual describes the requirements and investigator responsibilities when performing research involving human subject research at the JBVAMC. The Principal Investigator, Local Site Investigator, and investigator must uphold professional and ethical standards and practices and adhere to all applicable VA and other Federal requirements, including JBVAMC's (and the JBVAMC/NU/UIC Collaborative IRB's) SOPs, regarding the conduct of research and the protection of human subjects.

II. DEFINITIONS

Investigator. An investigator is any individual who conducts research involving human subjects including, but not limited to, the PI, co-PI, and Local Site Investigator (LSI). The investigator must uphold professional and ethical standards and practices, adhere to all applicable Federal requirements, and comply with applicable local policies and procedures.

VA Investigator. A VA investigator is any individual who conducts research approved by the VA R&D committee while acting under a VA appointment on VA time, including full and part-time employees, without compensation (WOC) employees, and individuals appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970. In addition, a VA investigator must comply with all applicable VA and VHA requirements, and comply with applicable local VA facility policies and procedures.

Principal Investigator (PI). The PI is a qualified person or persons designated by an applicant institution to direct a research project or program and who usually writes the grant application. The PI oversees scientific, technical, and day-to-day management of the research. In the event of an investigation conducted by a team of individuals, the PI is the responsible leader of that team.
NOTE: FDA considers Investigator and PI to be synonymous.

Co-Principal Investigator (Co-PI). A Co-PI is when one of two or more PIs share equally in the accountability for a study. A Co-PI must meet the same qualifications of a PI.

Site Investigator or Local Site Investigator (LSI). The Site Investigator or LSI is an investigator at a site participating in a multi-site research project. The LSI oversees scientific, technical, and day-to-day management of the research at the local site. For example, a physician with a JBVAMC appointment is required to serve as the LSI for a trial where the primary site is one of the academic affiliates and the PI at the academic affiliate does not have a VA appointment.

Investigators' Research Records. Research records include the following when relevant to the study: copies of all IRB-approved versions of the protocol and amendments; case report forms and supporting data (including but not limited to signed and dated informed consent forms and HIPAA authorization forms); documentation on each subject including informed consent, interactions with subjects by telephone or in person, observations, interventions, and other data relevant to the research study; reports of adverse events; data analyses; codes and keys used to de-identify and re-identify subjects' PHI; reports (including, but not limited to abstracts and other publications); all correspondence (including, but not limited to, that with the funding source or sponsor) and with applicable oversight entities (including, but not limited to, IRB, R&D Committee, ORO, and FDA); and a master list of all subjects for whom informed consent has been obtained in the study.

III. REQUIREMENTS FOR CONDUCTING RESEARCH AT JBVAMC

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.

- A. **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.
- B. 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.
- C. **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. Please allow a minimum of one (1) week for review at the R&D Office. Your submission for IRB review will not be accepted without a signature from the R&D Office on the checklist.
- D. **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.

- E. **Amendments.** Any amendment that adds the JBVAMC as a performance site must receive written notice from the ACOS for R&D before implementation.
- F. **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.

- G. **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.
- H. **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.
- I. **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.

- J. **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*.
- K. **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.
- L. **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.
- M. **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.
- N. **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.

O. **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.

P. **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 polices 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.

- Q. **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.
- R. **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.
- S. **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.
- T. **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; VHA Handbook 1200.05, Paragraph 47). 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; VHA Handbook 1200.05, Paragraph 48).

- **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).

U. **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.

V. **Research Record Keeping.**

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.

W. **Questions, Concerns, and/or Comments.** Investigators, research team members, and other members of the VA Community should contact the Medical Administration Specialist, Research Services, at (312) 569-7441, if they have any questions, concerns, and/or comments regarding VA research. Questions, concerns, and/or comments can be addressed at the monthly Town Hall Meetings coordinated by the JBVAMC R&D Office.

Investigators, research team members, and other members of the VA Community should contact the UIC Office for the Protection of Research Subjects (OPRS) at (312) 996-1711, or 1-866-789-6215 (toll free) or e-mail OPRS at uicirb@uic.edu with any questions, concerns, and/or comments regarding the protocol submission process, review, and other IRB related issues.

IV. INVESTIGATOR RESPONSIBILITIES

The PI, LSI, and investigator must uphold professional and ethical standards and practices and adhere to all applicable VA and other Federal requirements, including the JBVAMC's SOPs, regarding the conduct of research and the protection of human subjects. The responsibilities of the investigator may be defined in the protocol or IRB application. Specifically, the PI's and LSI's responsibilities include, but are not limited to (some of the following responsibilities may be assumed by an investigator working under a PI or LSI):

- A. Disclosing to the Collaborative IRB any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of the research, and complying with all applicable VA and other Federal requirements regarding conflict of interest.
- B. Ensuring there are adequate resources to safely carry out the research. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
- C. Ensuring research staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials and, when relevant, privileges) to perform procedures assigned to them during the study. In a protocol, study team members are generally identified by name or by title.
 1. If a study team member is identified by name in the IRB-approved protocol, a replacement or termination of their role constitutes a change in the protocol. Such a change requires IRB approval (e.g., if an IRB-approved protocol specifically identified the name of a medical monitor and later another individual was identified to replace the medical monitor, the protocol would require an amendment reflecting the change in the name of the medical monitor. This protocol change would require IRB approval prior to initiation of the change, unless it was necessary to eliminate apparent immediate hazards to the subjects).
 2. If a study team member is replaced by another individual and the IRB-approved protocol identifies the person by title and not name, a replacement by another individual with the same title is not a protocol change. However the JBVAMC still requires that IRB approval for the personnel change even if the protocol document does not change.

3. IRB may also require a specific individual(s) by name to be part of the study team as a condition for IRB approval of the research. In that case, a proposed change in that specific individual would require IRB approval.
- D. Promptly reporting any changes in the PI or LSI to the IRB. Additions to other key research staff, if any, must be reported as soon as possible. However, removal of key research personnel may be reported at time of continuing review. Changes in the PI, LSI, Co-PI, or Co-LSI of an IRB-approved project must be evaluated and approved by IRB to ensure the new individual meets the criteria described in 38 CFR 16.111.
 - E. Overseeing and being responsible for ensuring the research staff under the investigator's direction complies with all applicable requirements including, but not limited to, implementing the research study in accordance with the IRB-approved protocol.
 - F. Ensuring the research protocol contains all required information (see section V below).
 - G. Obtaining written approval(s) before initiating research. Before initiating the research study at JBVAMC, you must 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.
 1. For a VA multi-site study, not only the PI, but also all LSIs, must obtain such approvals from the relevant local VA facilities' IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VA and other Federal requirements.
 - H. Ensuring the study is implemented as approved by the IRB and in accordance with other required approvals and with all applicable local, VA, and other Federal requirements including, when applicable, those for research involving investigational drugs or investigational devices.
 - I. Maintaining written documentation on file that the protocol is being implemented as approved by IRB and in accordance with other required approvals.
 1. Research records include the following, when relevant:
 - a. Copies of all IRB-approved versions of the protocol and amendments.
 - b. Case report forms and supporting data, including, but not limited to, signed and dated informed consent forms and HIPAA authorizations.
 - c. Documentation on each subject including, but not limited to:
 - 1). Informed consent,
 - 2). Interactions with subjects by telephone or in person,
 - 3). Observations,
 - 4). Interventions, and
 - 5). Other data relevant to the research study, including, but not limited to:

- a). Progress notes,
 - b). Research study forms,
 - c). Surveys, and
 - d). Questionnaires.
 - d. Reports of adverse events.
 - e. Data analyses.
 - f. Reports including, but not limited to, abstracts and other publications.
 - g. All correspondence including, but not limited to, that with the funding source or sponsor, and with applicable oversight entities including, but not limited to, IRB, R&D Committee, ORO, and FDA.
 - h. A master list of all subjects for whom informed consent has been obtained in the study.
 - 2. Documents must be maintained so that they may be audited by the facility RCO or other entities according to applicable sponsor, local, VA and other Federal requirements, and
 - 3. An Accounting of Disclosure must be maintained for each and every disclosure of information from this study to a non-VA entity. The facility Privacy Officer can assist in providing a mechanism to account for this disclosure.
- J. Ensuring that no human being is involved as a subject in research covered by this Handbook unless legally effective informed consent of the subject or the subject's LAR has been obtained (38 CFR 16.116). The informed consent must be obtained and documented prospectively (i.e., no screening or other interaction or intervention involving a human subject can occur until after the IRB-approved informed consent requirements have been met). The only exceptions are if the IRB of record determines the research is exempt (see 38 CFR 16.101(b)), or approves a waiver of informed consent (see 38 CFR 16.116(c) and (d), and par. 35), or approves a waiver of the signed informed consent form (see 38 CFR.117(c) and par. 34).
- 1. **Designating Responsibility for Obtaining Informed Consent.** If the PI or LSI does not personally obtain informed consent, the investigator must formally and prospectively designate to another research team member in writing the protocol or the application for IRB approval the responsibility for obtaining informed consent, whether or not a waiver of documentation of informed consent has been approved by the IRB. This designee must be a member of the research team.
 - a. Any person designated to obtain informed consent must receive appropriate training and be knowledgeable enough about the protocol to answer the questions of prospective subjects.
 - b. The policies and procedures of the collaborative IRB go beyond those of the VA and require the PI or LSI to designate the individual by name in Appendix P.
 - 2. **Version of Informed Consent Form.** The most current IRB-approved version of VA Form 10-1086, Research Consent Form, for each study must be used as the informed consent form.

3. **Circumstances Under Which Informed Consent is Obtained.** The investigator, or designee, must seek informed consent only under circumstances that:
 - a. Provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate, and
 - b. Minimize the possibility of coercion or undue influence.
4. **Usual Care.** The investigator, or designee, must ensure the Informed Consent process clearly defines for the subject which potential risks are related to the research and, therefore, must be discussed with the research team, versus those associated solely with usual care provided by the subject's health care provider. The informed consent process must include language advising subjects to review the risks of the latter with their health care providers.
5. **Documentation of Informed Consent**
 - a. When documentation of informed consent is not waived by IRB, the investigator or designee must ensure the documentation is in accordance with paragraph 33 of VHA Handbook 1200.05 and includes:
 - 1). The signature and date of the subject or the subject's LAR, and
 - 2). The signature and date of the person obtaining the informed consent, and
 - 3). The signature of the witness and the date of the subject's or LAR's signature was witnessed, when applicable (see subpar. 33c).
 - b. If use of facsimile is approved by IRB, the subject may submit the signed and dated informed consent form to the investigator or designee by facsimile.
6. **Storage of Signed Informed Consent Forms.** The investigator must ensure all original signed and dated forms are in investigator's research files, readily retrievable, and secure.

K Ensuring Consistency of Informed Consent Form, Protocol, and HIPAA Authorization.

This means ensuring the language in the informed consent form is consistent with that in the protocol and, when applicable, in the HIPAA authorization.

L. Ensuring HIPAA Authorization is Obtained. This means ensuring that no human being is involved as a subject in research, unless the investigator or a designee formally and prospectively designated in writing in the protocol by the investigator has obtained legally effective HIPAA authorization for the use and disclosure of the subject's PHI, or has obtained Privacy Board or IRB-approved waiver of HIPAA authorization.

1. If the investigator requires a waiver or alteration of the HIPAA authorization, the investigator must provide the Privacy Board or IRB with information sufficient for the Privacy Board or IRB to find that such waiver or alteration is necessary.
2. Investigators can obtain and use real Social Security numbers only when real Social Security numbers are required to meet the specific aims of the research protocol or to enter information into the subjects' health records. The collection and use of real Social Security numbers must be approved by IRB, and the investigators must follow all

applicable VA and other Federal requirements for obtaining and using real Social Security numbers.

- M. **Performing Subject Outreach.** This means ensuring that, as part of the local VA facility's Research Subject Outreach Program, the investigator is responsible for:
1. Making every reasonable effort to make available the informational brochure, "Volunteering in Research – Here Are Some Things You Need To Know," (<http://www.research.va.gov/programs/pride/veterans/tri-fold.pdf>) to potential research subjects in settings where investigators may recruit subjects (e.g., clinic waiting areas), and to prospective subjects, and their surrogates where applicable, when the individuals are approached to take part in a study.
 2. Ensuring that all informed consent forms provide subjects with required contact information for the VA investigator and relevant study staff. In addition, all informed consent forms must provide a contact independent of the research team in case the research staff cannot be reached and the subject wish to talk to someone other than the research staff, or the subject wishes to voice concerns or complaints about the research.
 3. Informing the contact person who is independent of the research team (e.g., the facility's patient advocate, a member of the research office staff, or IRB staff) of the relevant details of the study; documenting that this independent contact person has been informed; and ensuring the independent contact person's ability to render proper assistance to potential subjects.
- N. **Obtaining IRB Approval for all Changes.** This means obtaining IRB approval for all changes to the research protocol (e.g., amendments or modifications), including changes to the IRB informed consent form (the IRB informed consent form is unique to each research study), prior to implementing the changes. The only exception is when it is necessary to change the protocol to eliminate apparent immediate hazards to the subject. The investigator must promptly report these changes to the IRB.
- O. **Submitting Continuing Review Materials.** This means ensuring continuing review materials are submitted in a timely manner to provide IRB sufficient time for reviewing and approving the study before IRB approval expires. The collaborative IRB recommends submission 60 days prior to expiration to avoid a lapse in IRB approval. IRB approval automatically expires if the continuing review and approval does not occur by the expiration date of the current approval.
- P. **Reporting Deviations and Complaints.** This means reporting deviations from the protocol and subject complaints to IRB in a time frame specified in the Collaborative IRB's policy, Unanticipated Problems and Other Events Requiring Prompt Reporting, and Prompt Reporting form.
- Q. **Reporting Problems and SAEs.** This means reporting all unanticipated problems involving risks to subjects or others, and all internal (i.e., local) SAEs, whether related or unrelated to

the research, in accordance with the Collaborative IRB's policy, Unanticipated Problems and Other Events Requiring Prompt Reporting. Researchers should also report suspensions or terminations of the research and data safety and monitoring reports in accordance with the Collaborative IRB's policy.

- R. **Completing Appropriate Actions at Research Project Completion.** This means at completion of the research study, completing all required documentation and storing research records according to all applicable VA and Federal records retention requirements. 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. If appropriate, the investigator communicates the results to subjects or the community from which subjects were recruited.
- S. **Transferring of Records** by VA upon departure of the investigator. If the investigator leaves JBVAMC, all research records are retained at JBVAMC. If the grant is ongoing and the investigator leaves JBVAMC to go to another VA facility, the investigator must obtain approval for a copy of relevant materials to be provided to the new VA facility's research office. The approval must be obtained from the JBVAMC R&D office, any other relevant individuals or offices according to VA and JBVAMC local requirements (e.g., compliance, privacy, or Information Security Officers (ISOs)) and the sponsor. *NOTE: The investigator is not the grantee, nor does the investigator own the data.*
- T. **Maintaining a Master List of All Subjects.** The investigator must maintain a master list of all subjects from whom informed consent has been obtained whether or not IRB granted a waiver of documentation of informed consent (see 38 CFR16.117(c)).
1. Investigators must not add a subject's name to the master list of all subjects until after:
 - a. Informed consent has been obtained from that subject, and
 - b. When appropriate, informed consent has been documented using an IRB-approved informed consent form.
 2. IRB may waive the requirement for the investigator to maintain a master list for a given study if both of the following conditions are met:
 - a. There is a waiver of documentation of informed consent, and
 - b. The IRB determines that including the subjects on such a master list poses a potential risk to the subjects from a breach of confidentiality.
 3. If IRB waives the requirement to maintain such a master list, IRB must provide written documentation in the IRB minutes or IRB protocol file justifying the waiver.
 4. The investigator must secure the master list appropriately in compliance with all VA confidentiality and information security requirements in the investigator's file for each study.
- U. **Ensuring Appropriate Research Laboratory Test Reporting.** This means ensuring research laboratories not report laboratory results that are used for diagnosis, treatment, and

prevention of disease in patients, unless the research laboratories are properly accredited and meet all requirements of 42 CFR 493 (see VHA Handbook 1106.01).

V. . **Investigational Drugs.** To receive an investigational drug as defined by VHA Handbook 1108.04, in addition to FDA regulations for the conduct of research under an IND and investigator responsibilities outlined above, the investigator must: Provide the Pharmacy Service information on each subject receiving an investigational drug through the electronic medical record. Documentation is to include allergies, toxicities, or adverse drug events related to the investigational drug, or the potential for interaction with other drugs, foods, or dietary supplements, i.e., herbals, nutraceuticals

1. Ensure the local Pharmacy Service or Research Service Investigational Pharmacy receives:
 - a. Documentation of IRB and any other relevant approvals;
 - b. Copy of VA Form 10-9012, Investigational Drug Information Record, when applicable;
 - c. Copy of the current approved protocol;
 - d. Copy of the informed consent form for each participating subject with all appropriate signatures;
 - e. Documentation of the IRB continuing review approval;
 - f. Copies of sponsor-related correspondence specific to the drug(s) as appropriate;
 - g. Copies of all correspondence addressed to the investigator from the FDA (and other involved authorities) specific to the investigational drug(s) as appropriate;
2. Inform the Chief of the Pharmacy Service, the research pharmacy when applicable, and the IRB in writing when a study involving investigational drugs has been suspended, terminated, or closed;
3. Comply with all dispensing requirements;
4. Comply with all documentation requirements and make relevant records accessible to the investigational drug pharmacist when requested;
5. Comply with all VHA pharmacy requirements regarding receiving, dispensing, storing, and record-keeping for investigational drugs.

W. **Investigational Device**

The investigator must ensure the procedures, in the conduct of research involving an investigational device, are in accordance with all applicable local, VA and other Federal requirements, including FDA regulations.

V. **PROTOCOL REQUIREMENTS**

A. **Ensure Research is Scientifically Sound.**

B. **Ensure Research Compliance.**

C. **Provide a Plan for Recruitment and Selection of Subjects.** *The requirement for a plan for just, fair and equitable recruitment and selection of subjects applies to both prospective and*

retrospective studies, including studies that use clinical or administrative databases or bio-specimens.

D. **Minimizing Risks.**

E. **Describing Data and Safety Monitoring Plan for Prospective Studies.** Plan must include, but is not limited to, the following:

1. What safety information will be collected including SAEs (see VHA Handbook 1058.01);
2. How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects);
3. The frequency of data collection including when safety data collection starts;
4. The frequency or periodicity of review of cumulative safety data;
5. If not using a DMC, and if applicable, statistical tests for analyzing the safety data to determine if harm is occurring;
6. Provisions for the oversight of safety data (e.g., by a DMC); and
7. Conditions that trigger an immediate suspension of the research, if applicable.

NOTE: The data and safety monitoring plan may vary depending on the potential risks, complexity, and nature of the study. The use of an independent DMC needs to be considered if there are multiple clinical sites, the study is blinded, interventions are high-risk, vulnerable populations are included, or when required by the funding organization, FDA, sponsor, or other relevant entity.

F. **Describing Data and Safety Monitoring Plan for Retrospective Studies.** This means the investigator describes the safety and monitoring plan for retrospective studies, including studies involving pre-existing data and biological specimens. When applicable, the plan needs to include, but is not limited to, the following:

1. A discussion with the subject of potential study outcomes that may have an effect on the subject's health or well-being; and
2. A procedure to determine when and how to notify individual subjects or their health care providers of findings that may affect the subjects' health.

G. **Differentiating Usual Care from Research.** The investigator must describe in the Collaborative IRB application any "usual care" involved in the protocol clearly differentiating the research intervention(s) from "usual care" (whether the "usual care" is limited to one "arm" of the study or is being delivered to all study subjects).

1. When a study involves “usual care,” in the protocol or the IRB application, the investigator must clearly designate the individual or entity (e.g., the appropriate research personnel versus the subject’s health care provider) responsible for relevant aspects of both the research and the usual care.
2. The subject needs to be able to identify which activity (e.g., treatment or service) is research, and which is usual care, and know who (the researcher or the subject’s health care provider) is responsible for:
 - a. Explaining potential risks and benefits of the treatment or service to the subject;
 - b. Providing the treatment or service;
 - c. Monitoring the treatment or service, as applicable;
 - d. Defining whether the adverse events result from usual care or research, as applicable;
 - e. Alerting the subject if there is a problem with the treatment or service (e.g., a newly discovered risk, a product recall); and
 - f. Documenting the subject’s clinical course while receiving the treatment or service, as applicable.

NOTE: The researcher and the subject’s health care provider may be the same individual. If they are different individuals, and the subject’s health care provider is not involved in the research study, the health care provider is not considered to be a member of the research team.

- H. **Enlisting Clinical Expertise.** If the investigator is not a clinician, when appropriate, the protocol must have provisions for enlisting the services of a clinician with appropriate expertise and privileges to perform duties that may include, but not be limited to:
1. Reviewing the data, adverse events, and new study findings; and
 2. Making required decisions to protect the health of the subject (e.g., stopping the subject’s involvement in the study or determining when to notify the subject or the subject’s health care provider of information that may affect the health of the subject).
- I. **Providing for Privacy and Confidentiality.** To facilitate review of the protocol by the Privacy Officer, the investigator must either dedicate specific sections of the protocol to privacy and confidentiality, or the investigator must develop an additional document that specifically addresses all privacy and confidentiality issues in the protocol; this becomes part of the IRB protocol file. The description needs to be sufficiently specific for the reader to understand how this requirement protects the subject’s privacy and the confidentiality of the data. These procedures must be in compliance with all applicable VA and other Federal requirements.
- J. **Providing for Information Security.** To facilitate review of the protocol by the ISO, the IRB application collects the information below concerning data management and security measures for the research. The investigator should also include this information within their research protocol.

1. Whether or not individually identifiable information is to be collected or used;
2. How the data is to be collected or acquired;
3. Where the data (original and all copies) is to be stored and corresponding security systems;
4. How the data is to be transported or transmitted from one location to another;
5. Who is to have access to the data and how they are to access it (anyone who has access to the data is responsible for its security);
6. All entities or individuals outside VHA to whom the data is to be disclosed, and the justification for such disclosure and the authority (e.g., the HIPAA authorization);
7. Who is to have access and be responsible for the security of the information (e.g., the Coordinating Center, the statistician, and PI who has ultimate responsibility);
8. Mechanisms used to account for the information;
9. Security measures that must be in place to protect individually identifiable information if collected or used; and
10. How and to whom a suspected or confirmed loss of VA information is to be reported.

K. **Providing Special Safeguards.** When applicable, the protocol includes a narrative section that:

1. Identifies any circumstances that may warrant special safeguards to protect the rights and welfare of subjects who are likely to be vulnerable including, but not limited to, those subjects who may be susceptible to coercion or undue influence; and
2. Describes appropriate actions to provide such safeguards.

L. **Providing for Reuse of Data.** This means the investigator, if the data may be reused in other studies, describes the research data repository in which the data is to be stored (see VHA Handbook 1200.12). There must be a research informed consent and a HIPAA authorization associated with the protocol unless these requirements are waived by the IRB. If the IRB does not waive the requirements then the informed consent and HIPAA authorization content must include language on the uses and disclosures of the data as defined in the protocol as well as information on how privacy and confidentiality will be maintained and how the data will be secured. If the creation and operation of the data repository is not included in the data collection protocol, there must be a separate IRB-approved protocol for the creation and operation of the data repository (see VHA Handbook 1200.12).

VI. VHA Requirements For Obtaining And Documenting Informed Consent

The Investigator is referred to UIC (Collaborative IRB) policy, *Informed Consent Process and Documentation*, for information on the DHHS and FDA rules and regulations related to informed consent.

- A. Circumstances Under Which Informed Consent May Be Sought. The Common Rule requires (38 CFR 16.116):
1. The investigator to seek informed consent only under circumstances that:
 - a. Provide the prospective subject or the subject's legally authorized representative (LAR) sufficient opportunity to read the informed consent document when applicable,
 - b. Provide the prospective subject, or the subject's LAR, sufficient opportunity to consider whether or not to participate, and
 - c. Minimize the possibility of coercion or undue influence.
 2. The information that is given to the subject or the subject's LAR must be in language understandable to the subject or the subject's LAR.
 3. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the subject's LAR:
 - a. Is made to waive, or appear to waive, any of the subject's legal rights; or
 - b. Releases, or appears to release, the investigator, the sponsor, the institution, or its agents from liability for negligence
- B. Person Obtaining Informed Consent. If someone other than the investigator conducts the informed consent process and obtains informed consent from a subject or the subject's representative, the investigator must formally and prospectively designate in writing in the protocol or the application for IRB approval, the individual who will have this responsibility. The person so designated must have received appropriate training to perform this activity. This person must be knowledgeable about the research to be conducted and the consenting process, and must be able to answer questions about the study.
- C. Observing the Process. The IRB has the authority to observe or have a third party observe the informed consent process.
- D. Informed Consent Form. The most current IRB-approved version of VA Form 10-1086, Research Consent Form, for each study (or the most current IRB-approved electronic version of VA Form 10-1086) must be used as the informed consent form.
1. All required elements must be completed as well as any additional elements required by the IRB.
 2. The informed consent form must contain a designated block for each required signature (e.g., subject, person obtaining the informed consent, and witness when applicable) and for the date of each signature. Please refer to the JBVAMC Informed Consent template for formatting instructions. **NOTE:** *For the purposes of the informed consent form, a "block" may be a labeled line, window of a table,*

or other format that clearly indicates what type of signatures and dates the IRB specifically requires for that study's informed consent form.

E. Required Elements Of Informed Consent

1. Elements of Informed Consent Required by the Common Rule. Except as provided by IRB approval of a waiver of consent or documentation of consent, 38 CFR 16.116(a) requires the following elements of informed consent be provided to each subject:
 - a. Statement That the Study Involves Research.
 - b. Explanation of the Purposes of the Research.
 - c. Expected Duration of the Subject's Participation. A description of the expected length of the subject's commitment to active participation in the interventions or interactions of the study, including long-term follow-up. This does not include the time after all interventions and interactions with the subject have ended and the study activities include only analysis of specimens and/or data, and/or preparations for publication of results.
 - d. Description of the Procedures to be Followed.
 - e. Identification of any procedures that are experimental.
 - f. Description of any reasonably foreseeable risks or discomforts to the subject.
 - (1) Description is to include, but not be limited to, physical, social, legal, economic, and psychological risks.
 - (2) Risks that do not result from the research, but that result solely from treatments or services that have been designated in the IRB-approved protocol to be the responsibility of the health care provider, should not be described in the consent form. The informed consent process is to include language advising subjects to review the risks of such clinical treatments or services with their health care provider(s).
 - g. Description of any benefits to the subject or to others that may reasonably be expected from the research.
 - h. Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
 - i. Confidentiality. A statement describing the extent to which confidentiality of records identifying the subject will be maintained. If appropriate, a statement that Federal agencies including, but not limited to, the FDA, OHRP, ORO, and the VA Office of the Inspector General (OIG) may have access to the records. If an FDA-regulated test article is involved, FDA requires a statement that the FDA may choose to inspect research records that include the subject's individual medical records.
 - j. Research-Related Injury
 - (1) For research involving more than minimal risk, a statement that includes:
 - (a) Explanation as to whether any compensation is available if injury occurs, and

- (b). Explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
 - (2) Although the Common Rule at 38 CFR 16.116(a)(6) only requires that the informed consent contain information on research-related injury if the study is more than minimal risk, VA regulations (38 CFR 17.85) require the VA to provide care for all research-related injuries including those studies that are considered minimal risk.
 - k. **Contact Information.** An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of research-related injury to the subject (38 CFR 16.116(a)(7)). There must be at least one contact other than the investigator or study personnel.
 - l. **Statement that participation is voluntary, refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled (38 CFR 16.116(a)(8)).**
2. **Other Elements of Informed Consent Required by VA.** In addition to the elements for informed consent required by the 38 CFR Part 16, VA requires the following elements of informed consent:
 - a. **Name of the Study.**
 - b. **Name of the PI.** The name of the PI and, in multi-site studies, the name of the LSI.
 - c. **Sponsor of the Study.**

F. **Additional Elements Of Informed Consent**

- 1. **Additional Elements of Informed Consent Required by the Common Rule.** When appropriate, the Common Rule requires one or more of the following elements of information be provided to each subject (38 CFR 16.116(b)). Also, when any of these additional elements are appropriate, VA requires them to be documented in the IRB-approved informed consent form unless documentation of informed consent is waived.
 - a. **Unforeseeable Risks.** Statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or becomes pregnant) which are currently unforeseeable.
- 2. **Termination of Subject's Participation.** Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

3. Additional Costs. Any additional costs to the subject that may result from participation in the research.
 - a. Pursuant to 38 CFR 17.102, subjects in VA-approved research cannot be charged, nor can their insurance be billed, for research-related interventions or procedures (e.g., tests, drugs, clinic visits, hospital admissions, transportation) that are required by the protocol. If medical services are furnished to a person who is not eligible for medical services as a Veteran, the medical care appropriation will be reimbursed from the research appropriation.
 - b. When appropriate for the informed consent for VA-approved research to include information on additional costs to the subject that may result from participation in the research, the informed consent must contain a statement that a Veteran subject or a non-Veteran subject will not be required to pay for medical services received as a subject in an approved VA research study. The only exception is that certain Veterans are required to pay applicable co-payments for medical care and services provided by VA that are not rendered as part of the VA-approved research study (see 38 U.S.C. 1710(f) and 1710(g)). An example of language that may be appropriate is provided in the JBVAMc consent template, “What are the costs for participating in this research?”
4. Consequences of a subject's decision to withdraw from the research and procedures for orderly and safe termination of participation by the subject.
5. Statement that any significant new findings which may relate to the subject’s willingness to continue participation, developed during the course of the research, will be provided to the subject.
6. Number of Subjects. The approximate number of subjects involved in the study.
7. Additional Elements of Informed Consent Required by VA. When appropriate, VA requires one or more of the following elements of information be provided to each subject. Also, when any of these additional elements are appropriate, VA requires them to be documented in the IRB-approved informed consent form, unless documentation of informed consent is waived.
 - a. **Commercial Product.** If applicable, that the investigator believes that the human biologic specimens obtained could be part of, or lead to the development of, a commercially valuable product.
 - b. **Future Use of Specimens.** If the specimens are to be retained after the end of the study for future research, where the specimens will be retained, who will have access to them, and how long they will be retained. Current applicable institutional, VA and other Federal requirements must be met for handling, use and storage of biologic specimens and data (see VHA Handbook 1200.12).
 - c. **Future Use of Data.** If any of the data will be retained after the study for future research, where the data will be stored, and who will have access to

the data (see VHA Handbook 1200.12). Current applicable institutional, VA and other Federal requirements must be met for use and storage of data (see VHA Handbook 1200.12).

- d. **Re-contact.** If the subject will be re-contacted for future research whether within VA or outside VA.
- e. **Payment for Participating in the Study.** If appropriate, a statement regarding any payment the subject is to receive for participating in the study and how the payment is to be made.
- f. **Disclosure of Results.** If the subject will receive a report of the aggregate results or any results specific to the subject.

G. Documentation Of Informed Consent

1. Informed consent must be documented prospectively by the use of a written consent form approved by the IRB (38 CFR 16.117(a), unless documentation of informed consent has been explicitly waived by the IRB (38 CFR 16.117(c)).
NOTE: Email communications do not constitute documentation of informed consent.
2. VA Form 10-1086, Research Consent Form, must be used as the consent form for JBVAMC research.
 - a. The requirement to utilize VA Form 10-1086 to document informed consent applies to all VA-approved research including, but not limited to, studies in which VA investigators working on VA Research enroll subjects at the affiliate hospital or other sites outside VA (e.g., community centers or shopping malls).
 - b. The “most recent” IRB-approved version of the informed consent form contains the date of the version of the informed consent form most recently approved by the IRB (i.e. in the footer on the JBVAMC template).
3. **IRB Approval Date.** The IRB approval must be documented in the IRB minutes or IRB protocol files for those studies reviewed by the expedited process. IRB correspondence with the investigator must clearly indicate which version of the informed consent form has been approved. The IRB approval date must be documented by the use of a stamp or preprinted box on each page of the informed consent form. This stamp or preprinted box must indicate the most recent date of IRB approval of the informed consent form. The IRB must maintain a copy of the approved informed consent form in its records.
4. **Signatures and Dates.** The informed consent form must be signed and dated by:
 - a. The subject or the subject's LAR (38 CFR 16.117(a)),
 - b. The person obtaining the informed consent, and
 - c. A witness, if required by IRB (e.g., the IRB may require a witness if the study involves an invasive intervention or an investigational drug or

device). A witness is always required when a short form consent is employed.

- (1) The witness is required to witness only the subject's or subject's LAR's signature, not the informed consent process (e.g., if the subject does not want the witness to know the nature of the research study), unless the sponsor or IRB requires the witness to witness the informed consent process.
 - (2) The witness cannot be the person who obtained informed consent from the subject, but may be another member of the study team or may be a family member.
5. The original signed and dated informed consent form must be filed in the investigator's research file for that subject so that it is readily accessible for auditing. If the subject submits the signed and dated informed consent form to the investigator or designee by facsimile, the person who obtains informed consent must sign and date the facsimile, and then the facsimile can serve as the original informed consent document. If facsimile is used for the informed consent document, measures must be employed to ensure the confidentiality of the information, and the privacy of the subject.
6. Copies of Signed Consent Form
 - a. Copy of the signed and dated informed consent form must be provided to the subject or the subject's LAR.
 - b. Where applicable, a copy of the signed and dated informed consent form must be placed in the medical record in accordance with VHA Handbook 1907.01.
7. Consent Documents. Except when the IRB approves a waiver of documentation, the informed consent form may be either of the following:
 - a. **Written Informed Consent With All Required Elements.** The consent may be in the form of a written consent document that embodies the elements of informed consent required by 38 CFR 16.116. This form may be read to the subject or the subject's LAR, but in any event, the investigator must give either the subject or the representative adequate opportunity to read it before it is signed; or
 - b. **Short Form Consent.** The consent may be in the form of a short form written consent document stating that the elements of informed consent required by 38 CFR 16.116 have been presented orally to the subject or the subject's LAR (38 CFR 16.117(b)(2)). When this method is used:
 - (1) There must be a witness to the oral presentation.
 - (2) The IRB must approve a written summary of what is to be said to the subject or the LAR.
 - (3) Signatures are to be obtained as follows:
 - (a) The short form is to be signed by the witness, and the subject or LAR.

- (b) The copy of the summary is to be signed by the witness and the person actually obtaining consent.
- (4) Copy of the summary and a copy of the short form are to be given to the subject or the LAR (38 CFR 16.117(b)(2)).
- (5) Original signed short form and summary must be filed in the investigator's research file for that subject.
- (6) Where applicable, a copy of the signed short form informed consent form must be placed in the medical record in accordance with VHA Handbook 1907.01.
- (7) The investigator must file all original, signed and dated, short form informed consent forms in the investigator's research file for that subject, so that they are readily accessible for auditing.

H. Waiver Of Documentation Of Informed Consent

The Investigator is referred to UIC (Collaborative IRB) policy, *Informed Consent Process and Documentation*, for information on requesting a waiver of documentation of informed consent.

I. Waiver Of Informed Consent

The Investigator is referred to UIC (Collaborative IRB) policy, *Informed Consent Process and Documentation*, for information on requesting a waiver of informed consent.

J. Surrogate Consent

1. Investigators' Responsibilities for Surrogate Consent. Investigators must:
 - a. Provide the IRB with a description of the procedures to ensure that subjects' LARs are well informed regarding their roles and obligations to protect persons who lack decision-making capacity.
 - b. Provide information (i.e., informed consent process and HIPAA authorization) to the subjects' LARs that would ordinarily be required by this Handbook to be made to the subjects themselves if they had decision-making capacity.
2. **LARs**
 - a. Authorized Person. The following persons are authorized to consent on behalf of persons who lack decision-making capacity in the following order of priority:
 - (1) Health care agent (i.e., an individual named by the individual in a Durable Power of Attorney for Health Care (38 CFR.17.32(a)(iii));
 - (2) Legal guardian or special guardian;
 - (3) Next of kin in this order: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or
 - (4) Close friend.

- b. Responsibilities of LARs. LARs are acting on behalf of the potential subjects, therefore:
 - (1) LARs must be told that their obligation is to try to determine what the subjects would do if able to make an informed decision.
 - (2) If the potential subject's wishes cannot be determined, the LARs must be told they are responsible for determining what is in the subjects' best interests.
 - (3) LARs generally assume the same rights and responsibilities as the individuals who lack decision-making capacity in the informed consent process.
3. Dissent or Assent. If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Although unable to provide informed consent, some persons may resist participating in a research (i.e., if they dissent) protocol approved by their representatives. Under no circumstances may a subject be forced or coerced to participate in a research study even if the LAR has provided consent.
4. Fluctuating Capacity. Investigators, IRB members, and LARs must be aware that decision-making capacity may fluctuate in some subjects. For subjects with fluctuating decision-making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary.

VII. VHA HEALTH RECORD: CREATION AND UPDATING

A VHA health record must be created or updated, and a progress note created, for all research subjects (Veterans or Non-Veterans) who are admitted to JBVAMC as in-patients, treated as outpatients, or when research procedures or interventions are used in the medical care of the VA research subject at a VA facility or at facilities contracted by VA to provide services to Veterans (e.g., contract CBOCs or contract nursing homes).

A. When a Health Record is Required.

1. When the research requires use of any clinical resources, such as: radiology, cardiology (e.g., electrocardiogram, stress test, etc.), clinical laboratory, and pharmacy; or
2. If the research intervention may lead to physical or psychological AEs.

B. What a Health Record Must Include. At a minimum, the health record must include the following information for an approved research study:

1. The name of the study;
2. The person obtaining the subject's informed consent;

3. A statement that the subject or the subject's LAR was capable of understanding the informed consent process;
4. A statement that the study was explained to the subject or the subject's LAR;
5. A statement that the subject or the subject's LAR consented before participation in the study began;
6. A statement that the subject or the subject's LAR was given the opportunity to ask questions;
7. A copy of the signed and dated research informed consent form (i.e., VA Form 10-1086) in accordance with VHA Handbook 1907.01;
8. A copy of the HIPAA authorization for data use or disclosure;
9. A copy of the initial enrollment progress note and other applicable progress notes;
10. Information on possible drug interactions and/or toxicity of the pharmaceutical agents that are being administered to the subject because of the research (i.e., investigational drugs);
11. VA Form 10-9012, Investigational Drug Information Record, or superseding forms for investigational drugs as defined in VHA Handbook 1108.04;
12. A copy of any research results that are used for medical care (see VHA Handbook 1907.01);
13. Information on all research and experimental interventions including potential risks, indications, and applicable progress notes see (see VHA Handbook 1907.01); and
14. VHA Form 10-3203, Consent for Use of Picture and/or Voice, if applicable.