

**Operating and Coordinating
Procedures for the Administration of
the Collaborative JBVAMC/NU/UIC
IRB (UIC IRB #4)**

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- I. **OBJECTIVE.** This SOP describes the review of human subjects research at the JBVAMC by the UIC IRB#4 as the IRB of Record. The arrangement concerning IRB #4 is formalized and each institution's responsibility outlined in a memorandum of understanding (MOU) between UIC and the JBVAMC and an authorization agreement between UIC and Northwestern (NU), another JBVAMC affiliate. The UIC, NU and the JBVAMC each hold institutional federalwide assurances (FWA 00000083, 00001549, and 00000290, respectively) for conducting human subject research.
- II. **IRBS OF RECORD DURING TRANSITION TO COLLABORATIVE IRB.** Through existing MOUs with the JBVAMC, two UIC IRBs (UIC IRB #1 and #3) and three NU IRBs (NU IRB #3, #5 and #6) currently serve as IRBs of record for the JBVAMC until the Collaborative IRB (IRB #4) becomes fully operational. Protocols active at the JBVAMC at the time of the establishment of the Collaborative IRB will be transferred from their original NU or UIC IRB to the Collaborative IRB at their next continuing review cycle. During the transition period, the term "Collaborative IRB" means the appropriate IRB of record, which may include UIC IRB #1, NU IRB #3, NU IRB #5, NU IRB #6, UIC IRB#4 or UIC IRB #3.
- III. **OVERVIEW.**
 - A. **Overview of Collaborative IRB Responsibilities.** Three institutions, JBVAMC, NU, and UIC, have agreed to rely on a single IRB with the authority to review biomedical and behavioral research that utilizes the JBVAMC as a recruitment and/or performance site in accordance with applicable federal and state regulations and VA and VHA requirements, including 38 CFR 16, 17 and VHA Handbook 1200.05. This IRB is referred to as the Collaborative JBVAMC/NU/UIC IRB (Collaborative IRB). This IRB is registered with the OHRP, DHHS as UIC IRB#4 (IRB 00006412). The Collaborative IRB reviews human subjects VA Research. VA Research is defined as research that is conducted by VA investigators (serving on compensated, WOC, or IPA appointments) while on VA time, utilizing VA resources, and/or on VA property

- including space leased to, and used by, VA. The research may be funded by VA, by other sponsors, or be unfunded. (Refer to VHA Handbook 1200.1). The Collaborative IRB is responsible for reviewing all applicable VA Research involving human subjects (as defined in 38 CFR 16.102 (f) or 21 CFR 812.3(p) and 50.3 (g)) and/ or human biological specimens (as defined in VHA Handbook 1058.03) 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 subjects research. (Refer to *ORD FAQ: Banking of Human Biological Specimens for Research*, dated 1/10/07). The JBVAMC relies on the Collaborative IRB to make the exemption determination and the not human subjects research determination. If research involving only human biological specimens is found to be exempt, only the R&D Committee is responsible for reviewing all applicable VA research involving human biological specimens prior to its initiation.
- B. Collaborative Institutional Responsibilities.** UIC OPRS provides day to day operational and administrative support for the Collaborative IRB. Communication exists among the Collaborative IRB, UIC OPRS, NU OPRS, and the JBVAMC in accordance with this SOP and the UIC HSPP policies *Executive Committee Supporting the Collaborative IRB* and *Handling Complaints and Allegations of Non-Compliance with Human Subject Protection Regulations*. NU and UIC manage the conflicts of interest for their respective faculty in accordance with their own policies. UIC COI Office develops management plans for conflicts of interest for personnel with JBVAMC only appointments in accordance with the procedures outlined in this SOP and the UIC COI policy for investigators. Final IRB approval is not to be granted until a conflict management plan has been submitted and reviewed by the Collaborative IRB. The protocol is not to be forwarded to the JBVAMC R&D Committee for review and approval until after Collaborative IRB approval.
- C. Relationship to JBVAMC Research and Development Committee.** The JBVAMC R&D Committee reviews all research under the auspices of the JBVAMC, initially and at least once a year, including research determined exempt by the Collaborative IRB. All NU, UIC, or JBVAMC research that engages the JBVAMC as a recruitment and/or performance site, including research involving only human biological specimens, must have the approval of the JBVAMC R&D Committee and its appropriate subcommittees before the research may begin.

The Collaborative IRB functions as the Human Studies Subcommittee for the JBVAMC R&D Committee, the findings of which are recorded and reported to the JBVAMC R&D Committee. The JBVAMC R&D Committee reviews and provides to the JBVAMC Director an evaluation of all JBVAMC R&D Subcommittees, including committees at external entities. Communication exists between the JBVAMC R&D Committee and the Collaborative IRB, including the timely exchange of meeting minutes and board actions as outlined in this SOP. The JBVAMC R&D Committee can accept or reject an

IRB decision, but cannot reverse an IRB disapproval of the research. If the R&D Committee disapproves the research, the R&D Committee must notify the Collaborative IRB in writing of the reason(s) for disapproval in accordance with VHA Handbook 1200.1.

- D. Executive Committee.** An Executive Committee supports the activities of the Collaborative IRB and facilitates communication among the three institutions. The Executive Committee composition and structure is outlined in the UIC HSP policy *Executive Committee Supporting the Collaborative IRB*.

IV. RESPONSIBILITY.

- A. University of Illinois at Chicago:** UIC OVCR, UIC Vice Chancellor for Research, UIC Associate Vice Chancellor for Research, UIC Associate Director for Research Compliance, UIC OPRS Staff, Collaborative IRB staff, Collaborative IRB Chairs, and Members, UIC PIs/Other Key Research Personnel with joint UIC/JBVAMC appointments.
- B. Northwestern University (NU):** NU Office of the Vice President for Research (OVPR), NU Vice President for Research, NU Associate Vice President for Research, NU Executive Director, Office for the Protection of Research Subjects, NU OPRS Staff, Collaborative IRB staff, Collaborative IRB Chairs and Members, NU Principal Investigators/Other Authorized Research Personnel with joint NU/JBVAMC appointments.
- C. Jesse Brown Veterans Administration Medical Center (JBVAMC):** JBVAMC Director, JBVAMC COS, JBVAMC R&D ACOS, JBVAMC R&D Chairperson, JBVAMC R&D Committee Members, JBVAMC R&D Office Staff, JBVAMC PIs/Other Key Research Personnel, JBVAMC Research Compliance Officer, JBVAMC AO for R&D, JBVAMC Privacy Officer, JBVAMC Legal Counsel, JBVAMC Grants and Contacts Administrator, JBVAMC Pharmacy.

V. PROCEDURES.

A. IRB Procedures.

- 1. Collaborative IRB Composition.** The UIC SOP *IRB Member Recruitment and Appointment Process* and VHA Handbook 1200.05 outline procedures for appointing IRB members and maintenance of IRB membership information. The Collaborative IRB meets the membership requirements in accordance with 21 CFR 56.107, 45 CFR 46.107, 38 CFR 16.107, and VHA Handbook 1200.05 (6); and consists of a minimum of seven voting members, including three NU affiliated representatives, three UIC affiliated representatives, and one non-affiliated, non-scientist (community) member from the JBVAMC veteran population. The IRB also includes alternates for the affiliated members and an alternate community member. IRB Chairs for this Collaborative IRB alternate between UIC and NU affiliated faculty for a three-year period. The Collaborative IRB includes a minimum of two voting members who serve as JBVAMC representatives, with at least one VA representative having scientific expertise. The JBVAMC representatives must be employees of the JBVAMC with a VA salaried

appointment and must be full voting members (i.e., vote on both JBVAMC and non-JBVAMC protocols).

At least one member of the Collaborative IRB is a member of, or liaison to, the JBVAMC R&D Committee in accordance with VHA Handbook 1200.1. The IRB must include one or more members knowledgeable about and experienced in working with vulnerable subject categories, particularly the economically and educationally disadvantaged, mentally disabled persons, and those with impaired decision-making capacity to review VA Research involving these vulnerable populations. An *ad hoc* consultant is utilized in instances that a research protocol involves children or pregnant women as individuals with expertise in these areas are not generally appointed as IRB members due to the rare occurrence of studies in these vulnerable groups at JBVAMC. If the study involves children, a CRADO waiver is required and the research can involve only minimal risk research. Studies involving adults unable to consent, such as decisionally or cognitively impaired, requires review by the fully convened IRB.

Other membership considerations include the appointment of at least one individual who is a non-scientist. At least one IRB member is not affiliated with UIC, NU, or JBVAMC and is not part of the immediate family of a person who is affiliated with the institutions. The member from the veteran community described above can typically fulfill this role and that of the non-scientist. Every non-discriminatory effort is made to ensure that the Collaborative IRB does not consist entirely of men or women and does not consist entirely of members of one profession.

The JBVAMC Privacy Officer and Information Security Officer attend the Collaborative IRB meetings to advise the IRB on privacy and information security issues; they function as advisors and do not vote with the IRB. The JBVAMC RCO acts as a liaison to monitor the Collaborative IRB sessions. JBVAMC R&D administration officials, including but not limited to the ACOS for R&D and the AO for R&D and RCO, are not eligible to serve as voting members of the IRB.

In accordance with VHA Handbook 1200.05 and 38 CFR 16.107(f), the IRB may invite *ad hoc* consultants to assist in the review of issues requiring expertise beyond or in addition to that available on the IRB. These individuals serve only as advisors and do not vote with the IRB. Procedures for identifying and soliciting *ad hoc* expertise for the IRB are described in the UIC HSPP policy *Identification and Use of Ad Hoc Consultants*.

- 2. Appointment of JBVAMC Representative.** Recommendations for JBVAMC representatives on the Collaborative IRB are provided by the

members and staff of the NU OPRS, UIC OPRS, and the JBVAMC R&D Committee. Other personnel from the institutions may also nominate candidates. After review of credentials, the R&D Committee forwards names for new JBVAMC representative IRB members to the JBVAMC Medical Center Director for consideration. The JBVAMC Medical Center Director must officially appoint the JBVAMC representatives to the IRB in writing for a period of three years. (VHA Handbook 1200.05, section 6.k & 6.l). Following written notification from the Medical Center Director, the UIC IO and Director of OPRS review and process the appointment according to the UIC SOP *IRB Member Recruitment and Appointment Process*, taking into consideration the following UIC HSPP policies: *Scientific and Scholarly Review of Research* and *Convened IRB Review Process*. The UIC IO solicits the input of the NU Vice President for Research for appointment of NU-affiliated IRB members. Changes in membership for the Collaborative IRB are reported to OHRP by UIC OPRS and to the VA ORO by the JBVAMC R&D Office in accordance with the UIC SOP *IRB Member Recruitment and Appointment Process*.

3. IRB Responsibilities.

- a) IRB members must review all human subjects research at the JBVAMC per UIC OPRS and JBVAMC R&D policies and procedures using the appropriate UIC OPRS review guides.
- b) IRB members are knowledgeable of UIC HSPP policy *IRB Member, Ad Hoc Consultant, and OPRS Staff Conflict of Interest Policy*, and complete and sign the UIC OPRS form *Conflict of Interest Declaration*.
- c) At least one IRB member or consultant with appropriate scientific or scholarly expertise must review each protocol in depth. The consultant cannot vote with IRB members. The consultant's analysis is provided to the IRB in a written report.
- d) For JBVAMC research requiring full review, the IRB cannot approve JBVAMC research without the presence of at least one JBVAMC representative at the convened meeting.
- e) A licensed physician must be included in the IRB quorum for FDA research.
- f) The IRB Chair must complete VA Form 10-1223, entitled *Report of Subcommittee on Human Subjects* so that it can be included in the JBVAMC R&D file.
- g) The Collaborative IRB cannot approve research for performance at JBVAMC without a JBVAMC representative present at each IRB meeting.
- h) The Collaborative IRB cannot approve research involving a vulnerable population, particularly the economically and educationally disadvantaged, handicapped or mentally disabled persons, and those with impaired decision-making capacity, without the review of at least one individual who is

- knowledgeable about or experienced in working with such subjects present at the meeting.
- i) The Collaborative IRB cannot approve research involving children or pregnant women without the review of at least one individual who is knowledgeable about or experienced in working with such subjects present at the meeting.
 - j) At least one member of the Collaborative IRB is a member of, or liaison to, the JBVAMC R&D Committee as recommended in VHA Handbook 1200.1.
 - k) Attempts to unduly influence members and staff of the Collaborative IRB are handled in accordance with the UIC HSPP policy *Undue Influence of IRB Members and OPRS Staff*.
 - l) The IRB must review that non-veterans are allowed to enter the research only when there are insufficient veterans available to complete the study.
 - m) The IRB must make the determination at **initial review** only as to whether the medical record needs to be flagged for expedited and convened protocols of all risk levels, starting February 2, 2009.

(1) **For expedited review:** The Collaborative IRB reviewer as delegated by the Collaborative IRB Chair answers a question as to whether they would like the medical record flagged on the JBVAMC review guide during expedited review. The Assistant Director of the Collaborative IRB or designee will compile the outcome in a spreadsheet. This information is delivered to the R&D Office on a monthly basis in accordance with other procedures in this SOP, which ensures that the appropriate medical records are flagged by the R&D Office. The UIC IRB is not permitted to access the JBVAMC medical records and cannot perform the actual flagging. Therefore, the R&D Office is ultimately responsible for implementation of the IRB determinations.

(2) **For convened review:** The convened review determination will be documented in the Collaborative IRB meeting minutes. The Assistant Director of the Collaborative IRB will prompt the convened IRB to discuss whether flagging is appropriate or not and assist the IRB with the regulatory nuances of this determination. At the end of the protocol discussion, the Assistant Director will ask the convened IRB to vote on whether the medical record should be flagged. The Assistant Director will ask a yes/no question as to this matter. The Assistant Director or designee will capture this vote in the meeting minutes as well as in a spreadsheet that indicates the overall outcome. The

Assistant Director or designee will compile the outcome in a spreadsheet. This information is delivered to the R&D Office on a monthly basis in accordance with the Collaborative IRB SOP, which then ensures that the appropriate medical records are flagged by the R&D Office.

The UIC IRB is not permitted to access the JBVAMC medical records and cannot perform the flagging. Therefore, the R&D Office is ultimately responsible for implementation of the IRB determinations.

- B. Institutional Responsibilities.** One OPRS staff member from NU OPRS and UIC OPRS serves as a liaison between the respective OPRS offices to the JBVAMC R&D Office and Committee and ex-officio (non-voting) member of R&D Committee. Each liaison has a designated alternate to serve when the liaison is absent or unable to attend a required meeting. These positions for UIC are typically filled by the Assistant Director and Coordinator for the Collaborative IRB. When the convened IRB requests substantive modifications or clarifications that are directly relevant to the determinations required by the IRB, the response must go back to the convened IRB.
- C. Collaborative IRB Assistant Director (AD) Responsibilities.**
1. The AD verifies that a JBVAMC member is present at every meeting.
 2. The AD verifies that a representative qualified to review VA Research as defined above involving vulnerable populations is present at the appropriate meeting.
 3. The AD documents that members required for quorum are present, such as a licensed physician when FDA research is involved.
 4. The AD documents that required members are in attendance at every meeting.
 5. The AD ensures that contingent modifications requested by the convened IRB that are not directly relevant to the determinations required by the IRB are reviewed by an IRB chair or IRB member and not by IRB staff who are not IRB members.
 6. The AD ensures that if the convened IRB requested substantive modifications or clarifications that were directly relevant to the determinations required by the IRB, the response goes back to the convened IRB.
- D. Training and Education Requirements.**
1. **IRB Member Responsibilities.** JBVAMC and NU representatives on the Collaborative IRB shall meet UIC education requirements and VA training and certification requirements for IRB membership. The affiliates shall make available to JBVAMC employee members the same human subjects training and educational programs offered by NU or UIC to other Collaborative IRB members. JBVAMC staff shall provide continuing education on VA policies and VA-specific requirements for human subjects research protections to the

Collaborative IRB. The training status of Collaborative IRB members and staff is documented at least annually by the JBVAMC staff.

2. **Investigator Responsibilities.** All individuals involved in the conduct of human research at the JBVAMC must receive training in human subjects protection and GCP on an annual basis in accordance with the VHA Handbook 1200.05 and ORD Guidance from the 2003 Stand Down Memorandum. This requirement is met by components of the CITI course as developed by the ORD and CITI. The CITI course is mandatory for PIs, co-investigators, and research staff at JBVAMC and is accepted in place of UIC and NU CITI training requirements. In addition to the CITI curriculum, other VA educational requirements, including VHA privacy policy training, VA cyber security awareness, and VA research data security and privacy, must also be completed. The JBVAMC R&D staff provide information to UIC OPRS regarding any new VA training or updates required for individuals.
3. **Compliance with VA Research Education and Training Requirements.** The JBVAMC R&D staff indicates to the Collaborative IRB at the time of submission of an initial or continuing review application whether the education and training requirements for PIs and other research personnel are up to date via the *JBVAMC R&D IRB Protocol Submission Checklist*. The Collaborative IRB will not review and approve research for performance at JBVAMC at initial or continuing review unless the PI is current with required VA training. If training is deficient at the time of continuing review even prior to the expiration date, IRB approval is considered to have lapsed and the procedures described in the UIC HSPP policies *Procedure for Notification of Continuing Review* and *Study Closure, Lapse in IRB Approval and Withdrawal of Research* are followed.

JBVAMC R&D Committee annually assesses VA training and education requirements for investigators and other research personnel involved in JBVAMC research. Failure by the PI to have met the annual training requirements results in a lapse of approval of any ongoing research at the JBVAMC. The R&D office immediately notifies the Collaborative IRB and the PI in writing of the lapse of R&D approval. The PI is instructed to stop all research activities and to submit to the IRB Chair a list of subjects who are still active in the research and for whom research interventions or interactions must be continued to prevent harm. The IRB Chair in consultation with the VA COS determines if it is in the best interest of the subject(s) to continue in the research. The failure to complete the required educational programs is considered by the Collaborative IRB as non-compliance and will trigger the non-compliance review process as described in the UIC HSPP policy *Handling Complaints and Allegations of Potential Non-Compliance with Human Subjects Protection Regulations*. If the noncompliance is found by the IRB to be serious and/or continuing, the

UIC reporting policy to investigators, institutional officials and the department or agency heads, the UIC HSPP policy *Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-Compliance*, is followed. If the investigator has not completely resolved or made a substantial effort to resolve the training deficiency after 14 days, the Collaborative IRB may lapse the research.

Co-investigators or other research personnel who are deficient in training and education requirements at the time of submission of an initial or continuing review or at the annual R&D review must be removed from the research before IRB review and approval may proceed. If research personnel are removed, submission of an amendment is needed to restore them to the protocol after the training deficiency is corrected.

E. IRB Submission Procedures.

1. The investigator prepares A) the relevant sections of the NU or UIC IRB and B) the JBVAMC R&D applications for initial review, modifications, continuing review, amendments, or final reports to approved research. This includes research requiring either convened or expedited review or a determination of exemption or not human subjects research. The separate institution-related forms are to be replaced by a single combined application specific for the Collaborative IRB within a year after its establishment. The PI is responsible for ensuring that the IRB application submission and implementation of research comply with the applicable VHA Handbook 1200.05 and other applicable VA requirements.
2. The investigator submits the applicable IRB and R&D application materials for pre-review by the JBVAMC R&D office. Once complete, including verification of VA education and training requirements for the PI and key research personnel and lack of institutional conflict of interest, the *JBVAMC R&D IRB Protocol Submission Checklist* is signed by the JBVAMC R&D staff. The UIC OPRS does not accept applications involving the JBVAMC without the JBVAMC R&D Office pre-review approval.
3. The investigator submits the NU or UIC IRB submission application and applicable sections of the JBVAMC R&D application to the applicable institutions' OPRS. Each OPRS confirms based on either the *NU OPRS Submission Checklist* or the UIC application that any reviews required from other units (conflict of interest, radiation safety, investigational pharmacy, IBC) within the NU or UIC HSPP have been completed. NU will attach the review guide on which a pre-review was conducted to the submission. If NU receives any clarification or documentation from the PI prior to the review, the NU staff will provide this information to UIC OPRS and the IRB.

4. Examples of JBVAMC-related application documents and/or procedures to be submitted with the IRB application include, but are not limited to, the following:
 - a) Approved *JBVAMC R&D IRB Protocol Submission Checklist*,
 - b) JBVAMC RAF pages 3-10;
 - c) VA consent documents printed on VA form 10-1086 with required JBVAMC consent template language;
 - d) VA Authorization for the Release of Protected Health Information for Research Purposes;
 - e) JBVAMC Request for Waiver of Authorization to Release Medical Records or Health Information (if applicable);
 - f) VA Form 10-9012 is included in submission materials when investigational drugs or devices as defined in 1200.05 are used in the research;
 - g) VA Tissue banking Application when the tissue bank is an approved VA bank or, when not, VA Form 10-0436 Application for an Off-Site Tissue Banking Waiver (if banking of tissues is part of the protocol);
 - h) Approval or pending approval of IBC (if applicable);
 - i) VA Form 10-3203 consent for use of picture and/or voice is included (if applicable);
 - j) JBVAMC PI Certification of Storage and Security of VA Research Information and Data Security Checklist for PIs; and
 - k) Approved Human Research Protocol Radiation Dose Supplement (if applicable).
 5. During Collaborative IRB review, the IRB members use the *JBVAMC Research Requirements Initial, Amendment, and Continuing Review Guide for IRB Members* (along with the standard UIC OPRS review guides) as a guide in conducting their review in addition to other submission specific applicable review guides.
 6. Review by the JBVAMC R&D Committee occurs after IRB review and approval.
 7. If the JBVAMC R&D Committee requires changes in the protocol, consent document, HIPAA Authorization, or recruitment materials, the JBVAMC R&D Committee notifies the PI to send an amendment request to the IRB addressing these issues. The R&D Liaison receives a copy of the letter sent to the PI and notes any requested revisions and the reasons for the revisions in accordance with VHA Handbook 1200.1. The JBVAMC R&D Committee does not issue final approval until IRB approval of the amendment has been secured.
- F. IRB Approvals Processing.** The following procedures apply to initial and continuing protocol reviews, exemption and not human subjects research determinations, final reports, amendments and modifications to the research, and unanticipated problems and other events requiring prompt reporting.
1. Following approval of VA Research, the UIC OPRS transmits directly to the PI only the IRB approval letter and any approved documents (e.g.,

- NU or UIC consents and authorizations) to be used solely at the NU or UIC performance sites. Originals of the IRB-approved VA consent documents, HIPAA Authorizations and recruitment materials are stamped with the appropriate IRB approval stamp and placed in a black file folder along with a copy of the IRB approval letter and approved IRB application (including revised protocol document, if applicable) to be sent to the JBVAMC R&D Office. After the JBVAMC R&D Committee has reviewed and approved the research, these documents are released to the PI by the JBVAMC R&D Office.
2. VA form 10-1223 is generated through the UIC IRB protocol management information system (RiSC) at the time the approval notice to the PI is prepared. This form requires the signature of the IRB Chair or Vice-Chair. Once the form is completed and signed, the UIC OPRS will retain a copy in the IRB protocol file with the copy of the IRB approval letter. The original VA Form 10-1223 should be placed in the black folder for distribution to the JBVAMC R&D Office.
 3. If an investigational drug or device, as defined in VHA Handbook 1200.05, is used in the research protocol, the PI is responsible for completing and submitting VA Form 10-9012, Investigational Drug Information Record, to the UIC OPRS as part of the IRB application submission. After the IRB has approved the protocol, Form 10-9012 is signed by the IRB Chair or Vice-Chair and sent with other approval documents to the JBVAMC R&D Office. UIC OPRS maintains copies of the signed documents in the protocol file.
 4. After completing steps 1 through 3, the black file folder is placed in the JBVAMC pick-up box located in the UIC OPRS office. The protocol number, date of letter, submission type, date of IRB action, whether any enclosures are included, date the item is copied/logged in, and the staff initials are all recorded on the *UIC-JBVAMC Document Transfer Form* located in the binder next to the pick-up box.
 5. At least weekly, the UIC JBVAMC Liaison will contact the JBVAMC R&D Office to inform them that IRB correspondence and related documents are ready for pick-up. All documents will be removed from the pick-up box by the UIC JBVAMC Liaison, inserted into a large envelope, along with a *UIC-JBVAMC Document Transfer Form*, and placed at the UIC OPRS front desk for pick-up. The *UIC-JBVAMC Document Transfer Form* will be signed and dated by the person picking up the documents. The person picking up the documents will receive a copy of the signed and dated *UIC-JBVAMC Document Transfer Form*.

Alternately, at the time of scheduled meetings, the UIC JBVAMC Liaison may deliver any items in the pick-up box to the JBVAMC R&D Office. The appropriate Document Transfer Form will be carried along with the documents, and signed by the JBVAMC R&D staff who receives the documents. The UIC JBVAMC Liaison will then return the

signed Document Transfer Form to UIC and place it in the “VA Documents Records” notebook located in the UIC Liaison’s Office.

6. For research involving NU-affiliated investigators, copies of approved letters and other applicable documents (i.e., informed consent documents, recruitment material, Form 10-1223, etc.) will be sent to the NU OPRS. Additionally, NU OPRS will be copied on all letters sent to NU PIs.
7. The Collaborative IRB will notify organizational officers and officials in writing of IRB findings and actions through the following process. The ACOS for R&D and JBVAMC IO receive the R&D Committee packets from the JBVAMC, which include the previous UIC IRB agenda related to JBVAMC research and meeting minutes related to JBVAMC research as previously determined by the Collaborative IRB (or applicable UIC IRB). The meeting minutes include IRB action on both convened and expedited protocols. UIC OPRS staff will deliver the UIC IO a copy of IRB meeting minutes related to JBVAMC research. As stated, the meeting minutes include IRB action on both convened and expedited protocols.

G. Responsibilities Delegated to the JBVAMC R&D Committee by the Collaborative IRB. As formalized in the UIC-JBVAMC MOU for the Collaborative IRB, the following duties are delegated to the JBVAMC R&D Committee by the Collaborative IRB:

1. Identification of protocols suitable for flagging of medical records for subjects involved in research (until February 2, 2009); and
2. Privacy Board Authority - Although the Collaborative IRB reviews all documents related to the research protocol, including the review of HIPAA Authorization and documents to grant waivers, the JBVAMC R&D Committee serves as the Privacy Board for the JBVAMC. Therefore, the JBVAMC R&D Committee, in coordination with the JBVAMC Privacy Officer, has the final responsibility for review of HIPAA Authorizations and approval of waivers or alterations of authorization related to JBVAMC subjects.

H. Collaborative IRB Record Retention. The UIC OPRS maintains copies of Collaborative IRB records on behalf of the JBVAMC and NU. The JBVAMC R&D Office and NU OPRS may keep copies of any research-related materials it deems necessary for oversight of research to be conducted at the JBVAMC. The JBVAMC R&D Committee has access to all relevant Collaborative IRB records at reasonable times and in a reasonable manner. After the closure of a research file, all related documents will be archived for a minimum of seven years or as required by the Illinois State Record Act (5 ILCS 160), other applicable state requirements and regulations, federal regulations, VA regulations, in accordance with applicable UIC HSPP policies and procedures, and the UIC Records Retention Schedule, as applicable. If the JBVAMC’s affiliation with UIC is terminated, copies of all research protocol files related to JBVAMC research will be provided to the JBVAMC R&D Office. Prior to document destruction, the UIC OPRS will notify the JBVAMC R&D

Office. Per the UIC HSPP policy *Inspections by Regulatory Agencies*, IRB records are accessible for inspection and copying by authorized representatives of federal agencies or departments at reasonable times and in a reasonable manner.

IRB Records must include the following materials, as applicable, in each study file:

1. Scientific Evaluations;
 2. Protocols;
 3. Protocol violations submitted to the IRB;
 4. DHHS-approved sample consent documents;
 5. Progress reports submitted by investigators;
 6. Reports of injuries to subjects;
 7. Records of continuing review activities;
 8. Correspondence between the IRBs and investigators;
 9. Statements of significant new findings provided to subjects;
 10. For exemption determinations: cite the specific category of exemption;
 11. Determinations required by the regulations and protocol-specific findings supporting those determinations for waiver or alteration of the consent process;
 12. For each protocol's initial and continuing review, the frequency for the next continuing review;
 13. Correspondence between the IRBs and the JBVAMC R&D Committee;
 14. Unexpected adverse events submitted to the IRBs;
 15. A resume for each IRB member;
 16. For initial and continuing review of research by the expedited procedure:
 - a) The specific permissible category;
 - b) Description of action taken by the reviewer;
 - c) Any findings required under the regulations.
- I. **Other Required Reviews Prior to IRB Approval.** NU and UIC follow their respective policies and procedures for required submission pre-approvals, including but not limited to Cancer Center, Conflict of Interest, Investigational Drug Pharmacy, Radiation Safety, Departmental Review, and IBC; however, when the research studies are to be conducted at both NU or UIC and JBVAMC, duplicate approvals may be necessary for certain aspects of the research to account for jurisdictional differences. For example, a study involving ionizing radiation conducted at NU and JBVAMC requires radiation safety approval from both NU and JBVAMC radiation safety committees. For research studies requiring IBC approval, only investigators with an UIC appointment may submit protocols for review to the Collaborative IRB.
- J. **Conflict of Interest Procedure.**

1. Investigators are required to disclose real and potential personal financial and institutional conflicts of interest for themselves and key research personnel on the JBVAMC financial conflict of interest form found in the initial review application. After initial approval, investigators must monitor on an ongoing basis for any new conflicts of interest. Additionally, investigators are required to disclose potential conflicts of interest via an amendment that submits a revised JBVAMC financial conflict of interest form if a new conflict occurs after initial approval. At the time of continuing review, the investigator is also prompted to summarize any new conflicts of interest that occurred since the initial or most recent IRB review including those reported via an amendment that submits a revised JBVAMC financial conflict of interest form during the approval period. Conflict of interest will be handled in accordance with the UIC HSPP policy *Investigator Conflict of Interest Disclosure Policy for Human Subjects Research*. During the transition to the Collaborative IRB, this reporting will occur on the NU or UIC IRB application until the Collaborative IRB application process is fully operational.
 2. NU and UIC manage financial and institutional conflicts of interest for research involving their respective faculty in accordance with their own policies. The UIC COI Office also develops management plans for financial conflicts of interest for personnel with JBVAMC only appointments. A research protocol with an identified potential conflict of interest is reviewed by the appropriate NU and UIC conflict of interest office to determine whether it requires a conflict management plan. Institutional conflicts of interest for JBVAMC are reported to the ACOS for R&D by UIC and NU and evaluated by the ACOS for R&D or designee at the time of the IRB pre-review by the JBVAMC R&D office. If an institutional conflict of interest is found, the Medical Center Director consults with the ACOS for R&D and regional counsel to develop a management plan.
 3. The appropriate IRB has the final, authority to decide whether the conflict of interest and management plan are acceptable and allow the research to be approved. Final IRB approval is not granted until a conflict management plan has been submitted, reviewed and approved by the IRB. The protocol is not forwarded to the JBVAMC R&D Committee until after IRB approval of the research, including any conflict of interest management plan.
 4. The identification and management of conflicts of interest of the appropriate IRB members, *ad hoc* consultants, and UIC OPRS staff in the review of research protocols is contained in the UIC HSPP policy *IRB member, Ad Hoc Consultant, and OPRS Staff Conflict of Interest*.
- K. Communication.** These communication steps help ensure that the JBVAMC R&D Committee has reviewed and approved all human subject research

activities conducted at the JBVAMC and that the UIC OPRS has been notified of the JBVAMC R&D Committee's actions.

1. Refer to the UIC HSPP policy *Executive Committee Supporting the Collaborative IRB*, which details the communication organization among NU, UIC, and the JBVAMC.
2. On a schedule agreeable to both the JBVAMC and the UIC OPRS, but no less often than monthly, the UIC OPRS provides to the JBVAMC R&D office such information, including but not limited to, the protocol number, PI name, protocol title, and status (i.e., completed, terminated, expired) as it regularly collects regarding JBVAMC human subject research protocols that have been reviewed.
3. On a schedule agreeable to both the JBVAMC and the UIC OPRS, but no less often than monthly, the JBVAMC R&D office will notify UIC OPRS of the disposition of all JBVAMC human subject research protocols acted upon by the JBVAMC R&D Committee in the most recent month (i.e., Committee approval, non-approval, etc.). If the JBVAMC R&D Committee disapproves a protocol, the reason(s) for disapproval shall be noted in the JBVAMC R&D Committee meeting minutes to the IRB.
4. A copy of all correspondence between the JBVAMC R&D Committee and the JBVAMC PIs is provided to the UIC JBVAMC Liaison. Copies of JBVAMC R&D approved research related documents displaying the JBVAMC R&D approval stamp are also provided. Correspondence received by the UIC OPRS VA Liaison are copied onto salmon-colored paper and distributed to the Assistant Director of the IRB. The Assistant Director places this correspondence, along with any attachments, into the corresponding IRB protocol file.

L. Adverse Events Including Unanticipated Problems and Other Events Requiring Prompt Reporting. Investigator reporting requirements for serious adverse events, unexpected adverse events, unanticipated problems/ events, and deaths occurring at the JBVAMC and UIC performance sites follow the procedures described in the UIC HSPP policy *Unanticipated Problems and Other Events Requiring Prompt Reporting*. Events occurring at the NU performance site for research approved by the Collaborative IRB are reported by investigators to the NU OPRS. These reports are forwarded by NU OPRS to UIC OPRS and the Collaborative IRB. The Collaborative IRB reviews investigator reports of adverse events as described in the above policy.

M. Handling of Complaints or Allegations of Noncompliance.

1. Complaints or allegations of noncompliance related to human subjects research approved by the Collaborative IRB may originate at JBVAMC, NU or UIC. The UIC OPRS, NU OPRS and the JBVAMC R&D office shall immediately report to the other in writing any non-compliance involving JBVAMC Human Subject Research, of which it becomes aware, including protocol violations. Each office also notifies the other if an oversight agency or organization initiates any action

- regarding non-compliance involving JBVAMC Human Subject Research.
2. Complaints or allegations of noncompliance originating at UIC will be handled as described in the UIC HSPP policy *Handling Complaints and Allegations of Potential Non-Compliance with Human Subjects Protection Regulations*. Complaints or allegations of noncompliance at the JBVAMC and NU performance sites are communicated to the UIC OPRS and the Collaborative IRB as described in the UIC HSPP policy *Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations*. The complaints or allegations are then handled by the Collaborative IRB as described in the UIC HSPP policy *Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-Compliance*.
 3. Non-compliance that is a result of a lapse in IRB approval will be managed in accordance with UIC HSPP policy *IRB Continuing Review Reminders, Lapses in IRB Approval and Non-Compliance Related to Lapses in IRB Approval*.
- N. Protocol Deviations, Violations and Exceptions.** Investigator reporting responsibilities and IRB review procedures for protocol deviations, violations and exceptions are in accordance with the UIC HSPP policies *Protocol Exceptions* and *Unexpected Problems and Other Events Requiring Prompt Reporting*.
- O. Reporting Procedures for Unanticipated Problems and Other Events Requiring Prompt Reporting, Serious, or Continuing Non-Compliance, and Suspensions and Terminations.**
1. Findings of serious or continuing non-compliance, unanticipated problems/ events, and suspensions or terminations are internally and externally reported in accordance with the UIC HSPP policies *Reporting Requirements to Institutional Officials, Supporting Agency Heads, and Regulatory Agencies for Unanticipated Problems and Other Events Requiring Prompt Reporting, Serious, or Continuing Non-Compliance, and Suspensions and Terminations*. When the research is performed at the JBVAMC, a copy of the report is sent to the ACOS for R&D. The ACOS prepares a cover letter, describing the reporting event and, for adverse events where the IRB takes substantive action or an unexpected death, attaches form 10-0420.
 2. The ACOS reports suspensions or terminations of IRB approval to the IRB Chair.
 3. The ACOS sends the report to the following:
 - a) COS;
 - b) Medical Center Director;
 - c) Chair, R&D Committee;
 - d) VA Legal Counsel;
 - e) JBVAMC Privacy Office (if the report involves the unauthorized use of, loss or disclosure of individually identifiable patient information);

- f) JBVAMC Information Security Officer (if the report involves violations of the information security requirements).

The following agencies are also sent the report by the ACOS:

- g) The Regional VA Office of Research Oversight (ORO RO);
 - h) The Office of Research and Development;
 - i) The DHHS, OHRP - The communication is sent even if the UIC IO or Director of OPRS has already notified OHRP. This duplication ensures that OHRP is notified as research at JBVAMC typically meets the criteria of being federally funded or conducted and, as such, falls under the purview of OHRP;
 - j) The IRB, as an information item in the agenda; and
 - k) Any "Common Rule" agency that is supporting or conducting the research when they require reporting separately from OHRP.
4. To facilitate submission of the report to the Director of ORO RO, the Medical Center Director initials the report and sends it by express mail and e-mail or fax. When reporting adverse events to ORO, a copy of the IRB meeting minutes relevant to the adverse event accompany the report or are sent to ORO RO within 4 weeks of the IRB meeting.
 5. The timeframe for sending reportable adverse events to ORO RO is described in the UIC HSPP policy *Unanticipated Problems and Other Events Requiring Prompt Reporting*.
 6. The Medical Center Director prepares a cover letter (with the exception of reporting to ORO RO), and notifies the following:
 - a) ORO RO;
 - b) VA R&D Office for VA-funded research;
 - c) VA Central office when the report involves an adverse event;
 - d) Privacy Office when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information; and/or
 - e) Information Security Office when the report involves violations of information security requirements.

P. Quality Assurance/Improvement Findings.

1. The JBVAMC provides UIC OPRS, NU OPRS and the UIC IO and HPA, with the results of the required annual VA review and evaluation of the Collaborative IRB. This evaluation of the structure, function, and performance of the IRB is completed by the JBVAMC R&D Committee for the JBVAMC Medical Center Director. The report may include recommendations for improvements of OPRS and the Collaborative IRB made by the JBVAMC R&D Committee.
2. The VA annual review and evaluation of the Collaborative IRB will be shared in its entirety with the following individuals:
 - a) UIC Director of OPRS;
 - b) IRB Chair;
 - c) IRB members;
 - d) IRB Assistant Director;
 - e) IRB Coordinators;

- f) OVCR Associate Director for Research Compliance;
- g) Executive Committee; and
- h) Other OPRS staff as necessary.

The Director of OPRS works with the EC in the evaluation and planning of appropriate action based on the VA annual review and evaluation and delegates the implementation of the actions as appropriate to OPRS staff. Possible actions include, but are not limited to: the development and implementation of additional educational sessions for appropriate OPRS staff and IRB members, the development, or updating, of policies and procedures, and/or the development of additional quality improvement measures.

3. The JBVAMC R&D Committee also evaluates the Collaborative IRB and documents in the IRB's consideration of the following in accordance with the same procedures as the VA annual review above:
 - a) Assessment of qualifications and experience of a new Collaborative IRB chair;
 - b) Appropriateness of the Collaborative IRB and Collaborative IRB membership given the research being reviewed;
 - c) Collaborative IRB representatives include either members or alternates interested in, or who have experience with, vulnerable populations involved in research; or *ad hoc* consultants who will supplement the Collaborative IRB's expertise in specific research areas; and
 - d) Adequacy of the Collaborative IRB's policy and procedures.
4. UIC agrees to allow the JBVAMC to evaluate the Collaborative IRB and document these findings. The UIC OPRS reviews the JBVAMC R&D Committee's findings and requests for improvements and responds to the JBVAMC R&D Committee's findings in a timely manner, including the requests for improvements.
5. The UIC OPRS and the Collaborative IRB may make changes based on for quality assurance and improvement recommendations from the JBVAMC when needed or if required following an oversight visit by a federal agency (i.e., OHRP, FDA, etc.) or an accrediting organization. All requests or recommendations for improvement between the two entities are handled through the Director of UIC OPRS and the Executive Committee Supporting the Collaborative IRB.
6. UIC OPRS and the OVCR Associate Director for Research Compliance have the authority to perform quality assurance and quality improvement audits on, and assessments of, the Collaborative IRB files. Additionally, the UIC quality assurance and improvement program extends to the members and support staff of the Collaborative IRB, and they are evaluated within the scope of the Collaborative JBVAMC/NU/UIC human subjects protection program.

Q. Research Funding: Grants and Contracts. When a research grant or contract from an external sponsor funds human subjects research being conducted by a NU or UIC and JBVAMC investigator, the affiliated university, Collaborative

IRB, JBVAMC R&D Committee and the JBVAMC Grants and Contracts Administrator follow the steps below:

1. The JBVAMC R&D Office identifies during pre-review of the Collaborative IRB protocol application (UIC or NU IRB application and JBVAMC R&D application during the transition) whether the JBVAMC is a performance site for extramural funded research.
2. When research with external funding is identified, the JBVAMC R&D Office sends the investigator an e-mail with a copy to the following listserve:
 - a) NU Office of Sponsored Research (OSR);
 - b) UIC ORS (the Executive Director of ORS, the Associate Director of ORS, and the Assistant Director of ORS); and
 - c) The JBVAMC Medical Administrative Specialist.

The email from the investigator must indicate that the Investigator is responsible for notifying the JBVAMC R&D Grants and Contracts Administrator and the NU OSR or UIC ORS concerning the funded research and providing copies of all sponsor contracts/clinical trial agreements to NU OSR or UIC ORS and JBVAMC R&D Grants and Contracts Administrator.

3. The JBVAMC R&D Grants and Contracts Administrator works with the NU OSR or UIC ORS to develop VA specific language for use in the extramural contracts/CTAs.
4. The NU OSR or UIC ORS notifies the listserve above and the JBVAMC R&D Grants and Contracts Administrator when the final contract/CTA has been approved. A signed copy of the contract/CTA will be provided to the JBVAMC R&D Grants and Contracts Office.
5. A copy of the extramural contract/CTAs approved by the affiliate is provided to the JBVAMC R&D Grants and Contracts Administrator.
6. The Collaborative IRB notifies the JBVAMC R&D Office of final IRB approval.
7. The JBVAMC R&D Committee does not grant final approval to the human subject research protocol application until notified of both the Collaborative IRB approval of the research and the JBVAMC R&D Grants and Contracts Administrator approval of the contract/CTA. JBVAMC R&D cannot give final approval until a signed contract is on file with the JBVAMC R&D Grants and Contracts Administrator.
8. The Collaborative IRB must be copied on the notice of approval and provided with any documents related to the approval of the research.

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 10/01/08	1.0, 05/19/08	Section V(E) - expanded types of submissions reviewed Section V(F)(7) - added description of

		<p>communication of Collaborative IRB actions; Section V(G) - added description of JBVAMC R&D Committee access to relevant Collaborative IRB records; Section V(G) - added cite to Inspections by Regulatory Agencies p/p and summary Section V(H) - added “protocols” and “protocol violations submitted to the IRB” to the list of IRB records Updated VHA Handbook 1200.5 to 1200.05 to reflect name change, replaced names of policies and procedures that had changed, replaced the term “participant” with the term “subject” and improved clarity.</p>
1.2, 01/23/09	1.1, 10/01/08	Clarification of Conflict of Interest procedures (Sec V.J.1))
1.3 04/10/09	1.2, 01/12/09	Reassignment of medical record flagging determination from R&D Office to Collaborative IRB starting February 2009.