

OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS

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A MESSAGE FROM THE DIRECTOR OF THE OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS

OPRS welcomes IRB #4!

Last month OPRS launched a new IRB - IRB #4. Reviewing only VA protocols, IRB #4 is also innovative in that it is a collaborative IRB composed of members from UIC, Northwestern and the VA. Chaired by Dr. Kathryn Rugen for the first 3 years, (and then by a Northwestern member), IRB #4 will help facilitate VA protocols in accordance with VA regulations.



James H. Fischer
Director, OPRS

UIC received encouraging feedback from AAHRPP concerning IRB #4. This summer, OPRS will submit the AAHRPP application for UIC's Human Subject Protection Program.

OPRS also looks forward to new additions to our Continuing Education offerings. This begins later this month with a new HIPAA presentation – streamlined and up-to-date.

Sincerely,

Jim Fischer
Director

OPRS Newsletter Publication Schedule:

Aug/Sept Oct/Nov Dec/Jan Feb/March



NEWS FOR INVESTIGATORS

Guidelines for Researchers Conducting Research at Jesse Brown VAMC

The Research and Development Committee (R&D) of the Jesse Brown VA Medical Center (JBVAMC) must approve all research activities that engage the JBVAMC before the research may begin at the JBVAMC. This includes research studies that recruit JBVAMC subjects (staff, patients, volunteers), use JBVAMC resources (funds, facilities, space, personnel), or wish to post advertisements for the recruitment of subjects on JBVAMC property. With the written approval from the JBVAMC R&D you will receive copies of the informed consent document(s), HIPAA authorization(s) and any recruitment or enrollment materials that have been approved by both the IRB and R&D for use at the JBVAMC.

IRB 4. The JBVAMC has appointed the Collaborative JBVAMC/Northwestern University (NU)/University of Illinois at Chicago (UIC) IRB, IRB 4, 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.

IRB Pre-Submission Process. Before submitting your application to the Collaborative IRB, you must come to the R&D office for review of the IRB and R&D applications. Please bring two (2) copies of the completed applications and any relevant forms/ appendices. The **IRB Protocol Submission Checklist** lists the required documents for submission. Your submission for IRB review will not be accepted without a signature from the R&D Office on the checklist.

Other submission processes:

- Initial Reviews
- Amendments
- Continuing Reviews
- Exempt Research
- Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), Serious Adverse or Unanticipated Events
- Final Reports

Additional guidelines, procedures, and information:

- HIPAA Authorizations for Research
- Advertisement for and Recruitment of VA Subjects
- Non-Compliance
- Audits, On-Site Evaluations, FDA Inspections, Reports to Sponsors or Federal Agencies
- New Facility Human Protections Program (FHPP) Policy: Allocation of Funds for WISE Foundation or General Post Fund (GPF) for JBVAMC
- Tissue Banking Guidelines
- VA Research Pharmacy Charge Form for Pharmaceutical Drug Proposals

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Guidelines for Researchers Conducting Research at Jesse Brown VAMC Continued from Page 2

- Flagging of Medical Records for Research Participants at JBVAMC
- Use of Radiation in Human Research Subjects
- Procedures for Use of Protected Health Information for Subject Recruitment Researcher Contacts with Veterans
- Special Populations (including Prisoners, Children, Pregnant Women, and Mentally Disabled Persons or those Persons with Impaired Decision Making Capacity)
- Data Privacy and Cyber Security Training
- Research Record Keeping

For more information, or a copy of the full “Guidelines for Investigators Conducting Research at the Jesse Brown VAMC,” please see the “Getting Started at JBVAMC” section of the website at: [http://tiger.uic.edu/depts/ovcr/research/protocolreview/irb/jbvamc/Getting Started.pdf](http://tiger.uic.edu/depts/ovcr/research/protocolreview/irb/jbvamc/Getting%20Started.pdf).

JBVAMC R&D IRB Protocol Submission Checklist

Before submitting your application to the Collaborative IRB, you must come to the R&D office for review of the IRB and R&D applications. Please bring two (2) copies of the completed applications and any relevant forms/ appendices. The **JBVAMC R&D IRB Protocol Submission Checklist** lists the required documents for submission. Your submission for IRB review will not be accepted without a signature from the R&D Office on the checklist.

The checklist ensures that the appropriate documentation is submitted; applicable education requirements have been met; and document any potential conflict of interest. By completing the checklist for each submission, this helps ensure that the research is compliant with the appropriate regulations and guidelines, including VHA Handbook 1200.5.

For more information and a copy of the “JBVAMC R&D IRB Protocol Submission Checklist,” please refer to the “Submission Checklist” on the website at: <http://tiger.uic.edu/depts/ovcr/research/protocolreview/irb/jbvamc/Checklist.pdf>

*Learn more about
research at the
JBVAMC at
[www.research.uic.edu/
protocolreview/irb/
jbvamc/index.shtml](http://www.research.uic.edu/protocolreview/irb/jbvamc/index.shtml)*



CONTINUING EDUCATION OPPORTUNITIES FOR INVESTIGATORS

OPRS requires that investigators and key research personnel take initial training before conducting research. Training also needs to be updated every two years with two Continuing Education credits.

Need CE Credit?

- Does your department hold lectures that would be appropriate for Human Subjects Research Education credit?
- Have you heard of a program that you would like to see offered for Human Subjects Research Education credit?
- Will you be attending a conference that would apply to Human Subjects Research?

OPRS unveils a new on-line HIPAA course for initial training!

We listened to your comments - Check our website at the end of June for a new concise version of HIPAA training.

Upcoming Department Lecture Available for HSPP Credit:

June 18th: **Military Medical Ethics After 9/11**

Speaker: Edmund G. Howe, MD, JD

Professor of Psychiatry, Uniformed Services, University of Health Sciences

INITIAL TRAINING IN HUMAN SUBJECTS PROTECTION

Offered throughout the year, Investigator 101 covers the history of research ethics, ethical principles and The Belmont Report, development and application of the federal regulations for human subject protections, UIC's Federal-wide assurance and policies, criteria for review of research, informed consent process, research protocol review processes, and the application of the ethical principles and regulatory requirements.

UIC Investigator 101 Training Calendar

Friday, August 22, 2008	1:00 PM - 4:00 PM	SCE, Room 713
Tuesday, September 9, 2008	1:00 PM - 4:00 PM	MBRB Auditorium
Tuesday, November 18, 2008	1:00 PM - 4:00 PM	MBRB Auditorium

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<http://tigger.uic.edu/depts/over/research/protocolreview/index.shtml>