

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

Fall begins and with it a new semester. And there is always change – changes in investigators, changes in staff, changes to requirements, changes to forms.

For JBVAMC investigators, many VA documents and research procedures have gone through major revisions as a result of the recently issued update of the VHA 1200.05 Handbook. Since many of these changes impact investigator responsibilities, OPRS has written an Investigator Manual to help you navigate these changes. See News for Investigators in this issue.



James H. Fischer
Director, OPRS

For any investigator, if you are changing personnel or adding students to your research personnel, make certain they are up to date on their IRB Training. Expired training slows down submissions. If you need to check on training status, contact Laurie Kennard at lkennard@uic.edu. And if you are a Faculty Sponsor on a student's research project, please make sure your training is up to date as well.

It's AAHRPP time once again – happily a reaccreditation. The JBVAMC reaccreditation site visit is this October. Always challenging, OPRS will guide investigators through the interview process with special training from our Assistant Director for Education, Chuck Hoehne.

And you may have noticed some changes to the OPRS Front Desk. Sonia Ibarra, our receptionist and a UIC employee for over 20 years, retired the first of September. Sonia was interviewed in the August 2010 Newsletter. We miss her but we just couldn't compete with retirement and a new grandchild!

Jim Fischer
Director, OPRS

Please note that older versions of **UPDATED** forms will no longer be accepted after **September 1, 2011**. Please make sure you are using the current forms!



NEWS FOR INVESTIGATORS

INVOLVED WITH VA RESEARCH?

Investigators with protocols involving the VA should be aware of the revisions and updates to the documents and procedures that affect their research submissions.

1. The Guidelines for Investigators as well as the Investigator Responsibility Poster have been updated.
2. Updates to forms include an updated [Submission Checklist](#) and an updated VA Protocol Submission Packet.
3. ALL the VA Standard Operating Procedures (SOPs) have been revised. These will be posted on the JBVAMC page in the coming weeks

Please note the following change regarding Human Subjects Protocols at the JBVAMC:

Per the direction of the Midwest Office of Research Oversight (MWORO) and JBVAMC Regional Counsel, in response to a recent Serious Adverse Event, **no recruitment-only human subjects research protocols will be allowed going forward at JBVAMC.** These protocols must be conducted at JBVAMC with a JBVAMC informed consent and UIC-IRB #4 and RDC approvals. An MOU between JBVAMC and the affiliate must be signed and executed for any protocol-related activities to be conducted off site, and must address Intellectual Property issues. This MOU must then be submitted to UIC-IRB #4 along with said protocol for review and approval. If there is funding associated with the study, there must be a CRADA or sub-contract in place through WISE (JBVAMC's NPC).

Please contact Jill Fahlgren, Executive Director of WISE for CRADA and sub-contract information at Jill.Fahlgren@va.gov. Please contact your respective legal counsel for MOU requirements.

"Guidelines, forms and SOP's have changed. Please visit the [OPRS website](#) to learn more.."

THE NEW JBVAMC INVESTIGATOR MANUAL

Due to the many revisions to the 1200.05 VHA handbook, OPRS created a manual for investigators involved in VA research. The manual clearly explains the requirements, roles and responsibilities of researchers working with veterans. Some of the aspects covered in the manual are VA consents, documenting study visits, keeping master lists, and conducting the research as written in the protocol. For more information, refer to the [OPRS website](#).

All research that engages the JBVAMC, including recruitment of JBVAMC staff, patients, and volunteers or use of JBVAMC resources, must have approval of the JBVAMC Research & Development (R&D) Committee before the research may be implemented at the JBVAMC. The Collaborative JBVAMC/NU/UIC Institutional Review Board (IRB #4) has the responsibility of reviewing human subject research to be conducted at the JBVAMC and involving investigators with joint UIC and JBVAMC appointments, joint NU and JBVAMC appointments, or investigators with solely JBVAMC appointments. Investigators participating in the research at the JBVAMC are required to follow both the UIC specific policies and procedures and the JBVAMC Standard Operating Procedures.

JBVAMC AAHRPP REACCREDITATION

The site visit for the JBVAMC AAHRPP reaccreditation will be October 24 and 25, 2011. During this time, AAHRPP will review protocol files and interview Research and Development staff, the VA Medical Director, IRB Chairs and several investigators and their staff.

NEW PROGRAM REGISTRATION OPEN! COLLABORATIVE TRAINING INITIATIVE FOR CLINICAL RESEARCH PERSONNEL

**Three Fridays in October 14, 21, and 28, 2011
8:30am – 4:00pm
5175 College of Medicine Research Building (COMRB)
909 S Wolcott St.
Chicago, IL 60612**

This three-day program offered October 14th, 21st and 28th, 2011 is designed to provide a basic framework for the role and responsibilities of the research personnel, the Federal and University regulatory and policy requirements for appropriate conduct of clinical research, and tools to assist research personnel to successfully perform their role.

The program is open to all UIC employees conducting clinical research and requires registration. Registration CLOSSES October 1st. Enrollment is limited so register early!

Follow the link to registration: <http://tigger.uic.edu/depts/ovcr/research/events/CCTS>

The program is sponsored by the UIC Center for Clinical and Translational Science, the UIC Office of the Vice Chancellor for Research and the UIC Clinical Research Forum.



TIPS FOR INVESTIGATORS

RESEARCH DATA SECURITY UPDATE: UIC PURCHASES CAMPUS-WIDE DATA ENCRYPTION SOFTWARE LICENSE

As a reminder, Electronic Protected Health Information (ePHI) cannot be stored, even for temporary storage or data transfer, on electronic portable devices, including but not limited to laptops, external hard drives, flash/thumb drives, and smart phones, unless the data is encrypted, de-identified or identifiers removed and stored in a separate location (pseudo de-identified dataset).

Further, the UIC IRBs are now requiring that all electronic sensitive and/or highly sensitive research data, including all Protected Health Information (PHI), be encrypted using software meeting the NIST standard. Encryption assumes even greater importance when data will be stored, even short term, on portable electronic devices.

To help investigators encrypt their electronic research data, UIC has purchased a campus-wide data encryption software license. As of July 1, 2011, acceptable (and free!) data encryption software is available to all UIC faculty, staff and students through the UIC Academic Computing and Communications Center (ACCC): <http://www.uic.edu/htbin/ulist/az?dispatch=find&style=uic&orgid=99449>

Finally, investigators are strongly encouraged to discuss research data security with their college IT representative prior to submitting their applications for IRB review, as these individuals have been extensively involved in the development and implementation of current best practices for data security. The contact information for IT representatives for each of the colleges can be accessed via the on-line ACCC Data Security FAQs: <https://www.uic.edu/wiki/view/ACCC/Security/SecurityFAQ>



MEET OPRS

BARBARA CORPUS— IT'S IN HER GENES!

Barbara Corpus is the OPRS Associate Director for External Relations and Quality Assurance, as well as the VA Liaison. What that lengthy title means is Barbara is the “Go to Gal” for issues relating to JBVAMC research, AAHRPP accreditation, internal audits, and updates on forms and policies. This new position was made official in the last few months and presents a kind of meteoric rise for Barbara in the world of the UIC IRB.

Barbara began her IRB career at the University of Chicago, first in the research lab and then as a study coordinator where she learned about IRB submissions and regulatory issues. In 2006, Barbara came to UIC as an IRB coordinator for IRB #3. After 3 years, she became the Assistant Director for IRB #4, the Collaborative JBVAMC/NU/UIC IRB. She was part of the team instrumental in forming the Collaborative IRB, a first at UIC.

“We could, actually, form our own IRB consulting firm – maybe that’s in the future.”

MEET OPRS CONTINUED FROM PAGE 4

“All the IRB’s are dedicated to subjects’ protection, but IRB 4 is very dedicated to the Veterans and attune to their situation. The VA board is stricter, with more regulations and therefore more paperwork. The IRB members accept this, because it’s part of what’s needed to protect the Vets.”

Now as the Associate Director for External Relations, she will guide UIC through the AAHRPP reaccreditation in 2013, among other adventures.

Another aspect of Barbara’s IRB life is that it runs in the family. Her older sister is the manager of the biomedical IRB at the University of Chicago, and another sister is a research study coordinator.

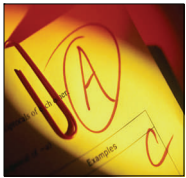


“We could, actually, form our own IRB consulting firm – maybe that’s in the future.”

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Research Subjects (OPRS)

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Chicago, Illinois 60612

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CONTINUING EDUCATION OPPORTUNITIES FOR INVESTIGATORS

Mandatory Childhood Vaccinations: Should Parents Have a Choice?

J. Tiemstra, MD

A review of the literature and research related to childhood immunizations and how this directly impacts on safe and appropriate patient care, in addition to how this issue impacts general public health.

Oct 5 12:00 -1:00
1 OPRS credit

UIH 1740 W. Taylor St.
Room 1130/1135

For additional Investigator Continuing Education opportunities, please contact Chuck Hoehne, OPRS Assistant Director, Education and Training: choehne@uic.edu or 312-355-2908

[http://tigger.uic.edu/depts/
over/research/
protocolreview/index.shtml](http://tigger.uic.edu/depts/over/research/protocolreview/index.shtml)