



University of Chicago

# CLINICAL RESEARCH UPDATES

## A Newsletter from the IRB & OCR

Volume 2 Issue 2

May 2008

### OCR Monthly Workshops

#### Put them on your calendar

- 1st Friday Sept–June
- 12–1pm Dora De Lee
- CME & CNE available
- Lunch Provided

6/6/08 “Religion, Conscience & Clinical Decisions”

Dr. Farr Curlin

Past workshops can be viewed on the OCR Website:

[http://clinicalresearch.bsd.uchicago.edu/faculty\\_staff/presentations/index.shtml](http://clinicalresearch.bsd.uchicago.edu/faculty_staff/presentations/index.shtml)

### Fundamentals in Clinical Research

Series 13: began 4/8/2008

Registration forms can be found:

[http://clinicalresearch.bsd.uchicago.edu/faculty\\_staff/training\\_education/documents/fundamentals\\_reg\\_form.pdf](http://clinicalresearch.bsd.uchicago.edu/faculty_staff/training_education/documents/fundamentals_reg_form.pdf)

A free course on the core competencies of clinical research management. Open to all research faculty and staff Series of 10 modules repeated 5 times / year [pgonzalez@bsd.uchicago.edu](mailto:pgonzalez@bsd.uchicago.edu) or 4-8992

### Principal Investigator Training Program

A self-administered training program required for all new Principal Investigators focusing on the responsibilities of conducting a clinical research study contact Linda DeSouza at [ldesouza@bsd.uchicago.edu](mailto:ldesouza@bsd.uchicago.edu) or 2-6277.

### IRB: Updates

#### Announcements

- Supplemental Form H has updated language from the RADRAC. New version date is December 2007

### Institutional Review Board Updates:

The IRB would like to welcome three new IRB administrators:

**Alicia Scott** ([ascott1@bsd.uchicago.edu](mailto:ascott1@bsd.uchicago.edu)) new IRB administrator for **Committee A**

**Cristina Morales** ([cmorales@bsd.uchicago.edu](mailto:cmorales@bsd.uchicago.edu)) New IRB administrator for **Committee B**

**Dawn Paulsen** ([dpaulsen@bsd.uchicago.edu](mailto:dpaulsen@bsd.uchicago.edu)) New IRB administrator for **Committee C**

The IRB would also like to recognize the following IRB administrators in their advancement to the Senior Regulatory Compliance Administrator position: (Senior Regulatory Compliance Administrators serve as the administrative lead for their designated IRB Committee.) Please join us in congratulating these individuals on their promotions:

**Alicia Cook** ([acook@bsd.uchicago.edu](mailto:acook@bsd.uchicago.edu)) New Senior Administrator for **Committee A**

**Christine Hudoba** ([chudoba@bsd.uchicago.edu](mailto:chudoba@bsd.uchicago.edu)) New Senior Administrator for **Committee B**

**Jill Navarro** ([jnavarro@bsd.uchicago.edu](mailto:jnavarro@bsd.uchicago.edu)) Senior Administrator for **Committee C**

**IRB FORM UPDATE:** The new version is labeled April 2008 and is effective for all new amendment submissions. The specific changes are:

- 1) Request for primary contact information on page 1 of the form; “New primary contact” is no longer a choice on page 2

Note that the IRB is now requesting that the primary contact information be filled in for **every** amendment. We hope that this will allow us to better communicate promptly with the correct study contacts.

- 2) Addition of request for an explanation of how currently-enrolled subjects may be re-consented (located on page 5 of the form)
- 3) The amendment form has been reformatted to allow for special characters in all text fields

**Additional information is available on the IRB website:** <http://ors.bsd.uchicago.edu/IRB/>

### Office of Clinical Research Updates:

**Bethany Martell** has been promoted to Director of the Office of Clinical Research (OCR). Beth joined the OCR in 2005 as the Associate Director for Financial Operations after serving as the section administrator for the Section of Rheumatology and Section of Infectious Diseases in the Department of Medicine. She has been OCR acting director since the departure of Kim Rusk last September

In conjunction with the Institute of Translational Medicine (ITM) and the Clinical Translational Science Award (CTSA), Beth will be taking the lead in a reorganization of the OCR, in which this office will act as the central administrative support unit for all human subjects research and all BSD Center and Departmental clinical research offices. In this manner we plan to streamline and expedite submission and approval of all regulatory and oversight documents, including IRB associated documents, in one support office. We will keep the BSD community informed of any changes through regular communications, as well as through our website at <http://clinicalresearch.bsd.uchicago.edu/>.

One major initiative the OCR has rolled out is utilizing **Velos** a web-based electronic data management system for human subject data for clinical trials. Velos eResearch web site [http://clinicalresearch.bsd.uchicago.edu/faculty\\_staff/velos/index.shtml](http://clinicalresearch.bsd.uchicago.edu/faculty_staff/velos/index.shtml).



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### **Velos eResearch – Clinical Trials Management System at UCMC**

**Velos eResearch** is a web-based system for managing clinical research. Velos will allow researchers to efficiently design protocols, track consents, coordinate schedules, and collect and manage data

**Our Objective:** To provide clinical researchers & study staff with user-friendly technology infrastructure for managing studies, tracking subjects, and facilitating analysis, while maintaining the privacy and safety of participants.

**Why Velos eResearch:** Comprehensive **web** based clinical trials management system; designed specifically for investigators and their research teams; all research-related information is centralized; successfully implemented at several medical academic centers that have been awarded CTSA grant; easily blends into any existing workflow, streamlining and accelerating the research process; HIPAA and 21 CFR Part 11 compliant

**Velos timeline in the BSD:** Velos was initially implemented in the Cancer Research Center in 2005 for better management of cancer clinical trials, regulatory monitoring and NCI and NIH reporting. The Department of Medicine and the Department of Surgery started to pilot Velos at the beginning of 2007. According to the Clinical Trial Enrollment/Registration Policy that was passed by the Clinical Research Policy Board, all of the clinical trials that involve human subjects will have to be entered and tracked in Velos. Department of Ophthalmology and Neurology are in the process of starting to use Velos. All the other departments doing research with human subjects will be contacted by OCR to discuss Velos implementation. If you are interested in using Velos for managing your clinical trials, contact OCR.

**OCR role:** OCR is managing Velos implementation at the BSD. Velos eResearch web site

**[http://clinicalresearch.bsd.uchicago.edu/faculty\\_staff/velos/index.shtml](http://clinicalresearch.bsd.uchicago.edu/faculty_staff/velos/index.shtml)** .

Contact us at [velosbsdhelp@bsd.uchicago.edu](mailto:velosbsdhelp@bsd.uchicago.edu) for more information.

**Velos training:** The OCR has added an elective to the Fundamentals of Clinical Research course entitled “Human Subject Registration” to instruct research staff on utilizing Velos. This 2 hour interactive course is scheduled for: May 20, May 21, June 17, September 16, & December 6. If you are interested in taking this course complete a velos access request form: [http://clinicalresearch.bsd.uchicago.edu/faculty\\_staff/velos/documents/velos-access-form.pdf](http://clinicalresearch.bsd.uchicago.edu/faculty_staff/velos/documents/velos-access-form.pdf) and email Dionisia Saner. Please note, class size is limited to 12 participants to accommodate the computer training rooms. If additional training opportunities are needed, please contact the OCR.

#### **About Velos from our Principal Investigators:**

"Velos has provided us with a user-friendly, paperless, and efficient method of organizing a large number of study patients. In addition, Velos serves as a powerful platform by which we can track important clinical variables over time. We are also using it to catalog biospecimens in our laboratory, so that members of our laboratory know how much and which samples are stored in a given location. Support from OCR has been invaluable in setting up our study."

Michael Morowitz, M.D,

"...[O]ur efforts to improve informatics [with Velos] within the cancer center have made an immeasurable difference in the ability to document activity for grant applications, and is a dramatic improvement from when I put this grant together just 2 yrs ago. I truly appreciate the yeoman's effort that has gone into this and hope to use it as a model for some our efforts within the BSD and CTSA."

Walter Stadler, M.D.