



CHICAGO RESEARCH MATTERS



September 2009 / Volume 3: Issue 4

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Q & A for Researchers

1. A small independent sponsor wants to take the protocol to an outside central IRB. Is this a good idea?

A: No. The UCMC requires that the local IRB (University of Chicago) be used. Also, a determination of why the protocol was not approved and consideration for a correction to the protocol should be made. If the sponsor decides on a different site and IRB, the second IRB should be made aware of the rejection of the study by U.C. IRB.

2. A monitor was at our site and noticed some data found in the CRF is not found in the source document. She said it was required to be there. Is that correct?

A: Neither ICH GCP nor FDA regulations require that source documents be kept for ALL entries on the CRF. However, it should be noted that the sponsor may disagree and not allow the study to continue.

New Training Requirements Released

Training requirements for faculty and staff participating in clinical research have recently been released by the Clinical Research Policy Board. These requirements will further ensure protection of human subjects and compliance with institutional and federal research regulations. Programs that meet training requirements include 1) [CITI](#), a brief web-based training, 2) NIH Online training (faculty only option), 3) Fundamentals of Clinical Research, a 10-module weekly class, 4) Graham School Certificate in Clinical Trials Management, 6 3-hour sessions that can be completed within an academic year. Choose the best training option for you [here](#). Initial training requirements must be completed by June 2010. Contact Pam Gonzalez in the OCR at 4-8992 or pgonzale@bsd.uchicago.edu for help with meeting training requirements.

Getting Smart About IRB Wise

IRB Wise is the new electronic system for clinical research submission. All new and continuing study protocols need to be submitted electronically. For further instructions on submitting continuing renewals electronically, see [Renewal Instructions](#). You must have a CNET ID to log into IRB Wise. The principal investigator will need to log on and approve protocol submission when it is ready to go to the IRB. Co-investigators and study staff will need to log into IRB Wise to complete a minimal registration process in order to be added to the study. More [FAQs](#) about IRB Wise.

FEATURES OF IRB Wise :

- Print the approved Informed Consent
- View personnel on the study
- Print current Protocol
- View Status of submission (Pending, Approved, Under Review, Withdrawn)

U.C. RESEARCH IN THE NEWS

Lupus Clinical Trial Makes Headlines

Dr. Tammy Olsen Utset and her research team are participating in a phase 3 clinical trial for a new lupus treatment. The drug trial has created a lot of buzz in the medical field due to early analysis of study data which indicates significant improvement in patients' response rate to the drug when compared to standard of care. The University of Chicago research team was recently interviewed about the lupus trial on the Chicago ABC 7 News. Watch the [coverage](#).



Lupus affects 1.5 million people in the U.S. and 90% of those diagnosed with the disease are women. Of the 10 subjects enrolled at the University of Chicago, 9 were female, reflecting the prevalence of lupus in women. Stephanie Green, the research coordinator on the study, believes that if the results of this study are comparable to early analysis of the international Phase 3 trial, then the study drug could potentially be the first lupus drug to be approved by the FDA in decades. "This progress in lupus research will be extremely important for lupus patients since currently approved drugs for lupus entail many harmful side effects, and many patients are running out of options," Green said. Additional clinical trial information can be found at the [Lupus Research Institute's](#) website.

Fall OCR Workshop Schedule

9/4/2009	What is going on in the OCR/IRB
10/2/2009	Stats for Research
11/6/2009	Clinical Research Town Hall Meeting
12/4/2009	Lessons from FDA Warning Letters

Location: Dora De Lee L168 Time: 12:00-1:00p.m.

Global Health & Medical Ethics Seminar Schedule

9/30/09	Lab to Village	P-117
10/7/09	HIV Prevention Research	H-103
10/14/09	Eradicating the Great Worm	L-168
10/21/09	Short Term Electives in Low-Resource Countries	L-168
10/28/09	Role of Religious Orgs. In Contributing to Health Care in Africa	H-103

All are welcome to attend. Time: 12:00-1:30 p.m.

Are You NEW to Research?

The Office of Clinical Research hosts a training program called Fundamentals in Clinical Research. The 10-module course reviews everything from the IRB to Informed Consent to Research Billing and Study Documentation.

Next session starts October 6th at 1:30 in room W632. See full [schedule](#) for more information.

The OCR Welcomes:

Kathleen Keen, OCR Financial Analyst
kkeen@bsd.uchicago.edu
 773-834-3192

The IRB Welcomes:

Sybil Medie, Committee A IRB Administrator
smedie@bsd.uchicago.edu
 773-834-5274

Lack of Study Volunteers?

Dr. Richard Schilsky, an oncologist and active researcher at U.C., was recently interviewed for a *New York Times* article titled "Lack of Study Volunteers Hobbles Cancer Fight." I caught up with Dr. Schilsky to further discuss the topic of research participation, the barriers he encounters in oncology research, and his response to the *Times* article.

Q: When the article was published on August 3, 2009 what was your initial reaction?



A: I knew the article was coming out and nothing in it surprised me. The harsh reality is that enrollment of adult cancer patients on clinical trials is pitiful, in large part because oncologists are not more engaged in the clinical trials process for all the reasons described in the article. The low rate of patient enrollment means it takes longer for studies to complete and for researchers to get answers. Sometimes by the time the study is completed the results are no longer of interest because the science or clinical practice have moved on. This problem no doubt also contributes to the low publication rate of some trials.

Q: Do you think recruitment for cancer research trials is challenging due to the reluctance of the patient to participate or the disinclination of physicians to oversee clinical trials?

A: In my view, the problem is primarily a failure of physicians to offer patients the opportunity to participate in a trial. In virtually every practice setting that has been studied, 80% of patients who enter trials are enrolled by 20-25% of the physicians. So many physicians don't bother or enroll very few patients. To be sure, not every patient enrolls if asked and sometimes there are not suitable trials available for patients but the primary problem is lack of physician participation. Again, the reasons for this are described in the *Times* article and include lack of adequate reimbursement for the time spent to manage patients on trials, lack of sufficient support to hire and train the clinical research staff required, enormous administrative burdens and substantial regulatory liability for not doing it right.

Q: What is your advice for researchers at the University of Chicago for increasing the recruitment of study volunteers?

A: First, develop trials that are scientifically sound and ask medically important questions. Second, understand the patient population available to you and whether that is the same population required by the study. Third, develop tools to provide information to patients about the trial (these must be approved by the IRB) and fourth, develop cues that prompt physicians to offer trial participation to patients seeking care at the U of C.

New Postings on the OCR Website:

- [Research Conduct Training Options](#)
- [Research Conduct Training Policy Announcement](#)
- [Concurrent and Centralized Routing \(CCR\) Memo](#)
- [Concurrent and Centralized Routing Reference](#)

Velos eResearch

our choice for clinical trials management systems



IRBwise

future electronic IRB management system

