

OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS

INSIDE THIS ISSUE:

<i>New Forms and Policies for Researchers</i>	2
• <i>Changes to the Initial Application Form</i>	
<i>News for Investigators</i>	3
• <i>Registration of Clinical Trials and Genome Wide Association Studies Database</i>	
<i>Continuing Education Opportunities</i>	4
<i>February FAQ:s</i>	5

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

As we begin 2008, I'd like to welcome back the community OPRS serves; the investigators, coordinators, research personnel and research participants.

The New Year brings two recent regulatory issues we want you to be aware of; the first is new FDA requirements and the second is new guidelines issued by NIH.

On December 20th a notice went out to investigators from Dr. Larry Danziger, then Associate Vice Chancellor for Research, with information from the FDA Amendments Act of 2007, which expands the requirement of clinical trial registration to most Phase 2, 3 and 4 FDA-regulated research.

On January 25, 2008, the NIH implemented new guidelines for contributing data to the Genome Wide Association Studies database. Please read more about these important issues and how they affect your research on the News for Investigators page in this newsletter.

We want our UIC investigators to be well informed. The Genome Wide Association Studies database is a complex issue and, as OPRS creates policies and procedures, one that needs your input. This year, OPRS will host a Town Hall on this issue to gather feedback from our community.

Keep informed via the OPRS newsletter and have a safe and successful 2008.



James H. Fischer
Director, OPRS

New Forms and Policies for Researchers

CHANGES TO THE INITIAL APPLICATION

FORM - Initial Review Application: Health and Biological Sciences

Version 3.6 07-07-07

Two changes have been made to the Initial Application for Human Subjects Research.

Number of Required Copies

It is required that **one** copy of the investigator's CV or biosketch be submitted with the initial application. If the research is a drug study or involves the FDA, one copy of Form 1572 and one copy of the professional/medical license for each member of the research team identified in Appendix P – Additional Co-Investigators/Key Research Personnel must also be submitted.

Federally Funded Research

As of November 1, 2007, all research that is federally funded requires a copy of the grant to be submitted with the initial application. The initial application **will not be accepted** without a copy of the grant submission.

*Always make sure you
are using the most
current version of a
form.*

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?

Please contact Laurie Kennard at (312) 413-9175 to see if your program might apply.



NEWS FOR INVESTIGATORS

REGISTRATION OF CLINICAL TRIALS AND GENOME WIDE ASSOCIATION STUDIES DATABASE

On December 20th, a notice went out to investigators from Dr. Larry Danziger, Interim Vice Chancellor for Research, with information from the FDA Amendments Act of 2007, which expands the scope of registration of clinical trials at ClinicalTrials.gov, increases the amount of information that must be provided at the time of registration, requires the eventual inclusion of trial results, and imposes penalties for noncompliance. Registration is now required for most Phase 2, 3 and 4 FDA-regulated research. Responsibility for registration falls to the sponsor of the clinical trial (as defined in 21CFR50.3) or the Principal Investigator if so designated by a sponsor, grantee, contractor, or awardee.

The OPRS guidance document on clinical trial registration describes the requirements and process:

<http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0268.pdf>.

Failure to provide the required information or the provision of false or misleading information may result in civil monetary penalties. For federally funded trials, the grant funds may be withheld or recovered. More information is available at the links below:

* Fact Sheet "Registration at ClinicalTrials.gov: As Required by Public Law 110-85, Title VII at - <http://prsinfo.clinicaltrials.gov/s801-fact-sheet.pdf>.

* Guidance from NIH Office of Extramural Research "Guidance on New Law (Public Law 110-85) Enacted to Expand the Scope of ClinicalTrials.gov Registration" - <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html>

On January 25, 2008, the NIH implemented a new policy for contributing data to the Genome Wide Association Studies (GWAS) database. This policy requires the IRB and institution to certify that plans for submission of genotype and phenotype data from GWAS to the NIH meet the criteria stipulated in the policy. We are currently working with the UIC Office for Research Services to develop a coordinated approach for handling the certification. For more information on structure, policies and facts, consult the following link: <http://grants.nih.gov/grants/gwas/index.htm>. If this policy will impact your research, please feel free to call OPRS for assistance at (312) 996-1711.

*Registration is now
required for most Phase
2,3 and 4 FDA-
regulated research.*



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.

NEW! HIPAA LIVE!

The popularity of Assistant Director Charles Hoehne's Investigator 101 training presentations prompted the initiation of live HIPAA sessions. Mr. Hoehne will present the HIPAA training (required for research using PHI) in a version that is more investigator friendly than the longer on-line course.

Friday, February 15, 2008

1:00 p.m. – 3:00 p.m.

MBRB Auditorium

You may still fulfill your HIPAA requirements on-line if you wish, but look for more live HIPAA training in the future.

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

Tuesday, February 12, 2008	1:00 PM–4:00 PM	MBRB Auditorium
Monday, March 31, 2008	1:00 PM–4:00 PM	SCE, Room 713
Thursday, May 22, 2008	1:00 PM–4:00 PM	MBRB Auditorium

*All UIC investigators
and other key research
personnel are required to
complete IRB 101.*

FEBRUARY FAQ: INITIAL APPLICATION

Q: Is it true that the initial application instructions have been expanded?

A: Yes, the instructions for the initial application have been expanded to provide a more detailed description of the requirements in each section. The instructions also give helpful hints on how to respond.

Q: The checklist appears to have been expanded to include submission of the professional or medical licenses for investigators and other key research personnel. Why is this being required? Is it necessary for all research?

A: The International Conference on Harmonization guidance (ICH E6) on Good Clinical Practices (GCPs) indicates that IRBs must ensure that investigator (s) are qualified by education, training, and experience and should provide evidence of such qualifications through up-to-date curriculum vitae and other relevant documentation. In order to accomplish this, the IRB is requesting copies of the investigator's professional/medical licenses. The need for requesting this information is reinforced by several recent determination letters issued by the Office of Human Research Protections (OHRP) and FDA of the DHHS citing institutions for failure to ensure that appropriately qualified personnel were performing study-related procedures. **Please note that documentation of the professional/medical licensure for investigators and other key research personnel is only required for research regulated by the Food and Drug Administration (FDA), i.e., drugs, biologics, or devices.**

Q: The checklist asks for copies of Form 1572. What is this form, where can I find it, and why do you need it?

A: Form 1572 is an FDA form that captures the investigator's name and address, location where the research will be conducted, any laboratory facilities to be used, name and address of the IRB, and identity of co-investigator. Form 1572 also states the investigator's responsibilities in conducting clinical investigations of drugs or biologics under 21 CFR 312, which by signing the 1572 the investigator commits to following during the research. Submission of **Form 1572 is only needed when the research is regulated by the FDA.** Form 1572 is located on the OPRS website under Forms and can be found at the following link (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-1572.doc>).

Office for the Protection of
Research Subjects (OPRS)

Room 203 AOB, MC 672
1737 West Polk Street
Chicago, Illinois 60612

Phone: 312-996-1711
Fax: 312-413-2929

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