University Committee on Human Subjects
www.osp.cornell.edu/Compliance/UCHS/homepageUCHS.htm
35 Thornwood Drive
255-5138 (phone)
255-0758 (fax)

UCHS Newsletter

Autumn 2005

UCHS is Moving to 35 Thornwood Drive

The office of the University Committee on Human Subjects will be moving to 35 Thornwood Drive (near the airport) on Monday, October 17. This means that investigators need to be sure to get application materials to us by the deadlines for their protocols (2 weeks minimum before the start of an exepedited project and 3 weeks minimum before the start of a non-expedited project).

This move marks the beginning of a transition as UCHS becomes a part of the new Office for Research Integrity and Assurance (ORIA). ORIA will encompas the compliance areas of human subjects research, animal research, biosafety, and conflict of interest. Cornell is currently interviewing candidates for the new position of Director of ORIA. We hope to be bringing you new of the appointment in our next newsletter.❑

Clinical Trial Registration

In September 2004, the International Committee of Medical Journal Editors (ICMJE) announced that they will consider clinical trials involving humans for publication only if it has been registered before the enrollment of the first patient. Cornell investigators associated with clinical trials, even those trials led and conducted at other sites, should become familiar with this editorial policy.

The ICMJE policy applies to trials where recruitment will begin or has begun after July 1, 2005. Not all ongoing trials were officially registered at that time. Thus the editors will consider for publication ongoing trials that are registered before September 13, 2005.

For more information about this policy see the editorial "Is This Clinical Trial Fully Registered? — A Statement from the International Committee of Medical Journal Editors" published in the *New England Journal of Medicine* June 9, 2005. (www.njem.org)

If you are conducting a clinical trial and need or wish to register it with the national Protocol Registration System, go to http://prsinfo.clinicaltrials.gov/index.html for key information and a link to a guided tour on how to register your trial.❑

Do NOT Request Social Security Numbers for Subject Payments

In a Memorandum dated August 11, 2005, Anne Shapiro, Cornell's Associate Controller, has informed UCHS that the University will no longer require Social Security numbers to pay subjects of University research projects. The reason for this is the threat of identity theft when individuals are required to give their Social Security numbers on forms. She emphasizes that: 1) subject fee payments are confidential; 2) we should **not** require Social Security numbers to process subject fee payments; and 3) Principle Investigators should **not** be collecting Social Security numbers, especially on the web.❑

Conducting Research in Public Schools

Investigators should not submit Initial Approval Request forms to UCHS before they have contacted schools in which they hope to conduct their research. It is important to work with schools and organizations first to learn their rules and guidelines before coming to UCHS. In the future, investigators will need to have their community collaborators' approval for conducting research at their institution before filing an Initial Approval request form with UCHS. This means starting much earlier and presenting the community group (school, business, NGO, etc.) with your research plan. When filing an Initial Approval Request with UCHS, you must include a hard copy letter from an appropriate individual at the community group certifying that they have approved your conducting research there. This certification may include any stipulations the organization desires.❑

Guidelines for Human Embryonic Stem Cell Research (2005)

This timely publication has been made available to read online at no charge by The National Academies Press. Go to http://www.nap.edu/books/0309096537/html/ to begin reading. (In addition to the full text, by chapter, it also offers a "skim" option so you can find what you're looking for with greater efficiency.)❑

☞

Are you offering your subjects copies of their signed consent forms?

In our Spring 2005 UCHS Survey, one widely reported problem we noted was that investigators are failing to offer subjects a copy of their signed consent form. According to the Code of Federal Regulations (45 CFR 46.117(a)), "A copy [of the written consent form] shall be given to the person signing the form." If you will not have a copier available at the site where your consent forms are signed, then you should have on hand two copies of your consent form for each subject you anticipate will be enrolling in your study.❑

Restricted Access Data Agreements

If you are working with a restricted access dataset which requires a signed contract, EVEN IF YOUR PROJECT IS **NOT** FUNDED, Sponsored Programs Services (formerly OSP) must handle the signing of this contract/agreement. UCHS will be carefully checking to make sure that all restricted access agreements are handled through the proper channels in the future. To save yourself time and aggravation, please contact SPS when your research project will require the use of a restricted dataset.❑

Transcription Services

If you are using a professional transcription service to transcribe your tapes of interviews, focus groups, etc., you need to know what is going to happen to the tapes and copies of the transcriptions after you have received the transcription. UCHS has recently learned that some transcription services retain a copy of transcriptions in their files after they have been sent to the investigator. We therefore strongly recommend that you get a written contract from your transcription service vendor describing exactly what will happen to each copy of a transcription. If the service is keeping a copy, it is imperative that a contract state that this transcription is confidential, will not be released to any other individuals, and will be destroyed at a mutually agreeable date in the future. You owe it to your subjects to be sure the information they have shared in confidence with you IS, in fact, secure.❑

ANNOUNCEMENT

The Cornell Institute for Social and Economic Research (CISER) is offering a new workshop on Using and Managing Confidential Data.

The intended audience is faculty, research staff, or graduate students who anticipate using restricted-use or confidential data for their research projects.

The focus will be on researcher obligations in working with data files that are not for public use, and of the process one needs to go through to acquire access to such data.

Topics will include an introduction to the computing environment and data analysis in the Cornell Restricted Access Data Center (CRADC). There will also be a discussion of the proposal process required for gaining access to confidential Census data via the New York Census Research Data Center (NYCRDC).

This new workshop will be offered twice this semester, and will be taught by Pinky Chandra, Administrator of the NYCRDC at Cornell, and manager of the CRADC.

Schedule details and registration are available at:
http://www.ciser.cornell.edu/ASPs/workshops.aspx.