University Committee on Human Subjects
www.osp.cornell.edu/Compliance/UCHS/homepageUCHS.htm
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New Issues in Human Subjects Protection

September 2004

Accreditation of Human Research Protection Programs: What it means to you (the investigator)

A number of universities, medical schools, and research centers are pursuing voluntary accreditation of their Human Research Protection Programs. The accreditation movement is a response to federal activity designed to improve compliance to federal regulations in human subject research. The major accreditation organization serving universities is the Association for the Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP was founded by a coalition of organizations that represent universities, medical schools, social and behavioral scientists, and medical researchers (www.aahrpp.org).

A number of major research universities have achieved accreditation or are in the midst of applying for accreditation. As one of the leading research universities in the nation, Cornell University is also making plans to pursue accreditation through AAHRPP. We have already begun the self-study process necessary to begin the application process. As a Cornell investigator, the process of achieving accreditation will mean two things to you:

First, the process of applying for accreditation will bring evaluators on campus to examine the Cornell human subjects review process from top to bottom. Researchers, research teams, and departments will be selected and examined for their compliance to federal regulations, including the reporting of all projects involving human subjects and informants to UCHS for determination of "exempt from further review" versus expedited or full review status. The AAHRP review team will randomly select research projects from UCHS files to determine whether reviews and status are in compliance with Federal regulations. If one of your projects is selected, you will be asked to show all your records pertaining to that project, including your original protocol, approval letter(s), any amendments, etc. If you are using signed consent forms, you may be asked to show that you have retained all consent forms on file and that all are signed. (Please keep in mind that investigators are required to retain signed consent forms for three years *beyond* the close of the research project.) You may also be asked to give a tour of the facilities that you use for research. The team will also check to make sure that your project is being conducted in accordance with the protocol records in UCHS.

Second, the AAHRPP team will investigate researcher education and knowledge of federal regulations regarding their research specialties. Members of the AAHRPP team will interview university officials, department chairs and unit heads, and a random selection of faculty in order to evaluate campus-wide knowledge of human research protection issues. Accreditation will be dependent not just on the actions of UCHS, but also on an evaluation of whether researchers and officials are cognizant of their responsibilities for the protection of human subjects.

Why are universities pursuing accreditation? First and foremost, successful accreditation by AAHRPP signals that a university is committed to maintaining the highest standards in research, a major component of securing public trust and support for scientific research. Second, it is expected that accreditation of their institution will give researchers an advantage in competing for federal funds, most particularly from NIH. Third, there is active discussion of amending current federal regulations to require accreditation sometime in the future.❑

Investigator education requirements are being stepped up

The Office of Human Research Protections (OHRP) is discussing adding a new Subpart E to existing federal regulations (45 CFR 46). Subpart E will deal explicitly with education requirements for institutional review board members and staff (UCHS and its staff at Cornell), research investigators, and employees who administer research projects involving human subjects.

UCHS already has instituted several initiatives on education for its members, staff, and Cornell investigators, including this newsletter series. However, we and other universities anticipate that investigators will be required to renew and refresh their human subjects protection

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Correction: In our May issue, alert reader Eric Eisenstein (JGSM) picked up an error in our definition of "Anonymous" as it relates to human subjects research. As Eric pointed out, a researcher could have a record of all subjects' identities and yet have anonymous data if they are collected separately. In a number of studies conducted at Cornell, identifying information on subjects is gathered so investigators may, for instance, pay the subjects or enter them into a raffle. However, this identifying information is not necessarily collected on the same form as the data (for instance, a quick pen-and-paper survey and a separate sign-in sheet). Hence, the researcher *does* have identifying information on all subjects, but the *data itself is anonymous* because it was never linked in any way with the subject's identity. We thank Eric for his insightful feedback.

If you have any feedback or questions regarding any material you read in the UCHS Newsletters, please address your comments to uchs@cornell.edu. Thank you.

education at regular intervals, probably every two years. UCHS will be evaluating new educational programs for investigators and others in the coming year.

The current UCHS investigator education program on our website will not fulfill the requirement for continuing education in human subjects protection. Please be alert for announcements in future issues of this newsletter regarding continuing education for investigators.❑

NEW
Performance Agreement and Release Form

If you plan to photograph or record your subjects for use in any future presentations or publications (including theses, dissertations, and web pages), you now need to have each subject sign a University "Performance Agreement and Release" form. This form is separate from your informed consent document because it serves a completely different purpose. In addition to the use of this form, UCHS now asks investigators to provide scientific justification for gathering data using photos or recordings. The Performance Agreement and Release form can be found at http://www.osp.cornell.edu/Compliance/UCHS/Performance.doc.❑

Tips on determining if your protocol will require a full committee review

The following is a list of some of the criteria UCHS uses to determine whether a protocol will require a full committee review. Although this list is by no means exhaustive, it is our hope to give investigators an idea of the types of studies UCHS and the Federal regulations consider more likely to be detremental to human subjects (and therefore requiring a higher level of scrutiny in the review process). If you are unsure of whether a study would fit into this category, please contact Sarah Demo at 255-5138 to discuss your particular research project.

- Deception in which the subjects are told something potentially disturbing about themselves. For example, a personality test revealing they are not likely every to marry; a saliva sample revealing they may be at risk for a disease; an interaction revealing they have poor social or mental skills, etc. Also deception studies which may in other ways have a lasting negative effect on the subjects. (Obviously, the subjects will be debriefed immediately following the interaction, but this does *not* take it out of the full-review category.)
- Studies involving minors, unless they would fit into one of the exempt categories in the Code of Federal Regulations. Please refer to http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101 or p. 3 of this newsletter for a list of exemptions from review for adult, non-vulnerable subjects.
- Any study whatsoever involving prisoners as subjects.
- Studies involving nutritional interventions.
- Studies involving survey or interview procedures that could elicit responses about illegal behaviors, such as theft, drug use, or underage drinking – unless the survey/interview is *anonymous* (no subject identification data is collected together with the responses).
- Studies involving surveys or interviews targeting extremely sensitive or medically critical topics, such as HIV status or suicidal tendencies.
- Studies targeting pregnant or nursing women other than *simple* surveys or interviews.❑

General Principles for Evaluating Oral History type Activities

The following has been excerpted with permission from a UCLA Office for Protection of Research Subjects Memorandum (the entire document may be viewed at <http://www.oprs.ucla.edu/human/newsletters/Oral%20History%20031209.pdf>)

1. Oral history activities, such as open ended interviews, that ONLY document a specific historical event or the experiences of individuals without an intent to draw conclusions or generalize findings would NOT constitute "research" as defined in 45 CFR 46.

ex: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the videotape does NOT intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.

2. Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) WOULD constitute "research" as defined by HHS regulations at 45 CFR 46.

ex: An open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings.

3. Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Since the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR 46, the creation of such an archive WOULD constitute research under 45 CFR 46.

ex: Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research under 45 CFR 46 since the intent is to collect data for future research.

An institution should perform an initial two-step ☞

evaluation prior to deciding whether an activity constitutes human subject research:

a. determine whether the activity constitutes "research" as defined by 45 CFR 46, and
b. determine whether the "research" includes human subjects as defined by 45 CFR 46.2

In summary, the August 26, 2003 Policy Statement attached to [Dr. Carome's] September 22, 2003 letter was not drafted by OHRP, does not constitute OHRP guidance, and the characterizations of oral history activities in the third paragraph of the Policy Statement alone do not provide sufficient basis for OHRP's determination that oral history activities in general do not involve research as defined by HHS regulations at 45 CFR part 46. Other activities involving open-ended interview that have similar characteristics can involve research as defined by HHS regulations when the activities are part of a systematic investigation designed to develop or contribute to generalizable knowledge.❑

Human Subject Exemption Categories

The following are Human Subjects Exemption Categories (45 CFR 46.101(b)). Please note that Exemption 2 in *most* cases *cannot* be applied to children. Although no investigator is allowed to "self-exempt" (i.e., exemption must be designated by UCHS only upon receipt of an Initial Approval Request form and supporting documents), the following may serve as a guideline on how to make your study exempt from review under federal regulations.

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, OR (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, IF these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

[(5) This exemption only applies to employees of the Federal government and is not relevant to Cornell employees.]

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or [contains] agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.❑