University Committee on Human Subjects
www.osp.cornell.edu/Compliance/UCHS/homepageUCHS.htm
115 Day Hall
255-5138

Fine Tuning your Approval Request Form

May 2004

Photography (and other types of recording) in Human Subjects Research

Be sure to specify if people or other identifiable things (a house, neighborhood, place of business) that could lead people to the subjects will be included in any photographic images you plan to take for your project. Remember that faces, even if not captioned with names, are identifiable in photographs.

Similarly, faces and/or voices on tape recordings (video and/or audio) may also be identifiable even if names are not given. Your protocol needs to include a way to keep subject identities confidential (if so promised), and consent forms should specify to the subject how their identities will be protected. Include a mention of when the photos or recordings will be destroyed, if ever. You must also disclose how the photos and recordings will be used in the future.

Finally, UCHS is moving toward a system whereby investigators will present a consent form AND a media release form when research will include recordings and/or photographs that may be used in publications or presentations. Please watch our web site for suggested release form formats in the near future.❑

Tips for describing "the design of your research and planned use of human subjects" on your approval request form

Often UCHS receives descriptions of study designs that are rather unclear. When deciding how to answer questions on the application, think of it in another way: If you were to tell another person what they would need to do in order to conduct your research, what would you tell them? Remember to include all of the procedures that relate to your subjects, including any photography or audio/video recordings.❑

Consent form lingo

UCHS continually finds investigators using "anonymous" and "confidential" interchangeably. The terms have distinct and somewhat contradictory meanings. In terms of human subjects documentation, those terms are defined as follows:

Anonymous - Subject's identity is not known to the researcher (and therefore CANNOT be disclosed).

Confidential - Subject's identity is known to the researcher, but will not be disclosed.

Based on these definitions, information cannot be both "anonymous and confidential," as many consent forms state. To your subjects, however, "anonymous" and "confidential" may be fairly ambiguous terms. You might therefore prefer to just describe the actual process you are following to keep their names secret, and this might stave off questions from the subjects as well.

Another area of confusion for some investigators is that of "minimal risk." Do not use a phrase such as "There are no risks to you in participating in this study." Take an unlikely but possible case: if your subject fell off her chair during an interview, she could say it wouldn't have happened if she hadn't been there for the interview (which would be true). This is why UCHS advocates that investigators use the following phrase (or something similar) for all minimal risk studies in which no real risk is foreseen: "We do not anticipate any risks for you participating in this study, other than those encountered in day-to-day life."❑

Do you need to renew your human subjects approval?

Did you know that you can continue analysis of your data after your human subjects approval expires IF you have taken out identifiers (i.e., name, address, phone numbers, etc.) that could link the data to individual subjects? To do this, assign a subject number to each of your subject's data, pull out any identifying information and add the subject number to it. This leaves you with two sets of information: de-identified data (including subject numbers) to work with, and a separate file of identifiers and subject numbers, which you must then store in a secure location. You also must respond to UCHS's renewal reminder e-mail with a Project Closure form if your data files are de-identified and you will not be renewing.❑

Renewal application consent forms

Please note a slight change in our procedure for renewal applications. For quality assurance purposes, in cases where you are using written consent forms we are now asking that you submit a photocopy of an actual *recently-signed* consent form with the signature covered or obscured in some way. Unfortunately, we have discovered numerous incidences in which investigators are NOT using the latest consent form approved by UCHS for their study. We hope that this new practice will prompt investigators to be more careful about which version of their consent form UCHS has approved for use.❑

Certificates of Confidentiality: Protecting your subjects' privacy

If you are conducting research into topics such as illegal behaviors (drug use, theft, even downloading music from the internet), you may wish to consider applying for a "Certificate of Confidentiality." Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure through U.S. court subpoena. (Although NIH is the agency that issues these certificates, you may apply for one even if your research is not funded by NIH.) They allow the investigator, and others who have access to research records, to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Once granted (nearly all applied for are granted), the investigator merely adds this information to the "Confidentiality" portion of their consent document (i.e., "We have a federal certificate of confidentiality so that any information you or your child give us about illegal substance use by you or your child is protected from use in potential prosecution"). For more information on Certificates of Confidentiality, please go to NIH's "Certificates of Confidentiality Kiosk" at http://grants1.nih.gov/grants/policy/coc/index.htm.❑

As a courtesy to our investigators, we are reproducing here recommendations for Investigators from the Final Guidance from DHHS on "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" Federal Register / Vol. 69, No. 92 / Wednesday, May 12, 2004 / Notices (found at http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/pdf/04-10849.pdf)

4. Investigators

The Department recommends that investigators conducting human subjects research consider the potential effects that a financial relationship of any kind might have on the research or on interactions with research subjects, and what actions to take.

Actions to consider:

Including information in the informed consent document, such as

- The source of funding and funding arrangements for the conduct and review of research, or
- Information about a financial arrangement of an institution or an investigator and how it is being managed.

Using special measures to modify the informed consent process when a potential or actual financial conflict exists, such as

- Having another individual who does not have a potential or actual conflict of interest involved in the consent process, especially when a potential or actual conflict of interest could influence the tone, presentation, or type of information presented during the consent process.
- Using independent monitoring of the research.

Dated: May 5, 2004.

Tommy G. Thompson, *Secretary, Department of Health and Human Services*

[FR Doc. 04-10849 Filed 5-11-04; 8:45 am]❑

The plural of anecdotal is not data.

-C.K. Gunsalus