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Revision to Conflict of Interest Disclosure Requirement

Ron Berge, Executive Vice President, Chief Operating Officer, and Chief Compliance Officer

Steve Leibold, MSHA, Corporate Compliance Manager and Privacy Officer

As many of you are aware, there are new federal regulations to minimize the impact of possible financial conflicts of interests on research conduct. To ensure that we are screening researchers adequately about their potential conflicts of interest, all individuals listed on a protocol submitted to the IRB or IACUC (principal investigators, co-investigators, research coordinators, technicians and other research staff) must complete a protocol-specific Conflict of Interest and Scientific Misconduct form. Completion of this form by each individual listed on each protocol will provide a more accurate and timely method for our institution to identify actual or potential conflicts of interest.

This requirement will be implemented for new human or animal protocols submitted or reviewed after January 1, 2013 or for personnel added to a protocol after January 1, 2013.

Wendy Charles, MS, CIP, CCRP; Director, Research Regulatory Affairs

Q: How has the IRB's Conflict of Interest disclosure form changed?

A: There are two main changes. First, the form has been changed to reflect National Jewish Health's new COI disclosure policy. While the previous form listed monetary thresholds, the revised form does not. Second, the previous form requested COI disclosure from only Investigators, but the revised form requests information from all members of the research team.

Q: What happens if I submit the old version of the COI form to the IRB?

A: Because the old version is not a reflection of National Jewish Health's disclosure policy, the obsolete version of the form will be returned and researchers will be instructed to complete the new version.

Q: Where can I find the new COI disclosure form?

A: It can be downloaded from the IRB website:

<http://www.nationaljewish.org/pdf/IRB%20COI-Scientific%20Misconduct.doc>

CONTACT US

National Jewish Health
Institutional Review Board
1400 Jackson Street
Room M211
Denver, CO 80206-2761

Phone: 303.398.1477
Fax: 303.270.2292

nationaljewishIRB@njhealth.org

For more information, contact:

Steve Leibold or Wendy Charles

leibolds@njhealth.org

303-398-1466

charlesw@njhealth.org

303-398-1855

Managing Subject Dropouts: When does “no” mean “no”?

Robert A. Sandhaus, MD, PhD, IRB Co-Chairman

Wendy Charles, MS, CIP, CCRP; Director, Research Regulatory Affairs

Subjects have the right to drop out of (i.e., discontinue participation in) research at any time and for any reason and without giving a reason. When subjects would like to drop out, Investigators express feeling torn between their commitment to successfully completing their research and their desire to demonstrate respect for the subjects, many of whom are also patients in their clinic. So what should researchers do when they are told that a subject would like to drop out? The IRB provides the following guidance in response to researchers' questions.

What should I say when a subject would like to drop out of the study?

First and foremost, the IRB encourages researchers to thank subjects for participation in the trial. These people gave of themselves with a goal of helping others and advancing science. Don't forget to thank them.

While researchers often want to collect the reasons why subjects drop out, it is important to remember that subjects do not have to provide a reason for their choice. Instead, the IRB recommends asking if the subject is willing to share the reasons why he or she would like to drop out of the study. If the subject declines to share the reason, he or she should not be probed further. Even though the IRB is also interested in the reasons why subjects drop out, the IRB does not want subjects to feel coerced into giving this information when they are not obligated to do so.

Investigators should not attempt to dissuade subjects from dropping out, as any statements about the “importance of the research” can be perceived as coercive. If there are any end-of-study or termination forms and/or evaluations in the approved protocol, it may be appropriate to ask the subject if they are willing to allow these to be completed. Once again, limit the discussion to a simple explanation of the procedures involved, answer any questions, and accept the answer provided by the subject as final. In addition, depending on the nature of the study, the investigator can inquire about the subject's willingness to continue in part of the study or with an alteration to the study. The following is advice

from the Office for Human Research Protections (OHRP).

Can a subject be asked to continue in part of the study?

Continued participation in secondary components of a research study may be particularly important in clinical trials designed to evaluate the safety and effectiveness of specific interventions in the management of diseases or disorders. For this reason, OHRP recommends that when a subject decides to drop out of a clinical trial, the investigator conducting the clinical trial ask the subject to clarify whether the subject wishes to drop out from all components of the trial or only from the primary interventional component of the trial (such as discontinue the investigational medication). If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the subject previously gave consent may continue under a protocol exception.

For example, consider an IRB-approved clinical trial testing the safety and effectiveness of an experimental chemotherapy regimen in patients with lung cancer that involves the following sequential procedures for each subject:

- Intervening with the subject by administering up to six monthly cycles of the experimental chemotherapy regimen;
- Intervening with the subject by performing a chest CT scan immediately following completion of the last chemotherapy cycle and every six months thereafter for the next five years;
- Obtaining information about the subject's health status through interviews and physical examinations immediately following completion of the last chemotherapy cycle and every six months thereafter for the next five years; and
- Analyzing the data that includes identifiable private information about the subject to determine complete and partial response rates of the lung cancer following the experimental chemotherapy.

(Continued on next page)

If a subject informs the investigator that he or she wishes to drop out from the clinical trial after the second monthly cycle of the experimental chemotherapy regimen because of unacceptable side effects, the investigator may ask the subject if he or she is willing to undergo the follow-up CT scans, interviews, and physical examinations that were described in the IRB-approved protocol and in the informed consent document signed by the subject. If the subject agrees, these follow-up activities may continue. The Investigator is reminded, though, to request a protocol exception to the chemotherapy regimen from the IRB (and sponsor, if applicable).

If a subject does not want to continue with any additional involvement, what must be discontinued?

If a subject decides to drop out from all components of a research study, the investigator must discontinue all of the research interventions and study activities, including obtaining additional information from the subject's medical records.

If a subject drops out, what can we do with the information we already collected?

OHRP notes that the HIPAA Privacy Rule gives an individual the right to revoke authorization for use and disclosure of protected health information (PHI) in writing, except to the extent a covered entity has taken action in reliance on that authorization. In the context of research, this permits the continued study of PHI already obtained under the authorization prior to its revocation, to the extent necessary to protect the integrity of the research

study. Thus, for HHS-supported research that is also subject to the HIPAA Privacy Rule, if a subject chooses to withdraw from that research and also revokes authorization in writing for continued use or disclosure of his or her PHI that was already obtained in the research, analysis of that PHI may only continue to the extent necessary to protect the integrity of the research study. For FDA-regulated research, retention and analysis of already collected data, including PHI, is always considered necessary to protect the integrity of the research study.

In conclusion, when a subject in a research study decides to drop out, it can be appropriate to ask if the subject is willing to answer questions about the reasons for their decision, it can be appropriate to ask for termination forms and procedures to be allowed, and the subject can be informed about the possibility of continuing in part of the study when appropriate. But, all this must be done without any attempt at coercing a change of mind, either perceived or actual. "No" should be considered to mean "no."

For more information, review: <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html>.

For more information, contact:
Wendy Charles
charlesw@njhealth.org
303-398-1855

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New Way to Find Approved Documents for COMIRB Protocols

Currently, approved documents for Full Board COMIRB protocols are emailed to study Primary Investigators' and Primary Contacts' UCDenver.edu email accounts. This includes approved documents for Initial Reviews, Continuing Reviews, amendments, along with "noted" Unanticipated Problem reports.

Approved documents will no longer be emailed to Primary Investigators or Primary Contacts. Instead,

approved documents will be available through the eRA(InfoEd) system.

Instructions for how to retrieve your approved documents can be found by clicking: http://gcruc.ucdenver.edu/comirb/COMIRB_Panel_Download_Approval_Packet_Instructions.pdf.

Please contact COMIRB at 303-724-1055 with any questions.