

**125TH MEETING OF THE NATIONAL CANCER ADVISORY BOARD (NCAB)
MEETING OF THE AD HOC SUBCOMMITTEE ON CONFIDENTIALITY OF
PATIENT DATA**

February 10, 2003
7:30 p.m. – 8:30 p.m.

Welcome/Introduction—Dr. James Armitage

Dr. James Armitage, Dean, University of Nebraska College of Medicine, chaired the meeting of the Ad Hoc Subcommittee on Confidentiality of Patient Data with Ms. Mary McCabe, Director, Office of Education and Special Initiatives (OESI), NCI, serving as Executive Secretary. The subject under discussion was recent changes to the patient privacy regulations and their impact on clinical research. Ms. McCabe presented a brief history of the National Privacy Rule mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA was initiated in response to concerns that insurance companies and others might seek to obtain access to an individual's confidential genetic information. The Department of Health and Human Services (DHHS) drafted regulations and, after multiple comment periods, a revised Privacy Rule was finalized with implementation to begin on April 14, 2003. The rules will be enforced by the DHHS Office for Civil Rights (OCR); noncompliance with HIPAA is considered serious, and can result in fines and imprisonment.

HIPAA Implications and Cancer Research—Dr. James Armitage

The Ad Hoc Subcommittee on Confidentiality of Patient Data was initially established to provide best practices to ensure patient confidentiality in clinical trials. Ms. McCabe summarized the outcomes of the two previous Subcommittee meetings. The current charge developed by the Subcommittee is to ascertain whether implementation of the new HIPAA regulations will present an impediment to cancer research. This information will be reported to the full Board, and an action plan developed.

Dr. Armitage proposed that more information is needed about the implications of HIPAA, specifically a more accurate interpretation of the HIPAA regulation. The Subcommittee agreed that individual research institutions might be overly cautious in their current interpretation of HIPAA because the penalties for inappropriate use of protected health information can be so severe. Dr. Larry Norton, Director, Medical Breast Oncology, Memorial Sloan-Kettering Cancer Center, noted, for example, that molecular profilers have been traveling to Europe to obtain datasets for analysis rather than deal with the U.S. regulations regarding individual patient consent in research protocols. The Subcommittee felt that it would be of genuine benefit to the research community to ascertain whether this caution is justified, or whether it is the result of an unsubstantiated "fear" of the consequences of HIPAA. The Subcommittee agreed that, in order to determine whether such concerns are real or perceived, additional information is required. Two approaches were agreed upon:

1. Invite a legal expert from the DHHS to explain to the Subcommittee the rules and the major issues of HIPAA.
2. Survey the Cancer Centers and Cooperative Groups for their concerns about how they anticipate HIPAA will be an impediment to conducting clinical research, and their proposed plan for compliance.

The legal expert will be invited to attend the next NCAB meeting in June 2003 to present an authoritative account of the rules from OCR's point of view. There will then be an opportunity to present the concerns gathered from the Cancer Centers and Cooperative Groups to the legal expert, and to discuss pertinent

issues that need to be addressed. The Subcommittee hoped that this would provide an opportunity to positively influence the implementation process, and define the boundaries of the new rule for the benefit of researchers and patients. Dr. Armitage stressed that the choice of the legal expert is critical; he or she must be able to communicate OCR's position on HIPAA implementation, must be knowledgeable of the issues surrounding patient confidentiality and clinical research, and must be in a position to give definitive answers to questions of compliance. The Subcommittee agreed that in light of this, the legal expert must represent OCR, the arm of DHHS that will enforce HIPAA. It was also agreed that legal participation would be limited to a single expert for the purpose of educating the Subcommittee rather than initiating a debate on implementation.

The Subcommittee discussed organizing a symposium to gather information from Cancer Centers, Cooperative Groups, and Specialized Programs of Research Excellence (SPOREs), but decided that a questionnaire would best allow respondents to articulate their concerns and provide the most objective data. It was agreed that, as the concerns facing any one individual SPORE would be common to all of them, it would be more effective to limit the survey to the Directors of Cancer Centers and Directors of Cooperative Groups. There are approximately 75 centers within these two categories. Rather than asking about specific problems associated with issues such as the confidentiality of clinical trials or tissue collection, the questions in the survey should be more generic. Ms. McCabe agreed to compose a questionnaire in the form of a letter that the Subcommittee will review. The responses will be in essay format; Dr. Norton proposed a method of quantifying the responses by first sampling 10 to 15 percent of the questionnaire responses for representative answers. After analysis of these responses, the Subcommittee could have a conference call to develop a definitive questionnaire that will be mailed to all of the Directors of Clinical Centers and Cooperative Groups. The Subcommittee members would see the raw data before the next NCAB meeting. The responses would also be provided to the legal expert so that he or she could address the investigators' concerns.

The Subcommittee hoped that by instituting now a review of HIPAA it could establish a "baseline" of what are perceived to be the concerns as implementation takes place.

Preparation of a Questionnaire and NCAB Meeting Agenda—Ms. McCabe

Three issues will require immediate attention in order to prepare a session on HIPAA for the June 2003 NCAB meeting:

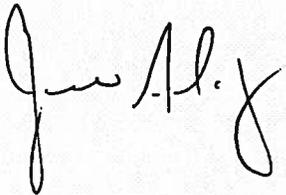
- Identify a legal expert and schedule a meeting session agenda (education, response to questionnaire concerns, and discussion of action).
- Draft, review, and distribute a questionnaire letter to Cancer Center and Cooperative Group Directors.
- Develop a timeline for data analysis.

Attendees

Subcommittee Members

- Dr. James O. Armitage, Chair
- Ms. Mary McCabe, Executive Secretary
- Dr. Samir Abu-Ghazaleh
- Dr. Jean B. deKernion \
- Dr. Ralph S. Freedman
- Dr. Larry Norton
- Ms. Marlys Popma
- Ms. Lydia G. Ryan

The meeting was adjourned at 8:30 p.m.



Dr. James Armitage, Chair

2/12/03
Date



Ms. Mary McCabe,
Executive Secretary

2/12/03
Date