Institutional Review Board
Meeting Summary
Monday November 28, 2011
Director's Conference Room
535 West Jefferson, 5th Floor, Springfield, IL
Room 711
122 South Michigan, Chicago, IL

Members Present

Jenny M. Aguirre, George J. Dizikes, Jane E. Fornoff, Arthur F. Kohrman, George A. Marchetti, Jerome Richardson, Kenneth L. O. Soyemi, Mildred Williamson.

Member Absent

Tiefu Shen.

Alternate Members Present

Craig S. Conover, Mark Flotow, Shannon R. Lightner, Jeff Lyon, Claudia Nash, Andrea D. Parker, Leticia E. Reyes.

Staff Present

Harold Duckler, Shirley Musgrave, Susan Shin.

The meeting began at 1:41 p.m.

The members and staff at both locations introduced themselves and indicated their roles in their respective areas within the Department and (the public members) outside the Department.

Dr. Conover provided information on:

- the Data Release and Research Committee (DRRC) which began seven years ago;
- the Department's referring protocols to other Institutional Review Boards (IRBs) including most recently to the one at the Chicago Department of Public Health (CDPH);
- the advantages of having Dr. Kohrman as Chair and an IRB within the Department;
- the scheduling of meetings quarterly;
- the expectation that the majority of the protocol reviews will be handled by the IRB Chair and staff by being exempt or expedited.

Dr. Kohrman indicated that:

- he was honored for having been selected as Chair and looking forward to working together as a group;
- Dr. Conover has been the engine in the creation of this IRB and developing the documents;
- the DRRC conducts the most stringent and exhausting pre-review and reviews;
- the role of the IRB is to protect the Department, its staff, researchers, research subjects the citizens of Illinois and the institution of science and research as well as to educate staff and investigators and on the boundaries of research and what their concerns ought to be;

- the IRB is to promote rather than to be a barrier to research;
- he expects to do expedited reviews on the majority of the protocols himself;
- the remaining protocols will be reviewed by the full committee and he will assign one or two members to present;
- outside consultation and expertise may be brought in infrequently to augment the depth of the expertise within the Department;
- members will be provided with periodic reports of the descriptions and disposition of protocols;
- in addition to the scheduled quarterly meetings it may be necessary to have ad hoc meetings when protocols may require such and members will be given adequate notice;
- CDPH Commissioner, Dr. Bechara Choucair, M.D., had been exceptionally generous in allowing the Department to use the facilities of the CDPH IRB while developing the Department to implement its own IRB;
- indicated that the DRRC would not be a bottleneck and that protocol referrals to CDPH will remain at CDPH in response to Dr. Richardson's questions about DRRC processing and bringing the referrals active at CDPH to IDPH.

Mr. Duckler:

- thanked Dr. Conover pulling together almost all of the information that the members will see during the meeting;
- indicated that scheduled meeting dates for the IRB meetings will be on the third Thursday of the second month of each calendar quarter–February 16, May 17, August 16 and November 15;
- suggested that members consider holding on their calendars the possibility of ad hoc meetings on the third Thursday of the other months–January 19, March 16, April 19, June 21, July 19, September 20, October 18, and December 19;
- informed the members that after consultation with the Attorney General's Office that the Department 's Legal Services staff indicated that the IRB was subject to the Open Meetings Act (5 ILCS 120);
- informed members that new or revised documents will be posted to the Department's Internet and Intranet site respectively for public information and internal use, respectively
- conducted a walk-through of the information posted on the internet at http://www.idph.state.il.us/irb/ that included the Department's policy, procedures, instructions to investigators, the list of primary contacts for data requests, IRB application documents and reference documents (Other Links page) that IRB members should become familiar with;
- indicated that the in-house documents and reference documents listings will be updated as needed;
- advised that electronic files will be established to reduce paperwork as much as possible
- indicated that the regulations allow for IRBs to have differing determinations of the same protocol
- reviewed the processing of requests: the pre-submission exchange of information between the investigators and the (RIs), the submission of documents to the RI and resolution of possible issues; referring the request to the DRRC where it will be

reviewed and approved after resolving any concerns, referral to the IRB for review, IRB approval sent to the RI after resolving any concerns, the execution of a data use agreement and providing the requested data;

- informed the members that orientation/training sessions will be scheduled for Responsible Individuals;
- will advise the RIs to submit template data use agreements to Legal Services for approval so that in the future the drafts of data use agreements will be able to be submitted with the IRB referrals;
- that three other staff have been identified to contribute on a part-time basis to staffing the IRB—Shirley Musgrave, Susan Shin and Elena Hernandez.

During this presentation the following information was contributed:

Dr. Richardson indicated that IT is in the process of changing the Department's Internet site starting with Winshop. In response to his query about filling documents on line through the use of a sequel server, he was informed that it is a future possibility. In response to his concern about the same members and staff filling out different sets of information he was advised that the focus of the documents to be completed is to avoid as much paperwork as possible and that every effort will be made to avoid duplication. In response to his query about any exceptions to requests going to RIs he was informed that the only exceptions would be those requests for data that are not covered by the programs/data sets that appear on the RI list on the Internet which would come to the IRB staff. He also recommended using a protocol for training members of the IRB.

Ms. Lightner suggested that the IRB staff consider using Share Point for document sharing.

Dr. Kohrman indicated that:

- the Office for Human Research Protections oversees all IRBs and has the right to come in and monitor our activities at any time and without notice and will include reviewing the status of certifications of IRB members;
- the IRB's activities will conform to the Health Insurance Portability and Accountability Act (HIPAA);
- .members should read the **Public Health Practice vs. Research** that describes the differences between public health research and public health practice.
- members who find any text that may need modification to bring such concerns to his and the IRB staff's attention;
- an amendment to a protocol that was expedited initially expedited may require a full committee review;
- the Department must be extremely careful about not compromising individual anonymity when releasing data.

Mr. Lyon asked about the number of protocols received during a year and was informed that an average of three to four a month. However some of those protocols result in aggregated data being provided instead and thus not subject to research processing.

Dr. Fornoff indicated that she would submit editorial comments on Department documents posted to the IRB Internet page.

Dr. Williamson asked about protocols that may involve the correctional population. The response was that protocols such protocols would be so infrequent that an ad hoc representative of the correctional population would be involved in those reviews.

In response to Dr. Soyemi's question about the (internal) form(s) to be used for processing the requests the response was that the investigators complete the Application and the relevant Appendices, the RI initiates the *IRB Submission Form* and forwards it to the DRRC along with the documents submitted by the investigators.

The meeting adjourned at 2:50 p.m.