

**Institutional Review Board
Meeting Summary
Thursday, February 16, 2012
Director's Conference Room
535 W. Jefferson, 5th Floor, Springfield, IL
122 South Michigan Avenue, 20th Floor, Chicago, IL**

MINUTES

- I. Call to Order:** A regular meeting of the Illinois Department of Public Health's Institutional Review Board convened at 1:33PM by the Acting IRB Chair Dr. Craig Conover.

Attendance: Quorum was verified, and meeting continued in accordance with IRB guidelines. Attendance status was as follows:

Members Present

Jenny Aguirre, George Dizikes, Jane Fornoff, Arthur Kohrman, George Marchetti, Jerome Richardson, Tiefu Shen, Kenneth Soyemi

Member Absent

Mildred Williamson

Alternate Members Present

Craig Conover, Mark Flotow, Shannon Lightner, Jeff Lyon, Claudia Nash, Andrea Parker

Alternate Member Absent

Leticia Reyes

Staff Present

Harold Duckler
Shirley Musgrave
Susan Shin
Carolyn Last

- II. Approval of Minutes:** Motion was made by George Marchetti, and seconded by Jerome Richardson to approve the minutes from the November 28, 2011 meeting. There were no oppositions. Motion carried.

III. Status of Requests

Harold Duckler provided an overview of the document "Status of Referrals to CDPH IRB":

- 0819 ISCR VR and 0818 PRAMS – will be assigned for review
- 0817 VR – currently being reviewed

- 0816 VR and 0811 ID – awaiting DUA draft before assigning for review
- 0808 ED ID – awaiting review by DRRC
- Page 2 Requests – most are on hold and will eventually be taken off
- Page 3 Requests with Blue Bars – were approved by IRB initially and will now go through the process of getting renewed through the CDPH IRB
- Staff asked Responsible Individuals to send draft template to legal to receive approval and then submit a specific data request form as a prerequisite to submit to the IRB.
- Four (4) requests are not listed on the document because they are based at NIU
 - PRAMS
 - Medical Monitoring Project
 - The other two are to be discontinued, but will check to see their current status
- There are no pending IRB referrals at the Cook County Stroger Hospital IRB.
- All new requests will be submitted to the IDPH IRB for review.
- There was one internal request from the Division of Patient Safety that was approved.

Dr. Conover:

- thanked Harold Duckler and Dr. Kohrman for pushing the IRB work forward.
- was pleased with the number of requests submitted and interest people have with IDPH data.

Dr. Soyemi had a question regarding the exempt status of study 0711 ISCR on page 6 of the “Status of Referrals to CDPH IRB” document. Harold Duckler will follow up with the group before the following meeting.

IV. Status of Operations

Dr. Conover addressed

- his position as IRB Acting Chair while Dr. Kohrman serves as the IDPH Acting Director
- Dr. Kohrman’s continued involvement in the IRB Process
- the need for a half-time coordinator dedicated to the IRB. Since Elena Hernandez has left the agency, Korin Acosta will provide support for the IRB in her place.
- the need to monitor federal regulations for confirmation; the IDPH IRB are following strict guidelines
- the need to test emails to make sure members and staff are receiving them
- The issues of the indemnification of IRB members who are not employees, and conflict of interest will be discussed with the Department’s Ethics Officer.

Harold Duckler provided information regarding:

- CVs – electronic files and hard copy files of member CVs are being prepared as they are required

- Certification – 2 members have not yet submitted their certifications for training for human subjects. This year, IRB staff will contact members that have not completed training or need to be recertified.
- IRB Documents – updated IRB Policies and Procedures will be posted on the internet by next month. IRB members are to keep a lookout for them.
- Mock Review – members will be asked to participate in a mock review prior to the first actual full board review.
- Emails – members are to check firewalls for possible blocks to IRB emails
- Guidelines – Harold Duckler will provide a sequence of events (flowchart), guidelines, and acronyms that may be applicable to the IRB

Dr. Soyemi asked if NIU IRB project files can be moved to IDPH. Dr. Kohrman mentioned that although it is possible it would be difficult for logistical reasons. Not having all of the documents in one place makes the IRB vulnerable. There was discussion on how file maintenance and transfer of files could occur. For programs like PRAM that are continuing, there was talk of having them resubmit a new application to IDPH. Harold Duckler will follow-up on best protocols for maintaining files.

V. Discussion of LSD Testing

Dr. Conover mentioned that the IDPH LSD testing of newborns using dry blood spots may come before the IRB for review. Therefore, he emailed the following 8 articles to board members for their review:

- Article #1: Public Act 097-0532, SB 1761 – “Newborn Metabolic Screening Act”
- Article #2: Newborn Screening for Krabbe Disease
- Article #3: Newborn Screening for Krabbe Disease: a Model of Cooperation – R. Rodney Howell
- Article #4: Newborn Screening for Pompe Disease: An Update 2011 – Barbara Burton
- Article #5: Neonatal screening for lysosomal storage disorders
- Article #6: Newborn screening for lysosomal storage diseases: an ethical and policy analysis
- Article #7: Weighing the evidence for newborn screening for early-infantile Krabbe disease
- Article #8: Optional Screening “Research studies of new tests (Pilot studies)

The subsequent discussion included:

- a suggestion for members to review Public Act 097-0532, SB 1761
- the 8 articles on LSD testing mentioned above were circulated for the members to review. Dr. Conover attempted to provide a selection of articles that provided well-rounded perspectives of the argument.
- next issue of New England Journal of Medicine will be publishing another newborn screening article
- Illinois’s new genetic advisory committee – currently, there are 38 tests conducted.

- Dr. Conover – Article #4 Barbara Burton refers to IDPH efforts; Article # 8 provides parents with a choice as to whether their newborn is screened
- Dr. Kohrman – Article #6 states it is against federal regulations to do screening without research protocol
- Jerome Richardson asked if LSD is the exception not the rule for public health practice. George Dizikes replied that it is passive consent. With pilot projects, consent and false positive rates are major issues.

George Dizikes, (Lab Director for Clinical Testing, Quality Assurance Manager, and Acting Chief of Newborn Screening)

- 60+ diseases known associated with certain enzymes.
- Similar to New York's Hunter's Hope Foundation, Illinois has the Evanovski Foundation, which is independent from the advisory committee, that lobbied legislatures to test dry blood spots
- HHS Secretary has a committee that advises on which diseases states should be testing. LSD testing was brought to the committee and turned down. In order to be approved certain criteria must be met: test must be performed on dry blood spots, it should be inexpensive, and therapy should be available for test-positive individuals.
- In reference to Dr. Ross's article, Krabbe is the only LSD that has had extensive screening done on a larger scale.
- Due to the fact that concerned parties went straight to the legislature, a bill passed to screen newborns but no policies and protocols were drafted. The agency must decide which LSDs fall into the criteria of research and when informed consent is needed.
- Due to the state's procurement process, it will take the labs about 1 year to receive the appropriate equipment. The agency has about 2 years to start up the program, which gives the deadline of March 2013 to begin a required testing of every newborn. IDPH labs will be ready for mass screening by the deadline.

Shannon Lightner, a recent mother, commented:

- She received a pamphlet on Newborn Screening at the hospital
- When she was pregnant, there were specific tests she had to take.
- When her daughter was born, she was not informed that the baby was tested and was not informed of the results.
- She suggests consent be provided prior to delivery in case of emergency deliveries and due to the state of mind of parents.

Dr Kohrman:

- The IRB's alternatives:
 - Do not bring it to the IRB
 - Bring it to the IRB and consider it exempt from research
 - Bring it to the IRB and consider it is research and require informed consent

Jane Fornoff asked about drawing of blood for consented testing, requested table for treatments for appropriate screenings – Dr. Conover to provide the table.

Dr. Shen asked if the law specifies IRB oversight. David Carvalho, Deputy Director of Policy, Planning and Statistics, provide information on the following:

- State law does not specify IRB oversight, but Federal law preempts State law. Since the IRB is a Federal requirement for human subjects research, their recommendations will need to be included if the IRB finds it to be necessary.
- Once and if rules are drafted, they will be submitted to the State Board of Health and Joint Committee on Administrative Review for approval.
- Mr. Carvalho is to meet with the rules committee today regarding implementation of statutes.
- Regarding implementation, usually the time required is 6 months, but this is not mandatory. It is more considered a goal to inform legislators that the Department is considering it seriously. If we do not meet the deadline because we have not fulfilled the criteria, the Department will not be against the law.

Some questions that stemmed from the discussion are:

- If informed consent is required, when do you ask the parents? Pre-labor, post-labor? Blood must be drawn within 24 hours from the time of delivery.
- What are other states doing?
 - Michigan has a dry blood cells bank for research. Parents are asked after blood is drawn if blood can be utilized for research.
 - Minnesota had to destroy their blood spots, because it was determined that they obtained blood under unauthorized circumstances.
 - Illinois is only state besides New York and Massachusetts that statutorily requires LSD newborn screenings.
 - Some states are waiting to see what Illinois doing before moving forward.
- In instances where positive diagnoses occur, will parents be able to discuss options with their pediatricians?
 - Most pediatricians do not know much about dry blood spot testing or LSDs. Every effort is made to direct parents to the right physicians for follow ups.

VI. Adjournment: The meeting adjourned at 3:05 p.m.