Congenital and Inherited Disorders Advisory Committee
Minutes
January 23, 2015
12:00 p.m. to 2:00 p.m.
Conference Call

M i n u t e s

Members Present	Members Absent	Others Present
Sandra Daack-Hirsch	Bobbi Buckner Bentz	Kimberly Noble Piper
Stewart Boulis	Sarah Dricken	Carol Johnson
Lori Murphy-Stokes	Andrea Greiner	Myrl Holida
Val Sheffield	Sarah Grotha*	Christina Trout
George Wehby	Shannon Sullivan	Alvaro Serrano Russi
Dan Rowley	Michelle Gogerty	Hannah Bombei
Mary Larew for Debra Waldron	Kate Small	Judy Miller
Kelly Schulte		Emily Phillips
Kari Atkinson		Melody Hobert-Mellecker
Stacy Frelund		Kristin Conway
Stanton Berberich		
Francis Degnin	Representative Wessel Kroeschell	
Paul Romitti	Senator Ragan	
Cathy Evers		

Topics	Discussion/Action
Call to Order	▪ Degnin called the meeting to order at 12:03. ▪ Roll call attendance was taken – quorum is present.
Approval of October 24, 2014	▪ Minutes approved by exception vote.
Announcements	▪ Piper – CCID update. Piper is working with the IDPH Chronic Disease Prevention and Health Promotion staff and the Iowa Cancer Consortium to address genetic issues in their programming, as well as genetics in the State Cancer Plan. Working on a push for everyone to promote family health histories. CCID covers genetics/genomics through the life course, not just those programs we receive funding to provide. Iowa Administrative Code 641 IAC 4 that speaks to the programs of CCID has now been adopted and filed. This chapter took effect January 14, 2015. ▪ Johnson – Continue to recruit for medical geneticists and genetic counselors. There is a medical geneticist candidate being interviewed now, he is interested in lysosomal storage disorders and molecular genetics. (Since this meeting, the candidate has accepted a position with the U of I Division of Medical Genetics – more to come.) Cathy Evers and Kim Horton have announced their retirement in May 2015. We wish them well! Hannah Bombei will assume the coordinator position for the Regional Genetics Consultation Service. ▪ Daack-Hirsch – Informed Consent Subcommittee report - The committee is most recently looking at costs involved in obtaining informed consent and for the linking, monitoring and determination of consent status in relation to its specimen. The committee has ideas about how to implement the informed consent process, but does not know how it would be sustainable

	without ongoing funding support. Members are talking with other states about their experience with obtaining informed consent or use of similar processes and the expense involved. Berberich explained the implications of the Newborn Screening Saves Lives Reauthorization Act of 2014 that was signed into law by President Obama last December. An amendment to the law (Section 12) states: SEC. 12. INFORMED CONSENT FOR NEWBORN SCREENING RESEARCH. (a) IN GENERAL.—Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of title 45, Code of Federal Regulations, for purposes of Federally funded research conducted pursuant to the Public Health Service Act until such time as updates to the Federal Policy for the Protection of Human Subjects (the Common Rule) are promulgated pursuant to subsection (c). For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply. (b) EFFECTIVE DATE.—Subsection (a) shall apply only to newborn dried blood spots used for purposes of Federally funded research that were collected not earlier than 90 days after the date of enactment of this Act. (c) REGULATIONS.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed regulations related to the updating of the Federal Policy for the Protection of Human Subjects (the Common Rule), particularly with respect to informed consent. Not later than 2 years after such date of enactment, the Secretary shall promulgate final regulations based on such proposed regulations. The law implies that any specimens (which all contain DNA) are to be considered identifiable. This has implications for Iowa's informed consent process, as well as the use of residual specimens for research, possibly including INSP program-specific studies to improve the program. ▪ Holida –Lysosomal Storage Disorders Subcommittee. The subcommittee continues to look at the addition of LSDs to Iowa's newborn screening panel. Subcommittee members are researching the potential conditions, prioritizing the conditions with available testing methods and treatments.
Presentation of INSP and IMPSP budgets	▪ Berberich – the newborn screening budget for the current fiscal was presented and discussed. Since this is the current budget used, no vote is needed. The proposed budget for the Maternal Prenatal Screening Program (IMPSP) was presented. SHL staff and U of I OB/GYN staff including Dr. Berberich and Dr. Greiner, worked hard to reduce the cost of This budget is contingent upon the future direction of the IMPSP, as decided by the IDPH. Piper stated that IDPH leadership has decided to convene a task force to address the future of the IMPSP. Some committee members expressed concerns that an ad hoc task force will be convened, rather than using the CIDAC to evaluate the program and make recommendations. "A task force works contrary to what CIDAC does." Piper explained that some CIDAC members will probably be asked to serve on the task force, in addition to pulling expertise

	from outside the CIDAC. CIDAC will be kept informed and be able to provide feedback about the recommendations of the task force. Berberich would like to encourage the IDPH to realize that the work of CIDAC members to provide recommendations to IDPH on such matters lets members know they are valued by IDPH and encourages member participation on the CIDAC.
Policy for release of data	▪ Piper presented a draft of the policy for the release of CCID data, including newborn and maternal prenatal screening data, for the CIDAC to review and vote to approve. For the sake of time, Piper will post a survey for members to indicate their vote on whether or not to approve the policy. Questions may be addressed to Piper, and she will post the question and response for all members.
Research proposal	▪ Romitti presented a proposal to conduct a population-based, case-control feasibility study to evaluate the use of a web-based approach for molecular environmental epidemiological investigations of adverse pregnancy outcomes. Infants with pyloric stenosis (cases) and their mothers will be selected from the Iowa Registry for Congenital and Inherited Disorders, and infants without defects (controls) and their mothers will be selected from Iowa birth certificates. Mothers in each group will receive a questionnaire for maternal environmental exposures using standard (common) measures. For mothers in the web-based group, researchers will also request an electronically-signed informed consent to use residual newborn bloodspots from case and control infants for biomonitoring and exploration of genetic and other biologic factors that may contribute to the causes of pyloric stenosis. For mothers in the telephone-based group, researchers will use the US Postal Service to request a hand-signed informed consent for such bloodspots. The study will compare participation rates, sample representativeness, exposure reporting, and costs between the web-based and telephone-based groups. Researchers hypothesize that primary use of a web-based questionnaire compared to a telephone-based questionnaire for exposure data collection will produce higher participation rates in molecular environmental epidemiological investigations of adverse pregnancy outcomes. Researchers also hypothesize that web-based collection of informed consent for use of residual newborn bloodspots will produce higher participation rates than mail-based collection. Improved participation rates will permit increased generalization of study results to the target population and increased statistical power for investigation of environmental risk factors and gene-environment interaction effects. The research proposal and related application for access to public health data research agreement are attached. ▪ Daack-Hirsch moved to recommend approval of the research project to IDPH. Boulis seconded. Roll call vote = motion passed. Piper will prepare a letter for Dr. Romitti showing the CIDAC recommendations with the signature by Dr. Degnin, CIDAC Chair.
Next meeting date and agenda	The next meeting will be April 24 from 1:00 pm to 3:00 pm “ish” at the Drake Community Library in Grinnell, Iowa. Agenda items include a report from CIDAC subcommittees, a report on the status of the Iowa Newborn Screening Information System, and a report from the IMPSP task force.
Adjournment	Meeting adjourned at 1:38 pm.