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**CENTER FOR CONGENITAL AND INHERITED
DISORDERS ADVISORY COMMITTEE** Chair -Greg Garvin

Friday, November 4, 2011 12:00 pm to 1:00 pm

Conference Call

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Agenda

	<u>TOPIC</u> <i>Presenter</i>	<u>DISCUSSION</u> <u>POINTS</u>	<u>ACTION</u> <u>INDICATED</u>	<u>HANDOUT</u>
12:00 pm	Call to Order <i>Garvin</i> - Introductions - Minutes - Announcements	Review committee minutes	Approval of Minutes	July minutes
	Bylaws vs. CIDAC charter <i>Piper</i>	Approval of Charter	Vote	Draft charter
	SCID Update <i>Berberich/ Ramirez/Turner</i>	Discussion of SCID addition to screening panel	none	
	CCCHD newborn screening <i>Piper</i>	Discussion of the addition of screening for CCCHD	none	CCCHD paper
	Use of residual dried blood spot specimens <i>Ramirez, Piper</i>	Discussion of policy and procedure	Feedback needed	Draft policy
	Agenda Items - Next meeting January 20 , 2012 Conference call			FY2012 schedule
1:00	Adjourn			

Iowa Nurses Association
Sandra Daack-Hirsch, PhD, RN

American College of Obstetrician & Gynecologists
Kristi Borowski, MD, Vice Chair

College of Public Health
Paul Romitti, PhD

Consumer Representatives
Gayle Culbertson, CLMA
Brenda Walker, IHA

Maternal Screening Programs
Roger Williamson, MD

**INMSP Medical Director,
Division of Medical Genetics, U
of I**
Val Sheffield, MD

**Iowa Academy of Family
Physicians**
Bryon Schaeffer, MD

Iowa Dept. of Education
Shelley Ackermann, LISW

Iowa Insurance Division
Vacant

**Iowa Osteopathic Medical
Association**
Gregory L. Garvin, DO

Iowa Senate
Senator Amanda Ragan

Iowa House
Representative Beth Wessel
Kroeschell

American Academy of Pediatrics
Jeff Murray, MD

**Iowa Child Health Specialty
Clinics**
Debra Waldron, M.D.

Social Worker
Diana Hoogestraat, MSW, LISW

Parent Representatives
NancyLee Ziese
Becky & James McIlrath
Kori Ensley
Kathleen Cady
Becky Lutgen Gardner

**University of Iowa
Clinical Genetics Staff**
Cathy Evers, RN, MS

**Voluntary Agency
March of Dimes**
Michelle Gogerty

University Hygienic Lab
Stanton Berberich, PhD,

Ethics/Bioethics Representative
Francis Dominic Degnin, PhD

**Iowa Registry for Congenital and
Inherited Disorders**
Paul Romitti

Attorney-at-Law
Allison Heffern, JD

Iowa Congenital and Inherited Disorders Advisory Committee
Grinnell, Iowa
July 15, 2011
1:00 p.m. – 4:00 p.m.

M i n u t e s

Members Present

Shelley Ackermann
 Kristi Borowski
 Paul Romitti
 Sandra Daack-Hirsch
 Nancy Lee Ziese
 Catherine Evers
 Francis Degnin
 Stanton Berberich
 Roger Williamson
 Bryon Schaeffer
 Becky Lutgen Gardner

Members Absent

Kori Ensley
 Brenda Walker
 Gregory Garvin
 Jeff Murray
 Debra Waldron
 Val Sheffield
 Diana Hoogestraat
 Gayle Culbertson
 Michelle Gogerty
 Alison Heffern

Others Present

Kimberly Noble Piper
 Carol Johnson
 Dr. Mary Larew
 Dr. Barbara Stegmann
 Anne Crotty

Senator Amanda Ragan**
 Representative Beth Wessel
 Kroshell**
 ** Honorary Members

Topics	Discussion/Action
<u>Call to order</u>	<ul style="list-style-type: none"> ▪ Dr. Kristi Borowski called the meeting to order at 1:12 pm. ▪ Introductions were made, and two new members – Becky Lutgen Gardner and Dr. Bryon Schaeffer - were welcomed. ▪ A quorum is present.
<u>Minutes of April meeting</u>	<ul style="list-style-type: none"> ▪ Motion by Schaeffer to approve the April minutes, second by Ziese. ▪ Minutes approved as written, pending correction of spelling of Dr. Serrano Russi's name.
<u>Announcements</u>	<ul style="list-style-type: none"> ▪ Johnson: Dr. Alvaro Serrano-Russi is a new medical geneticist that started this last Monday (July 11). He and dr. Oleg Shchelochkov will be taking their biochem boards this fall. ▪ Johnson: Dr. Greg Rice, a biochem geneticist and director of Wisconsin's newborn screening program, is coming for a recruiting visit later this month. He would be hired as the medical director of Iowa's dried blood spot newborn screening program. ▪ Johnson: a child that was diagnosed with MMA four years ago by Iowa's program just received a liver and kidney transplant, and is doing well. Good to hear of these great outcomes! Kudos to the screening program and follow up staff!

<u>Election of Officers</u>	The process of succession for the seat of committee chair and term lengths were discussed. Ziese moved that Dr. Greg Garvin and Dr. Kristi Borowski continue as chair and vice chair, respectively. Evers seconded the motion. Motion approved.
<u>Membership terms</u>	Four members' terms have expired: Cathy Evers, Alison Heffern, Francis Degnin, and Sandra Daack-Hirsch. Evers will talk to her cohorts in the clinical genetics area to see if they want to take the position. Degnin and Daack-Hirsch are both willing to serve another term. Piper will speak with Heffern about serving another term.
<u>Bylaws vs. CIDAC charter</u>	Piper states that the assistant attorney general recommends that legislated committees do not use bylaws. The option is to have guidance for the CIDAC in administrative code, or use a charter to provide direction for the committee. Piper has provided a draft of a charter for members to review. Degnin and Ziese volunteered to assist with editing of the charter with feedback from the committee members. A revised draft will be available to members for the next meeting in October.
<u>Research proposal</u>	Dr. Barbara Stegmann presented a proposal to use residual maternal serum screening specimens for a research study for markers of potential preterm birth. Dr. Stegmann will use aliquots from Dr. Borowski's research. Discussion was held about disposition of residual aliquots and if IRB approval was needed. Berberich recommended that if IDPH approves proposal, approval letter should be specific about disposition of residual aliquots. Motion from Ackermann to recommend IDPH approval of the proposal and use of residual maternal serum specimens. Evers seconded. Motioned passed.
<u>SCID update</u>	Berberich provided an update on the application for funding for a SCID pilot. No word yet about a funding award, however the application did pass the initial technical review. Iowa will start pilot screening for SCID in September. A work group is being organized by Kim Turner to address planning for the pilot screening and follow up system.
<u>CCCHD newborn screening</u>	The Secretary's Advisory Committee on Heritable Disorders in Newborn and Children has recommended to Secretary Sebelius that Critical Congenital Cyanotic Heart Disease be added to states newborn screening panels. Secretary Sebelius has taken the recommendation under advisement, and will make a decision about the recommendation soon. Piper is establishing a work group to review the recommendation and decide how screening for CCCHD would best be implemented in Iowa. Screening for CCCHD would be very different from dried blood spot screening. It would be hospital based, using various quality of hospital equipment, no monitoring or data collection system, and no follow up system in place.
<u>Use of residual newborn dried blood spots</u>	There is a work group addressing the issue of informed "opt out" for use of residual dried blood spots for research purposes. The group has discussed many options for obtaining the opt out signature and the timing of the education to parents about their options. The work group will have a draft policy ready for presentation to the committee at the next meeting. The policy will be combined with the existing storage, retention and use of residual dried blood spot policy. A policy for use of residual maternal serum specimens will be drafted parallel to the DBS policy.

<u>Agenda items for next meeting</u> <u>October 14, 2011</u> <u>via conference call</u>	Program annual reports Review sustainability planning Needs assessment Policy/Procedure update Status of SCID pilot/CCCHD screening planning/ Use of residual DBS/maternal serum for research policy
<u>Adjournment</u>	■ Meeting adjourned at 3:05 pm.

Congenital and Inherited Disorders Advisory Committee (CIDAC) Charter

July 2011

Name: CIDAC	Version: 1.1	Subject: CIDAC scope of practice
Mission Statement: The mission of the Congenital and Inherited Disorders Advisory Committee is to assure the availability of and access to quality genetic health care services by all Iowans and to assure statewide surveillance of congenital and inherited disorders, as determined by the Iowa Department of Public Health (IDPH). The advisory committee will represent the interests of the people of Iowa.		
Opportunity Statement: To advise the Director of the Iowa Department of Public Health regarding issues related to genetics, and hereditary and congenital disorders. To make recommendations to the Iowa Department of Public Health about the design and implementation of programs including but not limited to: the Iowa Neonatal Metabolic Screening Program, the Regional Genetics Consultation Service, the Expanded Maternal Serum Alpha-fetoprotein Screening Program, the Cystic Fibrosis Carrier Screening Program, the Neuromuscular and Related Genetic Disorders Program, and the Iowa Registry of Congenital and Inherited Disorders. To support the development of special projects and conferences regarding genetic health care services and issues. To advocate for genetic health care services for all residents in the state of Iowa.		
Sponsor: IDPH	Leader: Elected committee chair	Coordinator: State Genetics Coordinator
Membership: The Advisory Committee shall be comprised of regular, ex-officio, and honorary members. Membership will be comprised of representatives of professional groups, agencies, legislators, and professional health care providers. Every effort will be made to have gender balance and broad geographic representation on the Advisory Committee. Potential regular members are considered from interest groups, consumer organizations, and genetic health care service providers. The number of regular members shall not be fewer than 15 or more than 25. No more than 30 percent of regular members shall be representatives of or employed by programs that are contractors of the Center for Congenital and Inherited Disorders in the Iowa Department of Public Health. Two parent representatives and two consumer representatives are required for the membership of the Committee. Honorary members will be comprised of two legislators, one state senator and one state representative, and others deemed		

appropriate by the Director of the Iowa Department of Public Health.
 IDPH will appoint regular and honorary committee members for three fiscal years. Reappointment of regular and honorary members shall be at the discretion of IDPH.
 Ex-officio members are nominated by virtue of their positions held and the organizations they represent, and are appointed by IDPH. The members provide expert information and consultation to the Advisory Committee.

Officers: The officers shall be the chair and vice chair. The chair will be responsible for approval of meeting agendas, conducting CIDAC meetings, representing the CIDAC at appropriate or designated meetings, and the appointment of subcommittees as deemed necessary, and will designate the chairperson and membership of each subcommittee. The vice chair shall be responsible for approval of meeting agendas and will assume the responsibilities of the chair in the chair's absence. When so acting, the vice chair shall have all the powers of and be subject to all restrictions upon the chair. The vice chair shall also perform other duties as assigned by the chair.
 The chair and vice chair shall be elected to at the last scheduled meeting of the fiscal year.
 Upon succession of the chair, whether by term limits or other reasons, the vice chair shall assume the position of chair, and a new vice chair shall be elected. The chair and vice chair shall serve staggered terms of no longer than two consecutive years.

Members:	Area of Expertise:
American College of Obstetricians and Gynecologists, Iowa Chapter	
Iowa Osteopathic Medical Association	
American Academy of Pediatrics, Iowa Chapter	
Academy of Family Physicians, Iowa Chapter	
Nursing organization, e.g., INA, IANP	
Medical geneticist, U of I Division of Medical Genetics	
Iowa Department of Education	
Iowa Child Health Specialty Clinics	
College of Public Health	
National Association of Social Workers, Iowa Chapter	
Iowa Insurance Commission	

Attorney at law	
Ethics/bioethics	
Parent	
Parent	
Parent	
Parent	
Consumer/member-at-large	
Consumer/member-at-large	
Community-based organization	
Clinical genetics	
Iowa Registry for Congenital and Inherited Disorders	
State Hygienic Laboratory	
Maternal prenatal screening program	
Iowa Senator	
Iowa Representative	

Meetings: Meetings will be held as necessary and at the call of the Director or the Chair. There shall be a minimum of four meetings per year. At the last scheduled meeting of the fiscal year, the regular meetings for the following year will be scheduled. Notice of meetings will be mailed at least four weeks prior to the meeting date. All meetings will be open.

A majority of the total number of regular members (50% plus one member) shall constitute a quorum.

There must be a quorum of the regular members in attendance at a meeting for action to be taken. Attendance at a meeting is defined as presence at the meeting site in person, through the Iowa Communications Network (ICN), through webinar or web meeting, or via telephone. Action can be taken by a vote of the regular members. Ex-officio and honorary members are not eligible to vote. The Advisory Committee shall maintain information sufficient to indicate the vote of each regular member.

Regular members who represent programs that are contractors of the Center for Congenital and Inherited Disorders in the Iowa Department of Public Health are expected to refrain from imposing undue influence on regular members and to recuse themselves from voting on issues which directly affect the operation of their programs.

Attendance by the regular member or the regular member's designee shall be expected at all meetings. A designee of similar standing must be able to reasonably fulfill the member's role on the committee in discussions. Designees are not eligible to vote. Regular members

(not a designee) must be in attendance at least two meetings per fiscal year to remain in good standing. A regular member who misses more than two meetings per fiscal year shall be deemed to have submitted a resignation.

Customers: Iowa families; IDPH programming & staff; policy makers; contractors; grantees

Objectives: (SMART)

1. One-hundred percent of CIDAC members report “satisfaction” with committee activity by end of fiscal year, and annually thereafter.
2. One hundred percent of CIDAC members use individual expertise to contribute to CIDAC recommendations and advice to IDPH regarding genetic issues.

3.

4.

5.

Success Metrics: (Measures)

1. Annual questionnaire demonstrates member satisfaction with committee activities and structure.
2. Each member has actively participated in CIDAC activities, as indicated by attendance and meeting minutes.

Considerations: Constraints – limited staffing resources; limited funds; “silos”; political climate

Available resources: member skills/expertise; sponsor support; other advisory committees

Additional resources needed:

Key Milestones: Annual committee questionnaire

Date: June 30th each year

Communication plan: The state genetics coordinator will communicate committee activities as approved by committee membership. Meeting minutes are published on CCID web page within two weeks of meetings.

Revision of Charter: This charter may be amended, altered, or repealed, and a new charter may be adopted by majority vote of the membership, provided fourteen days written notice of the proposed changes is mailed, including electronic mail, to the members.

CENTER FOR CONGENITAL AND INHERITED DISORDERS ADVISORY COMMITTEE BYLAWS

I. Name

Center for Congenital and Inherited Disorders (CCID) Advisory Committee (CIDAC)

II. Mission

The mission of the CCID Advisory Committee is to assure the availability of and access to quality genetic health care services by all Iowans and to assure statewide surveillance of congenital and inherited disorders, as determined by the Iowa Department of Public Health (IDPH). The Advisory Committee will represent the interests of the people of the State.

III. Functions

To advise the Director of the Iowa Department of Public Health regarding issues related to genetics, and hereditary and congenital disorders.

To make recommendations to the Iowa Department of Public Health about the design and implementation of programs including but not limited to: the Iowa Neonatal Metabolic Screening Program, the Regional Genetics Consultation Service, the Expanded Maternal Serum Alpha-fetoprotein Screening Program, the Cystic Fibrosis Carrier Screening Program, the Neuromuscular and Related Genetic Disorders Program, and the Iowa Registry of Congenital and Inherited Disorders.

To support the development of special projects and conferences regarding genetic health care services and issues.

To advocate for genetic health care services for all residents in the State of Iowa.

IV. Membership

The Advisory Committee shall be comprised of regular, ex-officio, and honorary members. Membership will be comprised of representatives of professional groups, agencies, legislators, and individuals with an interest in promoting genetic services for the residents of Iowa. Every effort shall be made to have a balance between consumers of genetic health care services or consumer organizations and

professional health care providers. Every effort will be made to have gender balance and broad geographic representation on the Advisory Committee. Potential regular members are considered from interest groups, consumer organizations, and genetic health care service providers listed on Attachment I. The number of regular members shall not be fewer than 15 or more than 25. No more than 30 percent of regular members shall be representatives of or employed by programs that are contractors of the Center for Congenital and Inherited Disorders in the Iowa Department of Public Health. Two parent representatives and two consumer representatives are required for the membership of the Committee.

Honorary members will be comprised of two legislators, one state senator and one state representative, and others deemed appropriate by the Director of the Iowa Department of Public Health.

The Director will appoint regular and honorary committee members for three fiscal years. Reappointment of regular and honorary members shall be at the discretion of the Director.

Ex-officio members are nominated by virtue of their positions held and the organizations they represent, and are appointed by the Director of IDPH. The members provide expert information and consultation to the Advisory Committee. The Executive Committee will appoint ex-officio members for three fiscal years. Reappointment of ex-officio members shall be at the discretion of the Executive Committee.

V. Vacancies

The Nominations Committee will make recommendations to the Director of the Iowa Department of Public Health for appointments of all members.

VI. Meetings

Meetings will be held as necessary and at the call of the Director or the Chair. There shall be a minimum of four meetings per year. At the last scheduled meeting of the fiscal year, the regular meetings for the following year will be scheduled. Notice of meetings will be mailed at least four weeks prior to the meeting date. All meetings will be open.

A majority of the total number of regular members (50% plus one member) shall constitute a quorum.

There must be a quorum of the regular members in attendance at a meeting for action to be taken. Attendance at a meeting is defined as presence at the meeting

site in person, through the Iowa Communications Network (ICN), or via telephone. Action can be taken by a vote of the regular members. Ex-officio and honorary members are not eligible to vote. The Advisory Committee shall maintain information sufficient to indicate the vote of each regular member. Regular members who represent programs that are contractors of the Center for Congenital and Inherited Disorders in the Iowa Department of Public Health are expected to refrain from imposing undue influence on regular members and to recuse themselves from voting on issues which directly affect the operation of their programs.

Attendance by the regular member or the regular member's designee shall be expected at all meetings. A designee of similar standing must be able to reasonably fulfill the member's role on the committee in discussions. Designees are not eligible to vote. Regular members (not a designee) must be in attendance at least two meetings per fiscal year to remain in good standing. A regular member who misses more than two meetings per fiscal year shall be deemed to have submitted a resignation.

Robert's Rules of Order (Revised) shall govern all meetings except where they are in conflict with these bylaws as adopted or amended.

VII. Officers

The officers shall be the Chair and the Vice-chair. The Chair will be responsible for conducting Advisory Committee meetings, representing the Committee at appropriate or designated meetings, will appoint subcommittees as deemed necessary, and will designate the chairperson of each subcommittee.

The Vice-chair will be responsible for conducting Advisory Committee meetings in the absence of the Chair or if the Chair is unable to act, and representing the Committee at designated meetings at the requests of the Chair. When so acting, the Vice-chair shall have all the powers of and be subject to all restrictions upon the Chair. The Vice-chair shall also perform other duties as may be assigned by the Chair.

The Chair and Vice-chair shall be elected or re-elected by the members at the last scheduled meeting of the fiscal year. The Chair shall not serve more than two full consecutive years, beginning in the fiscal year following the effective date of these bylaws.

Vacancies in the office of the Chair that occur during the course of a term shall be filled by elevation of the Vice-chair. Vacancies in the office of Vice-chair shall be filled by election at the next meeting after the vacancy occurs.

VIII. EXECUTIVE COMMITTEE

The Executive Committee shall be composed of the Chair, Vice-Chair, and two regular members of the Committee appointed by the Chair at the beginning of the state fiscal year. The State Coordinator for Genetics Services and the Director of the Division of Health Promotion and Chronic Disease Prevention at the Iowa Department of Public Health will provide staff support and assistance.

The Executive Committee will meet as necessary to appoint members to the Advisory Committee and act on behalf of the full Advisory Committee when needed to make recommendations to the Director.

IX. SUBCOMMITTEES

The Chair may designate one or more subcommittees to perform such duties as may be deemed necessary. The Chair will appoint the Nominations Committee, which will make recommendations of officers (Chair and Vice Chair) to the CIDAC, and will also make recommendations to the Director of potential members.

X. BYLAWS AMENDMENT

These bylaws may be amended, altered, or repealed, and new bylaws may be adopted by a majority vote of the membership, provided fourteen days written notice of the proposed change(s) is mailed, including electronic mail, to the members.

ATTACHMENT 1

CIDAC Advisory Committee Membership Roster

Regular Members

1. American College of Obstetricians and Gynecologists, Iowa Chapter
2. Iowa Osteopathic Medical Association
3. American Academy of Pediatrics, Iowa Chapter
4. Academy of Family Physicians, Iowa Chapter
5. Nursing organization representative: e.g./ INA, IANP
6. Medical Geneticist, Division of Medical Genetics, U of I
7. Iowa Department of Education
8. Iowa Child Health Specialty Clinics
9. College of Public Health
10. National Association of Social Workers, Iowa Chapter
11. Iowa Insurance Commission
12. Ethics/Bioethics representative
13. Attorney at law
14. Parent
15. Parent
16. Parent
17. Parent
18. Consumer/member at large (Iowa Hospital Association, Iowa Clinical Laboratories Association, etc.)
19. Consumer/member at large (Iowa Hospital Association, Iowa Clinical Laboratories Association, etc.)
20. Representative from community-based organizations, such as the March of Dimes, the ARC, Sickle Cell Society
21. Representative from clinical genetic services (newborn screening follow up, neuromuscular, and regional genetics programs)
22. Representative from the Iowa Registry for Congenital and Inherited Disorders
23. Representative from the University Hygienic Laboratory
24. Representative from the Maternal Screening programs

Honorary Members

1. Iowa Senator
2. Iowa Representative

Iowa Department of Public Health

Policy on the Purpose, Storage, and Use of Specimens Residual to Those Collected for Newborn Metabolic Screening Services

I. Overview

The Iowa Department of Public Health (IDPH) is authorized pursuant to Iowa Code 136A and Iowa Administrative Code 641 IAC 4.3 to establish a newborn metabolic screening program and directs that all newborns and infants born in the state of Iowa be tested for specific hereditary and congenital disorders as determined by the Director of Public Health and approved by the State Board of Health. These disorders are listed in 641 IAC 4.3(1). Comprehensive newborn screening services including laboratory, follow up, consultative, and educational services, are provided through the Iowa Neonatal Metabolic Screening Program (INMSP).

INMSP is a program under the Center for Congenital and Inherited Disorders (CCID) pursuant to Iowa Code chapter 136A and Iowa Administrative Code 614 TAC 4.3. The CCID provides administrative oversight to the INMSP for the Iowa Department of Public Health. The State Hygienic Laboratory (SHL) at the University of Iowa is the designated central screening laboratory pursuant to Iowa Code chapter 136A and 641 IAC 4.3. SHL tests Iowa newborns for specific disorders as set forth in 641 IAC 4.3 (1) and is the custodian of the residual specimens collected for newborn metabolic screening services in Iowa. The University of Iowa (UI) Department of Pediatrics, Divisions of Medical Genetics, Endocrinology, Pulmonary and Allergy, and Hematology are the designated consultants for the INMSP pursuant to 641 IAC 4.3 and provide consultative, follow up, and education activities. IDPH and the University of Iowa entered into a 28E agreement in 2001 to ensure the provision of comprehensive newborn screening services for hereditary and congenital disorders in Iowa through the INMSP.

This policy shall be implemented by the INMSP, in conjunction with and upon revision of the SHL policy for storage, retention, use and disposition of specimens that are residual to testing performed by the INMSP. The new policy will address the definition of residual newborn metabolic screening specimens, stewardship, storage conditions, notice of storage and use of specimens to parents, validation of specimen integrity for specified analytes at defined time periods, access to residual specimens for specific diagnostic/clinical, quality assurance/improvement and research purposes and standard operating procedures for inclusion to, monitoring of, and retrieval from the specimen repository. It is understood that SHL policy may address additional technical and implementation matters not covered by this policy. In the event that there is a conflict between the policies, the provision of the IDPH policy shall be controlling with respect to the use of residual specimens collected for newborn screening services in Iowa.

II. Basis for Retaining Residual Newborn Dried Blood Spot (DBS) Screening Specimens

A residual newborn metabolic screening specimen is defined as a dried blood spot screening specimen using the INMSP collection form that is collected at the birth hospital, at the hospital of transfer, at the health care provider's office, an outpatient laboratory, or at home, as a result of IAC 641-4.3(1) a, **and** is leftover after the completed newborn screening services of the Iowa Neonatal Metabolic Screening Program. The INMSP collection form consists of dried blood spots on filter paper and attached baby and birthing center information.

Specimens are retained for several reasons:

1. Legal Accountability
 - a. To confirm the existence of a specimen and its adequate collection
 - b. Reconfirm newborn screening analytical results
 - c. Allow for retesting of a specimen when a child has been subsequently diagnosed with a screenable disorder
2. Laboratory Quality Assurance/Improvement
 - a. Necessary for laboratory to perform continuous quality assurance and improvement of testing methodologies
3. New Method Evaluations and Comparisons
 - a. Necessary for laboratory to compare testing methodologies
 - b. Necessary for laboratory to develop and validate new testing methodologies
4. Diagnostic/clinical purposes
 - a. Availability of a specimen for diagnostic purposes in the event of an unexplained infant death or SIDS death. Definitive diagnosis is beneficial for counseling families and providing risk assessment for future pregnancies.
 - b. Availability of a specimen when parent requests additional testing.
5. Epidemiological research to benefit the public health
 - a. Permit the conduction of population studies on anonymized specimens to determine the incidence and prevalence of biochemical markers and/or genetic polymorphisms for disorders and diseases. An anonymized specimen is defined as one which cannot be traced back to or linked by the researcher with the particular infant from whom the specimen was obtained.
6. Basic health-related research
 - a. Permit the conduction of individualized studies on anonymized and identifiable specimens to advance medical knowledge on congenital and inherited disorders and disease.

Specimens shall be retained for a minimum of five years. The specimens shall be retained for one year at -70° C and then archived for four additional years at room temperature.

III. Continuous Quality Improvement

Continuous quality improvement (CQI) includes those activities designed to ensure test accuracy and to determine the feasibility of modified, additional or enhanced newborn screening tests. Activities also include validation of the integrity of specimens for specified analytes at defined time periods in order to justify retention period. INMSP investigators shall have unlimited access to specimens for the purposes of CQI. The INMSP may use linked specimens in pilot

studies approved by the Congenital and Inherited Disorders Advisory Committee and the IDPH for the purpose of incorporating new tests or evaluating new test methodologies. When there is any concern that the activity may have a research component, the project will be submitted to the University of Iowa Institutional Review Board for an opinion on how to proceed, including whether informed consent is required.

IV. Research

Research on anonymized or identifiable specimens shall be allowed in instances where such research would further 1) newborn screening activities; 2) the health of a newborn or child, for whom no other specimens are available or readily attainable; or 3) general medical knowledge for existing public health surveillance activities. Research on anonymized specimens shall also be allowed for population studies to benefit public health medicine.

A. Requests for use of anonymized residual newborn metabolic screening specimens

Researchers/investigators shall submit a proposal to the Center for Congenital and Inherited Disorders within the Iowa Department of Public Health. Documentation of human subjects review committee approval shall accompany the proposal.

The proposal shall:

1. Discuss project objectives, methodology, and rationale of how it will benefit the public health.
2. Identify the person or persons who will perform the study, their qualifications and organizational affiliation.
3. List the number of residual specimens needed for the study and anticipated duration of the study.
4. Discuss how long the residual specimens will be kept and how the specimens will be discarded at the conclusion of the study.
5. Describe how the results will be disseminated.
6. Indicate that residual specimens will be used only for the purpose stated in the proposal.

Review process:

1. The State Genetics Coordinator will distribute the proposal to the Center for Congenital and Inherited Disorders Advisory Committee members and schedule a presentation of the proposal for the next planned committee meeting.
2. The advisory committee will provide their written recommendations to the Iowa Department of Public Health within two weeks of the presentation.
3. The IDPH will review the recommendations and the proposal. Research projects approved by the IDPH will be presented to the Iowa Board of Health.
4. The Iowa Board of Health shall give final approval of proposals. The State Genetics Coordinator and/or the researcher will present the proposal at the next scheduled Iowa Board of Health meeting.

5. The State Genetics Coordinator shall provide a written reply within three months of proposal submission.

B. Requests for use of identifiable residual newborn metabolic screening specimens

Researchers/investigators shall submit a proposal to the Center for Congenital and Inherited Disorders within the Iowa Department of Public Health. Documentation of human subjects review committee approval of the research project and the parental consent form shall accompany the proposal.

The proposal shall:

1. Discuss project objectives, methodology, and rationale of how it will benefit public and individual health.
2. Identify the person or persons who will perform the study, their qualifications and organizational affiliation
3. List the number of residual specimens needed for the study, the protocol for selecting and contacting subjects, and anticipated duration of the study.
4. Provide the protocol for selecting and contacting subjects.
5. Discuss how long the residual specimens will be kept, how the confidentiality of the specimens will be maintained, and how the specimens will be returned at the conclusion of the study.
6. Describe how the results will be disseminated.
7. Indicate that residual specimens will be used only for the purpose stated in the proposal.
8. Include a copy of the materials to be provided to the parent/guardian of the subject(s) of the residual specimens (i.e., educational materials, informed consent form).

Review process:

1. The State Genetics Coordinator will distribute the proposal to the Center for Congenital and Inherited Disorders Advisory Committee members and schedule a presentation of the proposal for the next planned committee meeting.
2. The advisory committee will provide their written recommendations to the Iowa Department of Public Health within two weeks of the presentation.
3. The IDPH will review the recommendations and the proposal. Research projects approved by the IDPH will be presented to the Iowa Board of Health.
4. The Iowa Board of Health shall give final approval of proposals. The State Genetics Coordinator and/or the researcher will present the proposal at their next scheduled Iowa Board of Health meeting.
5. The State Genetics Coordinator shall provide a written reply within three months of proposal submission.

V. Individual Diagnostic/Clinical Purposes

When no other specimen is available, specimens will be made available for additional testing by a diagnostic laboratory at the request of a parent/guardian or health care provider so authorized either for the medical benefit of the specimen subject, or for the benefit of that individual's family. Specimens will only be released for research studies pursuant to the procedures outlined in Section IV. Specimens will also be made available for additional testing to an authorized officer from the State of Iowa Office of the Medical Examiner for diagnostic purposes in the cases of unexplained infant and child deaths, SIDS cases and child abuse cases upon receipt of parental/guardian consent.

VI. Confidentiality

INMSP shall maintain the confidentiality of all newborn metabolic screening records in accordance with state and federal laws and regulations. The SHL newborn screening laboratory shall not disclose personally identifiable records and/or residual specimens without informed parental consent. The INMSP personnel including CCID, SHL, and UI pediatric consultants shall not release any confidential newborn metabolic screening records to investigators for the purposes of determining research subjects.

VII. Access to Residual Specimens

Only SHL newborn screening laboratory personnel shall have access to residual specimens. Personally identifiable records and/or residual specimens shall only be released to researchers upon documentation of project approval, list of residual specimens needed, and informed parental consents. Identifiable records and/or residual specimens shall only be released to the medical examiner's office or to a diagnostic laboratory upon documentation of informed parental consent. The SHL shall only provide to researchers, the medical examiner's office, or diagnostic, a portion of the residual newborn screening specimen(s). The SHL shall assess a fee for retrieval of residual specimens and the fee structure will be outlined in the SHL retention policy.

VIII. Notice

Notice shall be given to parents at the time they receive the pamphlet entitled "Baby's First Screening" and the information sheet from the dried blood spot collection form titled "Opting out of residual specimen for research use" that (1) residual specimens, if available, will be stored and may be used without identifying information for research, and (2) permission will be sought for any proposed research, which would require identification of specimens, (3) that parents/guardian may inform the SHL that their child's residual specimen is not to be used for research and the process for opting out.



Missouri Department of Health and Senior Services

P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466

Margaret T. Donnelly
Director



Jeremiah W. (Jay) Nixon
Governor

June 21, 2011

IMPORTANT NOTICE

A New Step in Newborn Screening Sample Collection!

Beginning July 1, 2011 a new step will be required in the newborn screening (NBS) sample collection process. This new step requires that the mother of the baby be given an information sheet provided by the Department of Health and Senior Services informing her that her child has been screened for certain disorders mandated by state law and that after the testing has been completed, the leftover NBS sample will be stored at the State Public Health Laboratory for five years. This storage is now also mandated by state statute (RSMo 191.317). In the past, NBS samples were destroyed one month after the screening was completed.

This is NOT a consent process but simply a way to provide important information that explains why the NBS sample is being stored, what the parent's options are and how they request them if they choose to do so (see attached information sheet). If the parents do nothing, the leftover NBS sample will be stored by the State Public Health Laboratory for five years and will eventually be made available for anonymous research. If the parents wish to opt-out of this process, they can write a letter to the state laboratory requesting one of three opt-out options:

- Give the extra newborn screening sample back to them
- Destroy the newborn screening sample after the newborn tests are done
- Store the extra newborn screening sample for five years but do not release it for study

With the storage of the NBS sample there are benefits for the child and child's family, benefits for the Newborn Screening Laboratory regarding quality assurance, and benefits for public health research. These benefits are stated on the back of the information sheet. The sample storage is secure and the anonymity and privacy of the family will be protected. The parents may opt-out at any time during the five year storage process. After five years the samples will be destroyed.

In order for this process to be successful, the DHSS needs your assistance. What we are requiring of you is for the information sheet to be given to the mother of the baby at the time of the NBS sample collection and to verbally provide her some information pertaining to it:

- Tell her that it is information about the NBS test that is being done on her child and what will happen to the sample after it is screened.
- Tell her there is information on both sides of the sheet.
- Tell her if she has any questions she can call the phone number on the sheet.

We have provided the attached copy of the information sheet for you to photo copy and hand out until your current inventory of collection cards is used up. With future shipments of NBS collection cards, this information sheet will be included as a tear off copy that can be detached and handed to the mother of the newborn at the time of sample collection.

If you have questions, please contact Patrick Hopkins, Newborn Screening Laboratory Manager, by telephone at 573-751-2662 or email Patrick.Hopkins@health.mo.gov

www.health.mo.gov

Healthy Missourians for life.

The Missouri Department of Health and Senior Services will be the leader in promoting, protecting and partnering for health.

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER: Services provided on a nondiscriminatory basis.



Detach This Copy and Give to Mother of Newborn!

Dear Parents of Newborn Baby:

To help give your baby a good start, Missouri law requires your baby's blood to be tested for more than 50 disorders. A few small drops of blood taken from the baby's heel are put on special paper and then sent to the State Public Health Laboratory for testing.

Many disorders are not noticed at birth. Yet they can put the baby at risk for disability or death if not found early. If results from this screening test are not normal, your doctor will tell you about more testing that needs to be done. Please make sure the hospital staff gives you a Newborn Screening pamphlet.

Once the newborn screening test is done, the Missouri State Public Health Laboratory will store the remaining newborn screening sample for five (5) years. The storage is secure. Missouri state law allows for the stored sample to be used for research. The research may help improve methods for spotting illnesses. The research may also find better ways to test, treat and cure major childhood diseases. Your baby is not identified to the researcher in any way. After five years, the rest of the newborn screening sample will be destroyed.

The law allows the parent or legal guardian the option of not having their baby's extra newborn screening sample stored or studied. You may ask the State Laboratory to:

- Give the extra newborn screening sample back to you
- Destroy the newborn screening sample after the newborn tests are done
- Store the extra newborn screening sample for 5 years but do not release it for study

If you choose NOT to allow your baby's extra newborn screening sample to be studied, select one of the above three options. Then write to the Laboratory Director at:

Missouri State Public Health Laboratory
Newborn Screening Laboratory
P.O. Box 570
Jefferson City, MO 65102-0570

Give this information:

Baby's name
Baby's date of birth
Mother's first and last name
Place where baby was born
The option you selected from above
State if you are the parent and legal guardian
Your current address
Your signature and current date



If you have questions or need assistance, please contact the.
Newborn Screening Laboratory at 573-751-2662

Benefits of storing newborn screening samples:

There are many reasons why newborn screening samples are kept, many of which benefit your family and other Missouri families.


- In some cases, samples are requested by the family or the baby's health care team.
- The baby's sample is available to you for other health-related testing within five years of storage.
- The baby's sample is available to help identify a missing or deceased child within five years of storage.
- If your child has an illness and is enrolled in a research study, parents may request that their baby's newborn screening sample be returned to them in order that they may send it to the researcher within five years of storage.

For research purposes, all identifying information is removed from the samples (baby's name, parent's name, parent's address, hospital of birth, etc.). The researcher does not know who the baby is. These samples may be used to:

- Provide quality assurance in the screening.
- Do public health studies and research to help develop newborn screening tests and better understand diseases for the benefit of the general public.
- Search for new markers for chronic diseases such as childhood leukemia, sickle cell disease, autism and diabetes.

Only those research projects that undergo careful scientific and ethical review will be given approval to use newborn screening samples.

CIDAC Meeting Schedule FY2012
 Face-to-face meetings held from 1:00 pm to 4:00 pm
 Wells Fargo Bank Building, Grinnell, IA (“Jewel Box Bank”)
 Sullivan Room
 (subject to change)

	<p>July 15, 2011 Annual Plan Elect of officers Review bylaws</p>
<p>October 14, 2011 conf call Program annual reports Review State Plan status Needs Assessment Policy/Procedure Update</p>	<p>January 20, 2012 conf call Budget Preview Bylaws Review/Update Nominations Committee Additional tests, procedures, initiatives</p>
<p>April 13, 2012 conf call Budget approval/recommendations New member nominations Election of officers</p>	

*Location not confirmed

Call in information:
Dial 1-866-685-1580
International – (660) 422-5009
Enter conference code 5152816466 #
You will be connected to the call.

CONGENITAL AND INHERITED DISORDERS ADVISORY COMMITTEE (CIDAC)

Iowa Department of Public Health

Appointed by Director, Iowa Department of Public Health

Iowa Administrative Code, Chapter 4, Sections 641-4.1-4.7

American Academy of Pediatrics, Iowa Chapter

Jeff Murray, M.D.
Department of Pediatrics
University of Iowa
Neonatology
2182 ML
Newton Road
Iowa City, IA 52242
Phone: (319) 335-6897
jeff-murray@uiowa.edu
Term Expires: 6/14

Phone Cell: (515)490-3377

walkerbs@ihs.org
Term Expires: 6/12

American College of Obstetrician and Gynecologists, Iowa Section

Kristi Borowski, M.D.
Department of OB/GYN
University of Iowa
SW44 GH
200 Hawkins Drive
Iowa City, IA 52242
Phone: 319-356-3180
Fax: 319-665-3837
Kristi-borowski@uiowa.edu
Current term expires: 6/14

Consumer Representative

Gayle Culbertson MT(ASCP) MGS
CLMA – Iowa President
Executive Director Laboratory at Iowa Health System
2514 53rd St
Des Moines, IA 50310
CulberGD@ihs.org
Term expires: 6/12

Division of Medical Genetics, U of I

Val Sheffield, M.D. Ph. D.
Medical Director, Neonatal Metabolic Screening Program
Department of Pediatrics
Division of Medical Genetics
University of Iowa Hospital
Iowa City, Iowa 52242
Phone: (319) 356-2096
Phone:(Sec) 800-260-2065
Fax: (319) 356-3347
Val-Sheffield@uiowa.edu

College of Public Health

Paul Romitti, Ph.D.
Director, Iowa Registry for Congenital & Inherited Disorders
Associate Professor,
Department of Epidemiology
University of Iowa
C21-E GH, 200 Hawkins Drive
Iowa City, Iowa 52242
Phone: (319) 384-5012
paul-romitti@uiowa.edu

Iowa Academy of Family Physicians

Bryon Schaeffer, M.D., FAAFP
parodocs.1@netzero.net
Term expires: 6/14

Maternal Health Programs

Roger Williamson, M.D.
Department of OB/GYN
SW44-13-1 GH, 200 Hawkins Drive
Iowa City, Iowa 52242
Phone: (319) 356-4119
roger-williamson@uiowa.edu

Iowa Department of Education

Early ACCESS (IDEA Part C)
Shelley Ackermann, LISW, ACSW
Iowa Department of Education
Des Moines, IA 50319-0146
(515) 281-8634
Fax: (515) 242-6019
shelley.ackermann@iowa.gov

Consumer Representative

Iowa Hospital Association
Brenda Walker, MSN, RN
Neonatal Clinical Nurse Specialist
Iowa Health-Des Moines
1212 Pleasant Street
Des Moines, IA 50309

Iowa Insurance Division

vacant
Iowa Insurance Division
Department of Commerce
330 Maple Street
Des Moines, IA 50319
Phone: (515) 281-5880

Parent Representative

Nancylee Ziese, LISW
1759 Applewood Place NE
Cedar Rapids, Iowa 52402
Phone: (319) 366-4666
znancylee@earthlink.net
Current term expires: 6/12

Parent Representative

Becky & James McIlrath
Son - James McIlrath IV
Duchenne MD
729 Newburg Road
Grinnell, IA 50112-8336
Phone: 641-236-5098
beckyjo@iowatelecom.net
Current term expires: 6/12

Parent Representative

Kori Ensley
Son with Neurofibromatosis
Phone – 515-331-8104 (w)
515-865-9336 (c)
515-457-3037 (h)
koriensleymk@hotmail.com
Term expires: 6/14

Parent Representative

Bleeding Disorders
vacant

Parent Representative

Becky Lutgen Gardner
Son with Pallister-Killian Syndrome
Becky.LutgenGardner@sourcemedi.net

Parent Representative

Kathleen Cady
Daughter with PKU
640 6th St
Waukee, IA 50263-9554
Phone: 515-978-4062
Cady5@juno.com

Iowa Nurses Association

Sandra Daack-Hirsch, Ph.D., R.N.
Assistant Professor
Parent Child & Family Area
University of Iowa College of Nursing
Room 372
Iowa City, Iowa 52242
Phone: 319 335 7061
Sandra-Daack-Hirsch@uiowa.edu
Current term expires: 6/11

Iowa Osteopathic Medical Association

Gregory L. Garvin, D.O.
1351 West Central Park, Suite 4100
Davenport, Iowa 52804
Phone: (563) 383-2581
ggarvin6@mchsi.com
Current term expires: 6/12

Iowa Senate

Senator Amanda Ragan
20 Granite Court
Mason City, Iowa 50401
Phone: (641) 424-0874
amanda.ragan@legis.state.ia.us

Iowa Child Health Specialty Clinics

Debra Waldron, MD
Child Health Specialty Clinics
100 Hawkins Drive, Room 247-CDD
Iowa City, Iowa 52242
Phone: 319-467-5009
Debra-Waldron@uiowa.edu

Iowa House

Representative Beth Wessel Kroeschell
Ames, IA
Home Telephone:
Office Telephone:
Beth.Wessel-Kroeschell@legis.state.ia.us
Current term expires: 6/09

Social Worker

Diana Hoogestraat, MSW, LISW
Glenwood Resource Center
711 South Vine Street,
Glenwood, Iowa 51534
Phone: (712) 525-1215 (w)
(712) 527-4688 (h)
(712) 527-0708 (c)
dhoooges@dhs.state.ia.us
Current term expires: 6/12

University of Iowa Clinical Genetics Staff

Catherine Evers, RN, MA
Clinical Coordinator
Regional Genetic Consultation Service
2613 JCP, 200 Hawkins Drive
Iowa City, IA 52242-1083
Phone: (319) 356-1160
Fax: (319) 356-3347
Current term expires 6/10
cathy-evers@uiowa.edu

Ethics/Bioethics Representative

Francis Dominic Degnin, M.P.M., PhD.
Assistant Professor, Philosophy & Religion
University of Northern Iowa
Baker Hall 148

Cedar Falls, IA 50614 -0501
Phone: (319) 273-3015
Francis.Degnin@uni.edu
Current Term expires: 6/11

Iowa State Bar Association

Allison Heffern, JD
Simmons Perrine, PLC
115 3rd Street, SE, Ste 1200
Cedar Rapids, IA 52401-1266
Phone: 319-366-7641
AHeffern@SimmonsPerrine.com
Current term expires: 6/11

Iowa Registry for Congenital and Inherited Disorders

Paul Romitti
Director
100 Oakdale Campus, W117 OH
Iowa City, Iowa 52242
Phone: 319/335-4107
paul-romitti@uiowa.edu

Voluntary Agency

Michelle Gogerty
March of Dimes
State Director of Programs and Public Affairs
Iowa State Chapter
2910 Westown Pkwy, #301
West Des Moines, IA 50266
Telephone 515-657-6294
MGogerty@marchofdimes.com

State Hygienic Laboratory

Stanton L. Berberich, Ph.D. for Christopher
Atchison
University Hygienic Laboratory
102 Oakdale Campus, #H101-OH
Iowa City, Iowa 52242-5002
Des Moines Phone: 515-243-0141
Iowa City Phone: 319/335-4500
sberberi@uhl.uiowa.edu

EXOFFICIO MEMBERS

Stanley Grant, RN, MSN, APNG
MSAFP Program Coordinator
E415GH, 200 Hawkins Dr.
Iowa City, IA 52242
319/356-3561
stanley-grant@uiowa.edu

Carol Johnson
Pediatrics, Division of Medical Genetics
2612 JCP, UIHC, 200 Hawkins Dr.
Iowa City, IA 52242-1083
319/356-7248
carol-johnson@uiowa.edu

Katherine Mathews, MD
Pediatric Neurology
2503 JCP, 200 Hawkins Dr.
Iowa City, IA 52242
319/356-2436
katherine-mathews@uiowa.edu

Pam DeBoer, RN
Department of Pediatrics
Division of Medical Genetics
University of Iowa Hospitals and Clinics
Iowa City, IA 52242
Phone: 319/353-6038
Fax: 319/356-3347
pamela-deboer@uiowa.edu

Judy Miller, R.N., A.R.N.P.
Metabolic Management Clinic
2605 JCP, 200 Hawkins Dr.
Iowa City, IA 52242
319/353-6131
Fax: 319/356-3347
judith-miller@uiowa.edu

Mavis Rike, RN, MSN
Pediatric Endocrinology
2832 JCP, 200 Hawkins Dr.
Iowa City, IA 52242
319/356-3690
mavis-rike@uiowa.edu

Elizabeth Dowd, ARNP
Cystic Fibrosis Program Coordinator
UIHC CF Center
200 Hawkins Dr.
Iowa City, IA 52242
Phone: (319) 356-1828
Elizabeth-dowd@uiowa.edu

Kimberley Turner, RN, BSN
Manager, INMSP Follow-up
Division of Medical Genetics
University of Iowa Hospitals and Clinics
CDD, Room 133-1
Iowa City, IA 52242
Phone: 319/335-4500
Kimberley-Turner@uiowa.edu

◆ **Staff**

Julie McMahon, RN
Director
Health Promotion & Chronic Disease Prevention
Iowa Department of Public Health
Lucas State Office Building-5TH Floor
321 East 12th Street
Des Moines, IA 50319
515/281-3104
Fax: 515/242-6384
jmcmahan@idph.state.ia.us

Kimberly Noble Piper, RNC, BS, CPH, CPHG
State Genetics Coordinator
Center for Congenital and Inherited Disorders
Bureau of Family Health
Iowa Department of Public Health
Lucas State Office Building
321 East 12th Street
Des Moines, Iowa 50319
Phone: 515/281-6466
Fax: 515/242-6013
kpiper@idph.state.ia.us

Jinifer Cox
Support Staff
Bureau of Family Health
Iowa Department of Public Health
321 E. 12th Street
Des Moines, IA 50319-0075
Phone: 1-800-383-3826
515/281/7085
Fax: 515/242/6013
jcox@idph.state.ia.us