
CHARTER
OF THE
KANSAS ADVISORY COUNCIL ON NEWBORN SCREENING

Effective Date: May 15, 2008
Revision Date: August 18, 2011

ARTICLE I. AUTHORITY AND MISSION

The Kansas Advisory Council on Newborn Screening (KACNS, sometimes referred to as “KACNS” or the “Council”) was established under amendments to KSA 65-180 in 2007 by the Kansas Legislature to advise the Kansas Department of Health and Environment (KDHE) on the implementation of a comprehensive, quality system for the screening of all Kansas newborns and for follow up, counseling and health care services for those having or at risk for heritable disorders.

ARTICLE II. PURPOSE

The purpose of this Charter is to establish operational guidelines for the conduct of business of the Kansas Advisory Council on Newborn Screening.

ARTICLE III. MEMBERSHIP

The membership of the KACNS shall not be less than 15 nor more than 25 voting members appointed by the secretary of KDHE. Members shall be representative of stakeholders with interest in and concern for screening of newborns for congenital and inherited diseases/disorders and conditions and inborn errors of metabolism. Members shall be appointed for three year terms and may be reappointed for additional term(s). Terms will be staggered so one third of the Council will be filled each year. The Secretary of KDHE shall appoint a person to fill any unexpired vacancy.

Ideal membership may consist of representation from the following categories: pediatric specialist relevant to each disorder screened (e.g., pediatric hematologist for hemoglobinopathies; pediatric metabolic specialist for metabolic diseases such as PKU, MCAD, biotinidase deficiency and galactosemia; pediatric endocrinologist for diseases such as congenital primary hypothyroidism, etc.); pediatrician practicing in a Kansas community; family physician practicing in a Kansas community; neonatologist; pathologist; laboratory Ph.D. level or above chemist; hospital representative; registered/licensed dietitian practicing at a Kansas metabolic clinic; geneticist; genetic counselor; nurse practitioner practicing at a Kansas metabolic clinic; parent or consumer representative for each disorder, or class of disorders screened; medical ethicist; and such others as the Council determines necessary. Some members may fulfill representation of more than one role.

The KACNS members shall:

1. Attend biannual Council meetings and/or participate in meetings conducted by conference call;
2. Give prior notice to the assigned newborn screening staff member if unable to attend or participate in a biannual Council meeting; two consecutive missed meetings may result in dismissal from the Council;
3. Participate in committee meetings which may be conducted in person at the biannual meeting, by teleconference, interactive email, or other electronic means for holding meetings;
4. Review agenda items and the supporting documentation before meetings;

5. Provide input on ideas and participate in discussions;
6. Review and comment on research, reports and other background information;
7. Recommend strategies for program improvement;
8. Vote on issues requiring a vote;
9. Provide to the KDHE Secretary nominations of candidates to fill vacant member positions;
10. Tender their resignation in writing to the chairperson, with a copy to the assigned newborn screening staff member;
11. Abide by the requirements of the Conflict of Interest Procedures, Disclosures and Responsibilities for Members on the Kansas Advisory Council on Newborn Screening, which will be signed by the member;

Members shall not participate in legislative activity in the name of the Council or KDHE. Council members may represent themselves or other entities in the legislative process.

ARTICLE IV. CHAIR/VICE-CHAIR MEETINGS

The Council shall elect a Chairperson and Vice-Chairperson from KACNS voting members by majority approval who shall preside for a term of two years. The Chairperson shall have in addition to the responsibilities of regular members the following additional responsibilities:

1. Preside over semiannual meetings and emergency meetings;
2. Approve meeting agendas;
3. Decide points of order;
4. Call for votes on issues;
5. Consult with Vice-Chair and program staff in developing reports and recommendations;

The Vice-Chairperson shall have the same responsibilities as regular members and will perform all the duties of the Chairperson when that person is absent or incapacitated. The Vice-Chairperson shall serve Chairperson when that position has been vacated until the membership is able to select a new Chairperson.

ARTICLE V. MEETINGS

The KACNS shall meet semiannually and at other times as needed in person or through teleconference, videoconference or other electronic means for holding meetings. The Chairperson may call for emergency/interim meetings at his/her discretion. The semiannual meetings are open to the public and will occur in the months of April and October.

The KACNS must have a simple majority of the voting membership to constitute a quorum at any meeting including teleconferences or other electronic means for holding meetings. The Council may meet without a quorum but may not conduct votes on any official business.

Issues requiring a vote must follow *Roberts' Rules of Order*. A simple majority of the quorum voting in favor of the motion is needed for the motion to pass. Issues requiring a vote are those that would require significant change by the program, such as addition of a new disease to the required screening panel, regulation or statutory revision, or requiring a new or additional

expenditure of funds. These changes shall be given as formal written advice to be transmitted by the Chairperson and/or Vice-Chairperson through the Director of Division of Health and Director of Kansas Health and Environmental Laboratories to the Secretary of KDHE.

ARTICLE VI. COMMITTEES

KACNS may establish committees as necessary to assist in the carrying out the duties of the Council. Committees may be utilized by the KACNS as deemed appropriate by the Council for review of special topics on an ad-hoc basis. Committee membership may include members and non-members of the Council in order to obtain appropriate professional and technical expertise relevant to the topic. The subcommittees must report back to the council. The following standing committees are established to carry out the duties of the Council.

Education and Advocacy. The education and advocacy committee shall assist in development of an Education Plan; review Parent Education Materials; review/advise on Professional Education Materials selection, preparation and distribution; and assess the extent to which program processes and operations respect the needs of individuals and their families and are effective in meeting their needs.

Program Administration, Evaluation and Sustainability. This committee shall assist in the development and review of written operations manuals guiding screening, follow-up and treatment and all other program processes ensuring program integrity. It shall assist in the selection of critical data to be collected, periodically reviewed and recommendations for systems change, in line with the recommendations for short-term and long-term evaluation of the national Program Evaluation and Assessment Scheme. It shall help determine what resources and means are needed in order to sustain newborn screening and the follow up programs.

Clinical Conditions. This committee will assist in the development of methodologies and protocols guiding screening, short-term and long-term follow-up diagnosis and general management of newborns with heritable disorders. It will recommend clinical conditions to be added or removed from the screening panel. It may have the following subcommittees or others as needed:

- Hemoglobinopathies;
- Endocrine Conditions;
- Cystic Fibrosis;
- Metabolic Conditions;

ARTICLE VII. MISCELLANEOUS

- Section 1. Quality Assurance: The KACNS shall meet semiannually, and as needed, to review quality assurance reports developed by or obtained by the KDHE Newborn Screening Program. The Newborn Screening Program will issue reports quarterly. The quality assurance reports shall reflect measures of quality on all aspects of the screening system, including but not limited to: specimen collection, handling and transport, laboratory testing, laboratory reporting, initial notification, follow-up and retrieval, confirmatory testing, and for infants with a confirmed diagnosis for each of the diseases screened: diagnosis, management and treatment outcomes. The KACNS shall make recommendations for strategies the program may employ to improve on any quality assurance measure deemed by the Council to need improvement.
- Section 2. Composition of Screening Panel(s): Any member of the Council or Program Staff may request review of a disease or diseases for addition to or deletion from the required/mandatory newborn screening panel or as a supplementary optional disorder to be made available systematically to all newborns in Kansas. The actual review of a disease/disorder or condition must be approved by a simple majority of the Council. The KDHE Newborn Screening Program must make all review materials available to the Council membership 2 weeks prior to the next meeting.
- Section 3. Technology Review: The Council is responsible for thoroughly reviewing technical aspects and clinical utility of analytical test methods proposed for use by the Kansas Health & Environment Laboratory (KHEL) Health Chemistry Section, Neonatal Unit, or subcontractors. Following such review, the Council shall recommend approval, disapproval or modification of any aspect of the methodology.

ARTICLE VIII. PROGRAM STAFF

The KACNS shall be assisted in its work by the Newborn Screening staff of the KDHE. The Neonatal Screening Program Manager, the Follow-up Coordinator/Manager and Administrative Assistant to the program shall provide support to the Council in the following ways:

1. Locating, organizing and preparing pertinent background information;
2. Interpreting programmatic policies, regulations and statutes;
3. Drafting reports and meeting minutes;
4. Making meeting arrangements;
5. Collaborating with the Council Chair and Vice-Chair in establishing meeting agendas and approval of meeting minutes;
6. Writing reports for the review, revision and approval of the Chair, Vice-Chair and membership on recommendations to KDHE.

ARTICLE IX. AMENDMENTS

This charter may be amended by the Council at any meeting, by a two-thirds vote of those voting, a quorum being present, provided at least ten (10) days notice of the proposed amendment has been given to the membership in writing. .



Member Disclosure Document Kansas Advisory Council on Newborn Screening (KACNS)

Definition of *Conflict of Interest* for Kansas Advisory Council on Newborn Screening (KACNS) Members

A *conflict of interest* occurs when a KACNS member is in a position where he or she is on both sides of an actual or potential allocation of financial resources, or in a decision-making position which may potentially benefit either one of the sides he or she is affiliated with.

For example, a genetic counselor is a Council member and is employed by recipient of a grant from the newborn screening program for genetic counseling. When this geneticist participated in proposal reviews, she may not have been completely objective because the outcome may have benefited her personally as well as benefiting the newborn screening program and the community. She may have advocated strongly for her organization's proposal, may have given other proposals low scores, or may have pressured other Council members.

When a Council member has a *conflict of interest*, her/his vote, opinion, or advice may be affected by her/his personal or organizational allegiances.

A *conflict of interest*, in and of itself, does not prevent consideration of a specific course of action. Conflicts of interest may be remedied through *disclosure*, in writing, to both sides of the conflict of interest issue, and submission of a request for a determination as to how to proceed. In some instances, the party with the conflict of interest may be required to refrain from decision making in connection with conflict of interest matter. Leaving the room during discussion of a particular grant may meet this requirement, or refraining from voting, depending on the circumstances. Documentation of all disclosures and decision making regarding resolution of such matters should be recorded and maintained.

Procedures for Council Management of *Conflict of Interest*

All Council members must review Conflict of Interest Procedures and Disclosures, and complete and sign the attached Disclosure Form upon appointment to the KACNS. Each KACNS member must update annually, thereafter, the Disclosure Form. If a member's personal or employment circumstances change before 12 months have elapsed, it is that member's responsibility to update the Disclosure Form and submit it to the chair.

These forms are maintained with the newborn screening program. The Council chair and the appointed newborn screening program staff are responsible for maintaining a file of accurate and current forms and being familiar with their contents.

Awarding of community grants, cooperative agreements, and contracts will be conducted in a way that ensures open and free competition among community organizations. Applicants, Council members, and newborn screening program staff should be alert to organizational conflicts of interest or non-competitive practices that may restrict or eliminate competition.

All Council members are required to disclose to the Council in a timely manner, any actual or potential financial or non-financial interest which he or she may have pending before the KACNS that can be construed as resulting in a conflict of interest. Once any conflict of interest situation is disclosed, the Council must come to a formal resolution of the matter by following the guidelines and procedures provided herein. Formal resolution will be on a case by case basis. Actions must be documented in the minutes of the meeting.

Procedures for Addressing the Conflict of Interest

Once an interest is disclosed to the relevant parties, they generally will be able to evaluate and adjust for the possible influence of the disclosed interest. If it is determined that a conflict of interest exists, KACNS, or the appropriate committee, may require any action it deems appropriate, including, but not limited to, the following:

1. Investigation of alternatives to the proposed transaction or arrangement that may be equally advantageous but not give rise to a conflict of interest.
2. Disclosure of the interest to the other participants in the decision- or policy-making body.
3. Written and/or oral disclosure of the interest to an audience receiving the results of the project, activity, or transaction (e.g., research results).
4. Recusal from voting on a matter and limitation of an individual's participation only to the provision of factual information of benefit to the group discussion or decision-making process.
5. Complete recusal from a portion of the meeting or from other review of, or participation in, the project, activity or transaction.
6. Replacement of the individual in the subject position or activity.

Council members are prohibited from accepting any gratuities or favors from potential or approved grantees that are intended to influence Council decisions.

Grants cannot benefit Council members directly (through salary, or salary enhancement) or indirectly (by benefiting the institution for which the member works, or resulting in employment for the member) unless the member has disclosed the potential conflict for discussion and resolution by the Council.

I (write name) _____ do hereby affirm that I have read and understand the Conflict of Interest Procedures and Disclosures and Responsibilities for Council members set forth above. I will abide by same.

Signature _____ Date _____

Disclosure Form for KACNS Council Members

Name: _____ Address: _____

Instructions: Answer the questions below, checking the appropriate box and provided details as directed. Answers may be hand written in ink or typed. Keep a copy for your records.

1. Are you currently employed?
____ Yes (answer the following questions) ____ No (proceed to question 2)

1a. Check the description below that best fits your employment situation:

____ Not for profit organization Name: _____

____ For profit organization Name: _____

____ Self-employed Type of work: _____

2. Do you serve on the Board of Directors of any not-for-profit organization?
____ Yes (enter name and address below) ____ No (proceed to question 3)

3. List any organizations in which you or any member of your immediate family has a substantial or material interest and, to your knowledge, the KDHE newborn screening program has a contract with, has awarded a grant to, or has entered into a cooperative agreement with.

4. List or summarize any allegiance or financial interest you or any member of your immediate family has that might affect or appear to compete with the discharge of your duties and responsibilities to the KACNS.

Signature: _____ Date: _____

**Responsibilities of Voting Members
of the Kansas Advisory Council on Newborn Screening**

As a voting member of the Kansas Advisory Council on Newborn Screen I shall:

Attend semiannual Council meetings and/or participate in meetings conducted by conference call;

Give one week prior notice to the assigned newborn screening staff member if unable to attend or participate in a semiannual Council meeting;

Participate in committee meetings which may be conducted in person at the semiannual meeting, by teleconference, interactive email, or other electronic means for holding meetings;

Review agenda items and the supporting documentation before meetings;

Provide input on ideas and participate in discussions;

Review and comment on research, reports and other background information;

Recommend strategies for program improvement;

Vote on issues requiring a vote;

Provide to the KDHE Secretary nominations of candidates to fill vacant member positions;

Tender their resignation in writing to the chairperson, with a copy to the assigned newborn screening staff member;

Avoid participating in legislative activity in the name of the Council or KDHE unless authorized by the Secretary of KDHE.

I (write name) _____ do hereby affirm that I have read and understand the Responsibilities of Voting Members of the Kansas Advisory Council on Newborn Screening (KACNS) set forth above and will abide by same.

Signature: _____ Date: _____