DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Multifunctional Therapeutics Based on Nanotechnology, Phase II.

Date: June 1, 2010.

Time: 1 p.m. to 3:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard Room 706, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Jeffrey E. DeClue, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 8059, Bethesda, MD 20892–8329, 301–496–7904, declue@email.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Cancer Prevention Research Small Grant Program (R03).

Date: June 10–11, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Irina Gordienko, PhD, Scientific Review Officer, Scientific Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Rm. 7073, Bethesda, MD 20892, 301–594–1566, gordienkor@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Quantitative Imaging for Evaluation of Responses to Cancer Therapies.

Date: June 14, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: Kenneth L. Bielat, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 7147, Bethesda, MD 20892–8329, 301–496–7576, bielatk@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, NCI Clinical Studies.

Date: June 16–18, 2010.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.


Contact Person: Majed M. Hamawy, M.B.A., PhD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8135, Bethesda, MD 20892, 301–594–5659, mh101v@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)


Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Name of Committee: National Cancer Institute Initial Review Group; Subcommittee G—Education.

Date: June 15, 2010.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Jeanette F. Korczak, PhD, Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 8115, Bethesda, MD 20892, 301–496–9767, korczak@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)


Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Request for public comment on a Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children’s commissioned report: Considerations and Recommendations.
for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening.

SUMMARY: The Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) was established under Section 1111 of the Public Health Service (PHS) Act, 42 U.S.C. 300b–10, as amended in the Newborn Screening Saves Lives Act of 2008 (Act). The SACHDNC is governed by the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The SACHDNC provides advice to the Secretary about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance the ability of the State and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having or at risk for heritable disorders.

The changing dynamics of emerging technology and the complexity of genetics require an assessment of the state of the art in newborn screening and a perspective on the future directions such programs should take. Newborn screening is a highly successful public health program that identifies rare genetic, congenital and functional disorders, ensures early management and endeavors to ensure follow-up for those affected. Each State has a law that either requires or allows newborn screening and States are responsible for oversight and implementation of their respective newborn screening program. State newborn screening policies are usually developed with input from multidisciplinary advisory committees that include consumers, health care and public health professionals and other interested stakeholders. While State administration of newborn screening programs fosters local control and accountability, it also gives rise to wide variation in practices across the country, including disparate policies on the retention and use of dried blood spot specimens after newborn screening has been finished. Given the tremendous potential to advance science and clinical care for newborns, children and their families through the use of residual newborn screening blood specimens, the SACHDNC calls upon policymakers, the public health community, health care providers and families to work together to protect this valuable resource for the public good.

This notice is designed to review the issues facing State newborn screening programs related to the retention and use of residual newborn screening specimens. It will lay the foundation for developing national guidance to States in this area, and encourage an approach to future policymaking that enables residual specimens use to advance science and clinical care for newborns, children and their families. The core principles of protecting patient privacy, confidentiality and ensuring public trust are at the core of these recommendations.

Because newborn screening is the only public health screening program that reaches the entire population of newborns in the U.S., it is unique, and the processes surrounding it must be thoughtfully approached. Residual blood specimens provide an excellent opportunity for storage in a biobank for approved research uses after screening and validating are complete. However, at the present time, research is a secondary purpose that may not be adequately addressed in some existing State laws or policies. Newborn screening programs should approach the use of residual specimens carefully, anticipating both the potential benefits and risks.

The SACHDNC believes that national guidance on the retention and use of residual newborn screening specimens for research would help States to navigate these complex issues. To assist in this process, the SACHDNC makes the following recommendations to the Secretary of the Department of Health and Human Services (HHS) and requests action by the Secretary where applicable:

1. All State newborn screening programs should have a policy in place that has been reviewed by the State attorney general or other appropriate legal authority addressing the disposition of dried blood specimens remaining after newborn screening. Policymakers should consider the value of the specimens as a promising resource for research, the importance of protecting the privacy and confidentiality of families and the necessity of ensuring the public’s trust.

   • The policy should specify appropriate use and storage after the completion of newborn screen testing and verification according to laboratory Quality Assurance (QA) procedures. Parties responsible for drafting the policy should consider whether consent or dissent from families is necessary for uses other than newborn screening and, if so, under what circumstances.

   • Multidisciplinary input, including from consumers, should be solicited and thoughtfully considered in developing such a policy. The specimen disposition policy should include the length of time for which specimens will be stored and storage conditions. Compliance with storage processes included in NCCLS/CLSI Standard LA4–A5 or its current edition is recommended (Clinical and Laboratory Standards Institute (CLSI)).

   • Blood collection on filter paper for newborn screening programs; approved standard—fifth edition. CLSI document LA4–A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.) Any data linkages should be carefully addressed, and privacy and confidentiality should be ensured.

   • The strategy should include steps to inform and train health care professionals about the newborn screening system, the State’s policy on the potential use of residual newborn screening specimens, and their educational responsibilities with respect to expectant parents and parents of newborns. Educational programs should take steps to educate professionals treating new parents who did not have ready access to prenatal care, and, therefore, did not receive information about the newborn screening system at that time.

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educated about newborn screening as a part of prenatal and postnatal care.

- As part of the educational process, all State newborn screening programs should maintain and distribute educationally and culturally appropriate information that includes basic information about the use or potential use of the residual newborn screening specimens. Processes should be in place to evaluate the extent, timing and understanding of parental education with an eye towards educational program improvement. While prenatal care should serve as the primary target of educational programs, they also should be designed to reach parents that do not have access to those services and require postnatal education about newborn screening. Educational materials should address potential uses of residual newborn screening specimens, long-term storage policies, procedures for withdrawal of consent, opting-out of future research use, requesting the destruction of samples, limitations with regard to consent once samples have been distributed for research, and information on stewardship of specimens.

(5) If residual blood specimens are to be available for any purpose other than the legally required newborn screening process for which they were obtained, an indication of the parents’ awareness and willingness to participate should exist in compliance with federal research requirements, if applicable (45 CFR 46).

- Depending on the purposes for which specimens will be used, a parental consent (opt-in) or a dissent (opt-out) process may meet this requirement, if necessary, or a waiver of consent may be appropriate. The State attorney general or other appropriate legal authority should review this process. The use of residual newborn screening specimens for program evaluation (e.g., repeat testing as a quality check) or process improvement (e.g., non-commercial, internal program new test development or refinement) are valid components of the public health newborn screening program, and, therefore, should not require additional consent. However, once the use of a residual newborn screening specimens moves beyond the State mandated uses of program evaluation and quality assurance, treatment efficacy and test refinement, each State should consider whether separate or blanket consent/ dissent processes for approved studies is required from parents, legal guardians or individuals screened upon the age of majority for the use of residual newborn screening specimens.

(6) Provide administrative support and funding to SACHDNC to:

- Facilitate a national dialogue among federal and State stakeholders about policies for the retention and use of residual newborn screening specimens, including model consent and dissent processes;
- Develop national guidance for consent or dissent for the secondary use of specimens and mechanisms to ensure privacy and confidentiality, including methods for opting in or out of repositories; and
- Collect and analyze national data on the utility of any additional consent or dissent processes implemented relative to potential research uses of residual newborn screening specimens;

(7) Provide administrative support and funding to the Health Resources and Services Administration Maternal and Child Health Bureau to award grants to States to:

- Develop model educational programs for the general public on the importance of newborn screening and the potential uses of residual newborn screening specimens to generate population-based knowledge about health and disease; and
- Create educational materials directed to health care professionals and consumers with facts about potential uses of residual newborn screening specimens and other related issues, including those outlined in recommendation (Jinks DC, Minter M, Tarver DA, Vanderford M, Hejtmancik JF, McCabe ER. Molecular genetic diagnosis of sickle cell disease using dried blood specimens on blotters used for newborn screening. Hum Genet. 1989 Mar; 81(4):363– )

SACHDNC is now seeking public comments on the report and its recommendations.

DATES: The public is encouraged to submit written comments on the report and its recommendations by June 25, 2010.

ADDRESSES: The following mailing address should be used: Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, 18A–19, Rockville, MD 20857. HRSA/ MCHB’s facsimile number is 301–480–1312. Comments can also be sent via e-mail to screening@hrsa.hhs.gov. All public comments received will be available for public inspection at MCHB/HRSA’s office between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Questions about this request for public comment can be directed to Michele Lloyd-Puryear, MD, PhD, by e-mail (screening@hrsa.hhs.gov). The report will be posted on SACHDNC’s Web site at http://www.hrsa.gov/heritabledisorderscommittee/.

Mary K. Wakefield, Administrator.
[PR Doc. 2010–9625 Filed 4–23–10; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
[Docket No. FR–5409–N–01]

Notice of Web Availability: Notice of Fiscal Year (FY) 2010 Opportunity To Register and Other Important Information for Electronic Application Submission for Continuum of Care Homeless Assistance Programs

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: Through today’s Notice, HUD announces the availability on its Web site of its Notice of FY2010 Opportunity to Register and Other Important Information for Electronic Application Submission for the Continuum of Care Homeless Assistance Program (CoC Registration Notice). The CoC Registration Notice provides instructions to potential Continuums of Care (CoCs) applying for the approximately $1.68 billion of funding under HUD’s Continuum of Care Homeless Assistance Competition in FY2010. The CoC competition uses an electronic system outside of grants.gov for CoC registration as well as for submission of the CoC application called e-snaps. The CoC Registration Notice provides information to assist applicants understand the CoC registration and electronic application submission process through e-snaps, which is located at http://www.hud.gov/esnaps. Notification of the availability of the 2010 CoC application will be released via HUD’s Homeless Assistance listserv. To join HUD’s listserv, go to http://www.hud.gov/subscribe/mailinglist.cfm and click on “Homeless Assistance Program.”


FOR FURTHER INFORMATION CONTACT: CoCs may contact the HUD Field Office