HEARTLAND PILOT PROJECTS PROGRAM

GUIDELINES AND APPLICATION FORMS

DEADLINES FOR ELECTRONIC SUBMISSIONS

Friday, April 13, 2012
5:00 p.m. (CST)

Letter of intent requested by
Friday, March 16, 2012
5:00 p.m. (CST)

Email to: Shona-Whitehead@ouhsc.edu

ELIGIBILITY: Public health programs, specialty and primary health care providers, genetic counseling or Leadership Education in Neurodevelopmental Disabilities (LEND) programs, professional organizations, support organizations, consumer and family support organizations, and others from the community who are interested in genetics services and reside in Arkansas, Iowa, Kansas, Missouri, Nebraska, North Dakota, Oklahoma, and South Dakota, may apply. See Section II of Guidelines for details.

The Routing Form of the Projects & Sponsored Programs of your Office of Research Administration must accompany the electronic and hard copy of the project application. If your organization does not have an Office of Research Administration, please contact the Heartland Regional Coordinating Center (hrcc@ouhsc.edu) for further information.

For questions related to these guidelines, please contact Shona Whitehead at: Shona-Whitehead@ouhsc.edu (405-271-8001 x 42190) or Lori Williamson at LWDean@uams.edu (405-819-2135).

The Heartland Genetics and Newborn Screening Collaborative is supported by a cooperative agreement with the Genetic Services Branch of the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) Grant #U22MC03962 through May 31, 2012. These pilot projects will be supported by a renewal of that award anticipated in June 1, 2012.

GUIDELINES FOR THE HEARTLAND PILOT PROJECTS PROGRAM

Revised February 2012

I. OBJECTIVES

"The Heritable Disorders Program (Program) was established to enhance, improve or expand the ability of state and local public health agencies to provide screening, counseling or health care services to newborns and children having or at risk for heritable disorders. This Program shall improve the access to newborn screening and genetic services for medically underserved populations and shall enhance such activities as: screening, follow-up services; augmentation of capacity needs; training and education; subspecialty linkage, expansion of long term follow-up activities; strengthening of linkage to medical homes; strengthening of linkage to tertiary care; strengthening of genetic counseling services; and enhancement of communication/education to families and health practitioners and other forms of information sharing." (HRSA, 2006).

In the 2012 HRSA guidance for Regional Collaborative applications, HRSA further refined the **Program Goals** of the Regional Genetics Collaboratives to:

1) Continue to ensure that individuals with genetic disorders and their families have access to quality care and appropriate genetic expertise and other subspecialty expertise.
    a. Move individuals with genetic conditions and their families to the forefront of decision- making in the development of systems of services and demonstrate their satisfaction with the quality of the services throughout the life course.
    b. Address gaps and barriers to genetic services, especially for the medically underserved, populations in rural areas, and individuals and families uninsured.

2) Apply the translation of genome-based knowledge, genomics best practices, and new technologies to education and training, services, and dissemination to improve population health.
    a. Incorporate evidence-based clinical guidelines and genetic medicine practice models, using Health Information Technology (HIT) including but not limited to electronic health records, personal health records, telehealth, distance learning technology, and web portals.
    b. Disseminate and promote project information and outcomes through various media; examples are publications, social media, and public health information campaigns.

3) Quantitatively and qualitatively evaluate through program evaluation outcomes of projects undertaken to accomplish their goals.
    a. Facilitate integrated data collection and assessment systems using national quality indicators (ex. Healthy People 2020) and data for project evaluation.
    b. Collect data for national quality indicators to ensure that all children and adults have a chance for best possible outcomes.

c. Continue quality improvement projects and Learning Collaboratives conducted in the Medical home and specialty clinics to improve the quality of health care.
d. Continue the use of genetic systems assessment tools.

To address these goals, five priority areas were selected based on the Heartland's needs assessment, strategic planning process, and known strengths in the Heartland region.

HRSA Priority Area (1): *Treat in the context of a medical home that provides accessible, family-centered continuous, comprehensive, coordinated, compassionate, and culturally effective care.*

HRSA Priority Area (3): *Expand the pool of the genetic service workforce by determining needs and gaps across sectors to provide education and training, with emphasis on allied health providers, other subspecialties and educators.*

HRSA Priority Area (4): *Build capacity in state public health departments to enhance and sustain the delivery of newborn and child screening and genetic follow-up and treatment services.*

HRSA Priority Area (8): *Expand state and regional collaborative systems of cohorts of patients for long-term monitoring and analysis of follow-up and treatment for provider and/or patient access.*

HRSA Priority Area (7): *Improve insurance coverage policy and reimbursement of clinical genetic services for families, including genetic testing, medical food and formulas, and comprehensive and coordinated care.*

The Heartland Pilot Projects Program is a mechanism to address these regional goals and national priorities. Proposals must address one of the Heartland priority activities listed above or the quote from the HRSA guidance (2006 and 2012). Examples might include, but are not limited to: implementation of telemedicine for genetic services, fill gaps identified by the Genetic Systems Assessment, improving access to medical foods for genetic conditions, or enhancement of cultural competencies for genetics providers or services.

The Heartland Regional Coordinating Center (HRCC) intends to fund one pilot project in this cycle. Funding decisions are based on reviewers' scores and comments, the Advisory Board's assessment of adherence to priorities, and availability of funding.

II. ELIGIBILITY REQUIREMENTS

Primary applicants from public health programs, specialty and primary health care providers, genetic counseling or Leadership Education in Neurodevelopmental Disabilities (LEND) programs, professional organizations, support organizations, consumer and family support organizations, and others from the community who are interested in genetics services and reside in Arkansas, Iowa, Kansas, Missouri, Nebraska, North Dakota, Oklahoma, and South Dakota, may apply. Collaboration between at least two parties is required. These

collaborations can occur within the local community, between states within the Heartland, between two or more organizations within the same Heartland state or between a Heartland state and a state in another Regional Genetics Collaborative. In the latter example, however, the Pilot Project Director should reside in a Heartland state.

Projects must specifically address priorities listed in Section I.

NOTE: Visiting faculty or professionals, residents, interns, LEND trainees, genetic counseling students, and pre-doctoral trainees are not eligible to be principal investigators or co-investigators.

III. LETTER OF INTENT

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows HRCC staff to estimate the potential review workload and select appropriate reviewers. **A letter of intent is requested by 5:00 pm on Wednesday, March 14, 2012**.

A letter of intent should include the following information:

1. Brief description of proposed project (2-3 sentences or less than 250 words)
2. Collaborating partners
3. Name, address, email, and telephone number of the Pilot Project Director (PPD)

IV. APPLICATION COMPONENTS

A. A complete application consists of the following:

1. Face Page
2. Project Abstract (not to exceed one-page)
3. Detailed Budget for the 12-month project
4. Budget Justification
5. Project Director's Curriculum Vitae or Resume; for applicants from academic centers, a Biographical Sketch that follows NIH 4 page format (available at the NIH website: http://grants1.nih.gov/grants/funding/phs398/biosketchsample.doc) is acceptable.
6. Project Plan (not to exceed 5 single spaced pages, margins 1", 12pt Times New Roman font, tables can be in 10pt font)
    a. Specific Aims, Statement of the Problem, or Demonstration of Need: (This section is usually no longer than 1 page and succinctly states the problem and how this project will address the problem).
    b. Background and Significance: (This section provides the "story" behind the problem and explains why this problem is relevant and important).

c. Preliminary Experience: (This section tells the reviewers about you and the team doing the work. It should explain why you are capable of conducting the project).
d. Project Design and Methods: (This is the core of the proposal. In this section, describe how you will conduct the project).
e. Evaluation and Dissemination Plan: (All projects need to be evaluated for effectiveness. Describe how you will determine whether or not your project was successful. And, how will you share your experience with others?).

7. References: (List the bibliography of resources you used in the above sections).
8. Appendices (Do not use the Appendix to circumvent the page limitations of the Project Plan.)
    a. Other Biographical sketches (same format as PD) for other Key Personnel involved in the project.
    b. Letters of Support
    c. Other items
9. Institutional Routing Form (required of applicants from academic centers) or Letter of Support from a non-academic entity's Executive Director or equivalent.

B. Prior to proposal submission, Institutional Review Board (IRB) and other review committee protocols must be submitted at the primary site and at all collaborating sites where the project will be conducted, if applicable. Not all projects will require IRB approval.

If your project is selected for award, you must submit proof that all protocols have been approved by all relevant review committees before the sub-contract will be executed.

If your organization does not have an IRB and your project involves research on humans (including surveys), please contact the HRCC for further guidance.

V. SUBMISSION PROCEDURES

All applications must be submitted electronically, in a single PDF document, to: Shona-Whitehead@ouhsc.edu no later than 5pm (CST) on April 13, 2012

VI. PROGRAM RESTRICTIONS

A. The maximum project period is 12 months. Funding begins June 1, 2012.

B. The maximum budget request is $24,000; including direct and indirect costs. Indirect costs are allowed up to a maximum of 18%, the Arkansas Children's

Hospital Research Institute's (ACHRI) negotiated rate. If your organization does not require indirect costs (e.g., overhead), then all requested funds can be used for direct costs (e.g., actual expenses).

C. Funds may <u>not</u> be requested for the following:

1. Alterations and renovations
2. Office equipment or furniture, laboratory furniture, or therapeutic equipment
3. Hospital per diem charges
4. Books, periodicals or library services
5. Foreign travel
6. Office supplies, except those carefully justified as specifically required for project purposes
7. Professional membership fees
8. Tuition and fees

D. Development of new printed educational or informational materials is discouraged and must be discussed with the HRCC and the HRSA project officer.

VII. REVIEW PROCEDURES

If you do not meet the application submission requirements, your proposal may be administratively withdrawn and not submitted for review.

A. The review committee will evaluate the application for merit according to the following criteria:
    1. Relevance to national and regional priorities and goals.
    2. Feasibility and scientific, educational, advocacy or service merit.
    3. Benefit(s) to individuals and families affected by genetic conditions.
    4. Soundness of the project design.
    5. Qualifications and experience of the investigator(s).
    6. Involvement of family advocates (as co-investigators, advisors, participants, etc.) in a meaningful way.
    7. Evaluation method and dissemination plan.
    8. Likelihood of project resulting in:
        a. enhanced infrastructure;
        b. improved program performance; or
        c. increased attention to priority areas identified in program goals above.
    9. Inclusion of medical home principles: being accessible, family centered, continuous, comprehensive, coordinated, compassionate, and culturally respectful throughout the proposal.
    10. Innovation of the proposal.
    11. Demonstration of collaborative relationships between the parties involved.

12. Budget is reasonable and justified for the proposed project.

B. Upon completion of the peer review process, which includes a minimum of two reviewers (expert reviewer, an advocate, and a reviewer residing outside the Heartland region; one individual may fulfill two of these descriptions), the HRCC will submit the scores with summarized and anonymous critiques to the Heartland Advisory Board, which will make final award decisions.

C. Pilot Project Directors whose applications are selected for funding will be notified directly by the HRCC as soon as funding decisions are made and prior to the project start date of June 1, 2012.

VIII. AWARDEE EXPECTATIONS

Once award decisions have been made and IRB approval received, if applicable, a sub-contract between Arkansas Children's Hospital Research Institute (ACHRI) and the PPD's institution will be executed. Within this sub-contract, a scope of work will delineate the roles of the PPD and the HRCC. Specifically, the PPD will be expected to present results of the project at the annual Heartland meeting immediately following the conclusion of the project. **Please Note:** Travel-related costs for this presentation will be paid for by the HRCC and should not be included in the project budget. The PPD will also be expected to submit a written progress report at the six-month point (November 2012) and upon request. Roles of the HRCC typically include technical assistance and printing of poster(s) to assist in dissemination of project results for at least one Heartland annual meeting and for a national meeting, if applicable.