Health Resources and Services Administration/Maternal and Child Health Bureau

Measurement for Sickle Cell Disease Programs

Part A: JUSTIFICATION

1. Circumstances of Information Collection

This statement is a request for Office of Management and Budget approval for the measurement and quality improvement activities of the Sickle Cell Disease and Newborn Screening Program (SCDNBSP) and the Sickle Cell Disease Treatment and Demonstration Program (SCDTDP). The purpose of the measurement strategy and quality improvement activities is to monitor the service delivery processes and outcomes resulting from the systems of care delivered by SCDNBSP and SCDTDP networks to individuals affected by Sickle Cell Disease (SCD) who present at their sites for care. This is a new activity.

The Sickle Cell Disease and Newborn Screening Program and the Sickle Cell Disease Treatment Demonstration Program are administered by the Genetic Services Branch of the Division of Services for Children with Special Health Needs in the Health Resources and Services Administration's (HRSA) Maternal and Child Health Bureau (MCHB).

In response to the growing need for resources devoted to sickle cell disease and other hemoglobinopathies, the United States Congress, under Section 501(a)(2) of the Social Security Act, authorized the appropriation of funds for the purpose of enabling the Secretary to provide for special projects of regional and national significance, research and training with respect to maternal and child health and children with special health care needs, for genetic disease testing, counseling and information development, dissemination programs, for grants relating to hemophilia without regard to age, and for the screening of newborns for sickle cell anemia and other genetic disorders, and follow-up services.

As stated in House Report No. 107-229 regarding the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Bill 2002, the purpose of the SCDNBSP is "to enhance the sickle cell disease newborn screening program and its locally based outreach and counseling efforts." The American Jobs Creation Act of 2004, P.L. 108-357, states that "…the Bureau of Primary Health Care and the Maternal and Child Health Bureau, shall conduct a demonstration program by making grants to up to 40 eligible entities for each fiscal year in which the program is conducted under this section for the purpose of developing and establishing systemic mechanisms to improve the prevention and treatment of Sickle Cell Disease." (See Attachment A - 42 U.S.C. 300b-1). In addition, Section 712 of P.L. 108-357 authorized a demonstration program for the prevention and treatment of sickle cell disease. The legislation was enacted to (1) create an optional medical assistance program for individuals with SCD for treatment and education, genetic counseling and other services

to prevent mortality and decrease morbidity from Sickle Cell Disease, and (2) to create a demonstration program, the SCDTDP, under HRSA.

HRSA's activities under the legislative authorities relative to the SCDNBSP and SCDTDP have been delegated to the MCHB, Genetic Services Branch. The MCHB's Genetic Services Branch supports six community-based networks and the National Coordinating and Evaluation Center (NCEC) for the SCDNBSP, in addition to nine cooperative agreements and National Coordinating Center (NCC) for the SCDTDP. The programs fit within the broader goals of HRSA/MCHB. Specifically, they support three of the Bureau's five goals:

- Goal 3 – Eliminate Health Barriers and Disparities;
- Goal 4 – Improve the Health Infrastructure and Systems of Care; and
- Goal 5 – Assure Quality of Care.

2. Purpose and Use of the Information

I. *Sickle Cell Disease and Newborn Screening Program (SCDNBSP)*

Several nationally funded community-based SCD networks located in the U.S. and the National Coordinating and Evaluation Center (NCEC) comprise the SCDNBSP. In June 2011, The National Initiative for Children's Healthcare Quality (NICHQ) was recently named the NCEC along with its partners, Sickle Cell Disease Association of America and Boston Medical Center. The community-based SCD networks partner with state newborn screening programs, comprehensive sickle cell treatment centers, and health care professionals to provide support to infants who screened positive for sickle cell disease and carriers of the sickle cell gene mutation (known as sickle cell trait (SCT), and their families. The projects work cooperatively with the NCEC to implement a model program of sickle cell disease and sickle cell trait short and long-term follow-up to include notification of results of newborn screening, extended family testing, counseling and education of identified individuals and their families, and enrollment of affected infants into a medical home.

The National Coordinating and Evaluation Center was established for the SCDNBSP to (1) increase the knowledge about sickle cell disease for families with babies identified with sickle cell disease, sickle cell trait or other hemoglobin disorders, and to also increase the knowledge of their providers who are served by HRSA funded sickle cell disease community-based networks; (2) strengthen partnerships between the HRSA funded sickle cell disease community-based networks and their partners; and (3) improve the quality of care delivered through HRSA funded SCDNBSP networks for individuals identified with sickle cell disease or sickle cell trait.

The data gathered as part of the SCDNBSP will:

- Provide information about grantees' performance in achieving the following objectives of the SCDNBSP during the four year grant period:
    1. Improving the quality of newborn screening and follow-up activities for sickle cell disease and sickle cell trait within the HRSA funded sickle cell disease newborn screening community-based networks. Follow-up activities are defined as notification of the results of newborn screening, extended family testing, counseling and education of identified individuals and their families, and enrollment of affected infants into a medical home.
    2. Providing outreach and education to emerging populations such as Latino, Caribbean, African, Asian and multi-racial populations.

Specifically, the SCDNBSP seeks to answer the following:

Do individuals with sickle cell disease enrolled in the SCDNBSP receive appropriate treatment and genetic counseling; experience reduced morbidity; fewer hospitalizations and Emergency Room (ER) visits?

This portion of the information collection request seeks approval for two questionnaires (Attachments B and C). The questionnaires will be conducted by grantees with clients or their caregivers when they present for services. Data collection will involve an initial (baseline) and follow-up sessions for both sickle cell disease and sickle cell trait interviews during the project period. The information gathered and the settings for conducting the interviews are summarized below. Staff who interview the client will complete Sections A and B. Clients will be interviewed and their responses will be recorded on the questionnaires for items related to demographic information, family information, services received, and family communication (Sections C, D, E, and F on both questionnaires and Section G only on SCD Questionnaire). Data will be transmitted electronically to the NCEC on a quarterly basis.

Evaluation Center Minimum Database Project (MDP) Sickle Cell Disease Questionnaire
This questionnaire collects data on clients with sickle cell disease being served by grantees and includes questions on demographics including race, ethnicity, language spoken in the home, diagnoses, insurance status, family and healthcare systems of care, recent healthcare utilization and outcomes, and services received (genetic counseling, education, social services) by the client and/family. The questionnaire is completed at the grantee site with the client (if adult) or client's guardian/caretaker.

Evaluation Center Minimum Database Project Sickle Cell Trait Questionnaire
This questionnaire collects data on clients who are carriers of the sickle cell gene mutation being served by grantees and includes questions on the demographics including race, ethnicity, language spoken in the home, diagnosis, family systems of care, and provides grantees with an opportunity to document services received by the client and/or family, which includes genetic counseling, genetic testing, education on the disease, and other family members with the disease. The questionnaire is completed at the grantee site or by telephone with the client (if adult) or client's guardian/caretaker.

Measurement overview:

As aforementioned the objectives of the Sickle Cell Disease and Newborn Screening Program are to improve the quality of sickle cell disease and sickle cell trait follow-up activities as well as provide outreach and education to emerging populations who have sickle cell disease and sickle cell trait. These follow-up activities include notification of newborn screening results, extended family testing, genetic counseling and education of identified individuals and their families as well as ensuring affected infants are enrolled in a medical home.

The aim of the measurement strategy of Sickle Cell Disease and Newborn Screening Program is to gather information on the services provided through grantee networks to individuals with sickle cell disease and sickle cell trait. We will also gather information on the experience of care, the level of use of health care services and the health of the individuals receiving services in these grantee networks.

Participants and sample size: Our respondent universe for data collection is individuals with a positive screen for sickle cell disease or sickle cell trait who receive care at one of the six funded grantee networks of the SCDNBS. In June 2011, the total number of grantees was reduced from 17 grantees to 6 grantees. We anticipate a sampling frame of approximately 200 clients per grantee network based on current case load (N=1200 across all 6 networks). (Please refer to Part B for more details re: sample size and data collection procedures)

Data collection procedures and instruments: Clients at grantee networks will complete one survey depending on their condition (sickle cell disease or sickle cell trait). Data will be collected on an annual basis from clients receiving care at one of the SCDNBS grantee networks. For clients and caregivers completing the Sickle Cell Disease questionnaire, they will complete a baseline assessment when they are initially enrolled and then at 12 months following initial enrollment. Follow-up data will be collected 12 months after enrollment to allow for sufficient time for clients to receive program services as well as to allow for sufficient time for changes in health care utilization to occur. At the time of enrollment, SCDNBS participants will be informed about the data collection as part of the informed consent process.

Clients will complete one of the following survey instruments as part of the SCDNBS:

1) Evaluation Center Minimum Database Project Sickle Cell Trait (SCT) Questionnaire (See attachment B)
2) Evaluation Center Minimum Database Project Sickle Cell Disease (SCD) Questionnaire (See attachment C)

Analysis: We will perform a descriptive analysis that will focus on demographics of the sample, services delivered through the program, consumer experience of care, health services use and provision of recommended care. The data collected will be necessary for the preparation of the annual report to HRSA.

Variables that will be used for the descriptive analysis from each survey instrument are detailed below:

- Demographics:
  - Gender (question 2, section C of SCT questionnaire and SCD questionnaire)
  - Education (question 13 D, section F of SCT questionnaire/ question 37 D, section G of SCD questionnaire)
  - Language (question 13 A, section F of SCT questionnaire/question 37 A, section G for SCD questionnaire)
  - Race (question 14 and 15, section F of SCT questionnaire/questions 38 and 39; section G of SCD questionnaire

- Condition:
  - Type of trait: question 5,section D of SCT questionnaire
  - Sickle cell genotype: question 3, section C of SCD questionnaire

- Services delivered: question 7 and 8, Section E of SCT questionnaire/ question 34, section F of SCD questionnaire

- Health services use: (only on SCD questionnaire)

  - Primary care (question 22, section E);
  - Hematology care (question 23, section E)
  - Emergency department use (question 24, section E)
  - Reason for ED visit (question 25, section E)
  - Hospitalization (question 26, section E)
  - Reason for hospitalization (question 26, section E)

- Recommended care: (only on SCD questionnaire)
  - Prophylactic antibiotics (question 28, section E)
  - Pneumococcal vaccination (question 31, section E)
  - Treatments received (question 33, section E)

II. Sickle Cell Disease Treatment Demonstration Program (SCDTDP) Measurement and Quality Improvement Activities

The SCDTDP provides grants to nine federally-qualified and nonprofit health care providers to establish geographically distributed regional networks that will work with comprehensive SCD centers and community-based support organizations to provide coordinated, comprehensive, culturally competent, and family-centered care to families with sickle cell disease. The SCDTDP is designed to improve access to services for individuals with sickle cell disease, improve and expand patient and provider education, and improve and expand the continuity and coordination of service delivery for individuals with sickle cell disease and sickle cell trait.

The SCDTDP will carry out these activities by doing the following:

(1). improving access to services for individuals with sickle cell disease;

(2). addressing the knowledge gaps that exist in the federally qualified health centers (FQHCs) and other primary care settings; and

(3). promoting the adoption of new developments in care and routine delivery of genetic counseling for individuals with hemoglobinopathies.

A goal of the SCDTDP is to become a recognized model for quality care and education for sickle cell disease and sickle cell trait.

Sickle Cell Disease Treatment Demonstration Program Quality Improvement Activities

The nine SCDTDP network grantees are part of a broader group of HRSA grantees known as the "hemoglobinopathies grantees." The work of these grantees focuses on improving the quality of care for patients with any of several hemoglobin disorders (patients with genes that produce abnormal hemoglobin). HRSA-funded programs include the Sickle Cell Disease Treatment Demonstration Program, the Sickle Cell Disease Newborn Screening Program, and the Comprehensive Medical Care for Thalassemia program.

All hemoglobinopathies grantees will be participating in Quality Improvement (QI) activities beginning in late 2011. The QI Process is known as the Model for Improvement, a widely used approach to quality improvement used in health care settings.[1] Each grantee will be asked to report on a core set of measures related to quality improvement for hemoglobinopathies as described in the table below. This model for improvement uses a structured process which asks teams (grantees in this case) to build on small tests of change in their health care setting while measuring and reporting monthly on those small tests of change. The small tests of change are directly aligned to the measures outlined below. These quality improvement measures include:

[1] The Breakthrough Series: IHI's Collaborative Model for Achieving Breakthrough Improvement. *Diabetes Spectrum*. Volume 17, Number 2, 2004. Paper available upon request.

The QI Instrument
1. Percent of SCD individuals with a treatment plan reviewed in past 12 months 2. Percent of newborns screened for SC trait 3. Percent of positive screens with timely follow-up 4. Percent of SCD individuals with up to date immunizations 5. Percent of SCD individuals with documented Preventive Care Program (PCP) visited in past 12 months 6. Percent of teams that meet at least bi-weekly 7. Percent of teams participating in calls 8. Percent of teams rated 4 or above on project assessment

Sickle Cell Disease Treatment Demonstration Program National Coordinating Center

The aim of the SCDTDP measurement strategy is to gather information about the services provided through overall program and its component projects (the individual SCDTDP networks described above) to improve care and outcomes for those individuals with sickle cell disease and their families served through the SCDTDP Networks. A previous OMB information collection request was approved for the SCDTDP that recently expired (OMB #0915-0320). This new package combines the previously approved activities with the newborn screening program measurement strategy as mentioned earlier and the additional quality improvement activity, The National Coordinating Center (NCC) was established for the Sickle Cell Disease Treatment Demonstration Program to do the following:

(1) collect, coordinate, monitor, and report on promising practices and findings regarding the activities of the demonstration program;

(2) identify a model protocol for eligible entities with respect to the prevention and treatment of Sickle Cell Disease;

(3) identify educational materials regarding the prevention and treatment of Sickle Cell Disease; and,

(4) prepare a final report based on the data collected in the Sickle Cell Disease Treatment Demonstration program.

The SCDTDP NCC performed these functions including data collection, identifying educational materials, and generating a final report for its initial period of operation which was approved through OMB #0915-0320. This request combines the previous

work with modest revisions responding to lessons learned, the addition of the quality improvement activities, and evolving technologic capabilities enabling more efficient data collection.

The NCC will coordinate the collection of data from clients served in the SCDTDP networks in order to monitor the activities of the network sites and identify promising practices of the individual Networks and the entire program.

The Sickle Cell Disease Treatment Demonstration Program Networks collect health services utilization, health status, patient satisfaction and quality of life assessments from clients served at the demonstration sites. Data collected by the grantees, will be submitted on a regular basis to the NCC. These data, obtained from clients operating in real world settings, inform the assessment of the capacity of the demonstration projects to achieve important treatment outcomes for the individuals served.

Detailed information on the data collection items and instruments are provided in Attachments E through Q. More generally, however, the clients provide information on the following:

a) Demographics, health services use, disease specific treatment and complications are captured on the Individual Utilization Questionnaire (attachment E), an instrument specifically developed for this project. Information collected by this instrument is derived from two sources. Clients provide information on key demographic information (race, ethnicity, education, income); receipt of preventive services; usual source of care; care from specific providers (e.g., specialists, primary care, emergency department); receipt of specific therapies (e.g., hydroxyurea, chelation); and experience of specific complications (e.g., pulmonary crisis, pain crisis). Additional items collected by the instrument such as the patient immunization status are derived from medical record abstraction performed by a trained chart abstractor at each Network.
b) Experience of and satisfaction with care: Clients complete items from a standardized patient experience of care survey (the Medical Home Family Index-attachments F and G) that report on specific experiences related to their care in the primary care/medical home context. Questions include the extent to which the patient is known by staff and whether patients receive a written care plan.
c) Health Status and Quality of Life: Clients report on their health status and quality of life by completing an age appropriate, validated instrument for this purpose, either the age specific Pediatric Quality of Life measure (attachments I though O) or, for adults, the Short Form 36 Health Survey (attachments Q).
d) Emerging Population Survey: Clients report on their language preference, race, ethnicity, language spoken in the home and education to be better served by the program. (Attachment R).

Measurement overview:

As aforementioned, the ***Sickle Cell Disease Treatment Demonstration Program*** is designed to improve access to services for individuals with sickle cell disease, improve

and expand patient and provider education, and improve and expand the continuity and coordination of service delivery for individuals with sickle cell disease and sickle cell trait.

The aim of the measurement for the Sickle Cell Disease Treatment Demonstration Program is to gather information on the services provided through the grantee networks. We will also gather information about the level of use of health care services, health outcomes and health related quality of life for individuals with sickle cell disease receiving services in these grantee networks.

Participants and sample size: Our respondent universe for the data collection will be nine grantee networks and all the individuals with sickle cell disease and their caretakers enrolled in the SCDTDP at these networks. We are asking sites for a sample size of 100 individuals per network, for a total N=900. We believe that a sample size of 100 per network will be adequate to detect trends over time in the measures being collected. We will ask each network director to provide an estimate of the total number of clients, and provide on a monthly basis a set of sealed envelopes with randomly sequenced inclusion or exclusion information with an appropriate sampling fraction to generate the minimum number of required respondents (N=100 per network, N=900 across all 9 networks). More detailed regarding sampling and data collection procedures are in Part B.

Data collection procedures and instruments: Data will be collected on an annual basis from clients obtaining care at the SCDTDP grantee networks, including at baseline when the clients and caregivers are enrolled and at 12 months following enrollment. Grantee networks will enroll participants on a rolling basis such that new client will be added to the study over a specified period. At the time of enrollment, SCDTDP participants will be informed about the data collection as part of the informed consent process.

Participants will complete the following surveys at baseline and 12-month follow-up (i.e., two data collection points):

- Utilization questionnaire (all participants, N~900, separate versions for baseline and follow-up);
- One of the following, based on participant's age:
    - Short Form 36 (SF-36) Health Survey Health Survey (adults over 18 years of age, N~630),
    - Pediatric Quality of Life measure (PedsQL) version for *parents* of children and adolescents age 18 years or younger (N~270), or
    - Pediatric Quality of Life measure (PedsQL) version for children and adolescents 18 years or younger, (N~225);

- The Medical Home Family Index (all participants, N~900, assesses health care satisfaction)
- Hemoglobinopathies Emerging Populations Form (all participants, N~900, assesses Client Family Communication)

Grantee networks will complete the quality improvement instrument on a monthly basis. This instrument will be completed at the 9 grantee networks. Monthly reporting will allow teams to measure their performance on quality measures, implement small tests of change and then reassess their performance in a timely fashion with the ultimately goal of improving care for individuals with sickle cell disease.

For each instrument, specific details on burden hours are outlined in Section 12.

Analysis: We will perform a descriptive analysis that will focus on variables to assess health services, health status, patient satisfaction, quality of life, and client family communication. The data collected will be necessary for the preparation of the annual report to HRSA as well as the final Congressional report detailing the results of this program as requested by federal legislation.

Variables that will be used for the analysis for each survey instrument are detailed below:

- Demographics: Utilization questionnaire
    - Variables include race, ethnicity, education, income
- Health services use: Utilization questionnaire
    - Variables include receipt of preventive services; usual source of care; care from specific providers, e.g., specialists, primary care, emergency department
- Disease specific treatment and complications: Utilization questionnaire
    - Variables include receipt of specific therapies, e.g., hydroxyurea, chelation; and experience of specific complications, e.g., pulmonary crisis, pain crisis
- Patient satisfaction with care: Medical Home Family Index
    - Variable domains include: specific experiences related to care in the primary care/medical home context, i.e., the extent to which the patient is known by staff, whether patients receive a written care plan
- Quality of life: PedsQL or SF-36
    - Variable domains include: Physical functioning, bodily pain, general health, mental health/emotional functioning, social functioning, vitality, school functioning (children only)
- Client family communication: Hemoglobinopathies Emerging Populations Form
    - Variable domain: Language
- Quality improvement instrument:
    - Variables include: Percent of SC individuals with a treatment plan reviewed in past 12 months, Percent of positive screens with timely

follow-up, Percent of SC individuals with up to date immunizations, Percent of SC individuals with documented Preventive Care Program (PCP) visited in past 12 months

Clients are provided the opportunity to give informed consent to participate in completing the surveys surveyed at enrollment in the Network. For those who agree, data collection will then be undertaken and repeated annually. The individual sites and the NCC each have IRB approval.

Each program will hire and train their own data collector based on an assessment of the client population's characteristics and programmatic data needs. We plan a common initial (start of grant period) and refresher (as needed) training protocol for the overall HRSA national sickle cell disease program grantees to assure uniformity in the data collection and entry process for the entire funding period.

3. Use of Improved Information Technology

I. Sickle Cell Disease and Newborn Screening Program (SCDNBSP)

At each point of client contact, data collection will involve completing a structured interview questionnaire (see attachments B & C) for sickle cell disease and carriers of the sickle cell gene mutation. During this time, network interviewers will use traditional pen and paper data collection instruments. After completing interviews at each site, the interviewer will field edit all of the questionnaires for accuracy, completeness and legibility. The network data coordinator will be responsible for data entry. The data entry process will occur electronically via an online web-based data portal using secure data collection interfaces. HL7 standards will be applied to protect privacy by securing personal information from unauthorized access and use or disclosure. HL7 will protect secure information through the use of encryption such as the Secure Socket Layer (SSL) protocol. Each network data coordinator will be provided with a unique user name and password to log onto the web-based portal for data entry.

All data collected, entered and analyzed for reporting and publishing will not contain any personal identifiers. All procedures, including interviewing and data storage, will be IRB approved prior to data collection and implementation. The hard copies of the data forms will be stored at the network site securely which can be accessed by the network program coordinator only using lock and key. Memorandum of Understanding (MOU) will be provided by the NCEC to individual networks that do not have an IRB. We will protect secure information through the use of encryption such as the Secure Socket Layer (SSL) protocol consistent with IRB.

II. Sickle Cell Disease Treatment Demonstration Program (SCDTDP)

In the past, data collection has taken place using traditional pen and paper instruments involving a clerk entering data into a machine readable, digital format. Going forward,

the data collection instruments noted above will be converted into web based data entry forms for direct input of data via the internet by clients served at the SCDTDP Network sites (self administered) or by the data collection staff at the site (interviewer administered). Similarly the items on the Individual Utilization instrument (see attachment E) that derive from medical record review will be entered by the Network site data abstractor via a web form into the project database. All of the web based data collection will use secure data collection interfaces.

Because some grantees do not have the technology available for the purposes of electronic data collection, we will provide an option for grantees to provide paper submission to the NCC.

Health Insurance Portability and Accountability Act (HIPAA) standards will be applied to protect privacy by securing personally identifiable information from unauthorized access and use or disclosure. We will protect secure information through the use of encryption such as the Secure Socket Layer (SSL) protocol consistent with HIPAA for both components of the project. If electronic data exchange/messaging are used, an HL7-compliant interface will be available.

No personally-identifiable information will be requested or reported for the Quality Improvement activities. The data from the QI Process and Model for Improvement will be used to inform the grantees' work in their health care setting.

4. Efforts to Identify Duplication

There are no other HRSA/MCHB data collection activities that are evaluating the progress of these Sickle Cell Disease Programs. The information being collected is not available elsewhere.

5. Involvement of Small Entities

This activity does not impact small entities.

6. Consequences if Information Collected Less Frequently

I. Sickle Cell Disease and Newborn Screening Program (SCDNBSP)

Data collection and assessment periods are designed to correspond with quarterly and annual reports to HRSA, allow ample time for participants to provide the requested information and for electronic file-based information to be abstracted. The determination of these periods was based on the experience of the NCEC over the last six years. These quarterly and annual reports are reviewed by HRSA program staff to allow for adjustments to be made prior to finalization and submission to meet the required deadlines. Failure to meet the reporting deadlines places continuation of the program in jeopardy.

II. Sickle Cell Disease Treatment Demonstration Program (SCDTDP)

Quality Improvement data, from the QI Instrument, will be collected on a monthly basis throughout the duration of the program. All other data will be collected at baseline during the patient's first encounter at the program sites after the initiation of the site's participation in the program; data collection will then be repeated annually 12 months after the baseline assessment. Less frequent assessments will not provide sufficient timely feedback to inform program design and improvements nor the required data specified by the legislation noted above.

7. Consistency with the Guidelines in 5 CFR 1320.5(d) (2)

This data collection request is fully consistent with the guidelines in 5 CFR 1320.5(d) (2).

8. Consultation Outside of the Agency

The notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on August 26, 2010, Volume 75, Number 165, and pages 52533 – 52534. The 30-day *Federal Register* notice was published on April 14, 2011, Volume 76, Number 72, page 20993. No comments were received.

I. Sickle Cell Disease and Newborn Screening Program (SCDNBSP)

The National Coordinating and Evaluation Center convened an Advisory Panel of grantees and NCEC Task Leaders to ensure that the data collection for the SCDNBSP would be relevant and appropriate with minimum burden to the patients and the programs administering the data collection forms. A roster of members of the Advisory Panel is presented below in Table 1. The panel revised and adapted existing data collection tools to create the Minimum Database Project Sickle Cell Disease (MDP SCD) Questionnaire, and the Minimum Database Project Sickle Cell Trait/Carrier (MDP SCT) Questionnaire.

Table 1. SCDNBSP Advisory Panel

Organization	Contact Name	Role	Phone Number	Email
Brookdale Children's Hospital	Kusum Viswanathan, MD	Principal Investigator	(718) 240-5904	Kviswana@brookdale.edu
St. Jude Children's Research Hospital	Yvonne Carroll, RN, JD	Director, Patient Services	(901) 595-5684	yvonne.carroll@stjude.org
SCDAA, Mobile Chapter	Linda White Jones	Project Director	(251) 432-0301	ljones@scdaamobile.org
Columbia University Medical Center	Nancy Green, MD	Principal Investigator	(212) 305-0494	nsg11@columbia.edu
Sickle Cell Disease Foundation of Georgia	Janeth Spurlin	Patient Coordinator	(404) 755-1641 ext. 212	j_spurlin@sicklecellatlaga.org
University of North Carolina at Greensboro	Joseph Telfair, DrPH	Project Director	(336) 334-4777	j_telfair@uncg.edu

II. ***Sickle Cell Disease Treatment Demonstration Program (SCDTDP)***

For the purpose of ensuring that the data collection would be relevant and appropriate with minimum burden to the patients and the organizations administering the data collection forms, The National Coordinating Center (NCC) convened a Technical Working Group comprised of representatives of the grantee Networks that were participating in the SCDTDP at that time as well as expert sickle cell disease scientists and researchers. A roster of the prior Technical Working Group members is presented below in Table 2. Over the course of seven months, the Technical Working Group met monthly to develop a uniform data collection instrument (Individual Utilization Questionnaire) and to identify other instruments currently available and in use in SCD research that would meet the measurement needs of the project.

The Technical Working Group will reconvene in fall of 2011 throughout the funding period, including representatives of the new network sites, to provide ongoing guidance and oversight to the data collection process.

Table 2. SCDTDP Technical Working Group Members

Organization	**Contact Person**	**Role**	**Phone Number**	**E-mail**
University of Alabama-Birmingham	Roy McDonald, MPH	Data Manager	205-939-5849	rmcdonald@peds.uab.edu
University of Cincinnati	Thomas Webb, MD, MSc	Principal Investigator	513.556.2870	thomas.webb@uc.edu
Stedman-Wade	Dr. Kweku Laast, MD, MPH	Principal Investigator	910.483.6694	klaastmd@aol.com
Fayetteville State University	Akbar Aghajanian Ph.D.	Director, Research Center for Health Disparities	910-672-2927	aaghajanian@uncfsu.edu
Christian Community Health Center (CCHC)	Linda D. Drawhorn, MS, RN	Project Coordinator	773-298-2051	Linda.drawhorn@cchc-rchm.org

Sickle Cell Disease Association of Illinois	Valerie Beckley, MSW *Deceased*	Executive Director SCDAI	312-345-1100	valerie.beckley@mgci.com
University of North Carolina at Greensboro	Joseph Telfair, DrPH, MSW, MPH	Project Director	336-334-4777	j_telfai@uncg.edu
Meharry Medical College (MMC)	Maria del Pilar Aguinaga, PhD, CLDir (NCA)	Clinical Advisor	615-327-6591	maguinaga@mmc.edu
National Heart, Lung and Blood Institute/Univ of Colorado Health Sciences Center	Kathryn Hassell, MD	Technical Working Group Chairperson	303-372-9071	hassellk@nhlbi.nih.gov
Research Triangle Institute (RTI)	Marian Sullivan, MS, MPH	Project Manager	301-230-4677	msullivan@rti.org

9. Compensation of Respondents

Respondents will not be remunerated or compensated.

9. Assurance of Confidentiality

The need for a Privacy Act System of Records Notice (SORN) was assessed. It was determined that a SORN is not necessary for this data collection activity.

I. Sickle Cell Disease and Newborn Screening Program (SCDNBSP)

The project team will undertake the following measures to ensure confidentiality:

a. Individuals will be assigned a random digit identifier. The linkage between the identifier and the patient/client name will be kept at the grantee networks and will not be reported to the National Coordinating and Evaluation Center
b. All NCEC staff with access to data will undergo IRB and HIPPA training and certification
c. Any paper copies of survey instruments with personal health information or personal identifiers will be kept in a locked file with the grantee networks.
d. Electronic data will be encrypted and transmitted using Secure Socket Layer (SSL) technology. SSL is a file and data encryption protocol
e. Responses reported in final reports will be reported in aggregate.

II. Sickle Cell Disease Treatment Demonstration Program (SCDTDP)

The project team will undertake the following measures to ensure confidentiality:

a) Individuals will be assigned a project ID number. The linkage between project ID number and patient/client name will be kept at sites and not reported to the National Coordinating Center.
b) All NCC personnel with access to data will undergo IRB and HIPPA training and certification.
c) Any hard copies of information (paper instruments) with personal health information will be kept in a locked file. A log of individuals seeking access to the information will be kept and maintained by the NCC Project Director.
d) Electronic data will be encrypted and transmitted using Secure Socket Layer (SSL) technology. SSL is a file and data encryption protocol.
e) Publicly accessible reports will only provide aggregate data.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden

I. Sickle Cell Disease and Newborn Screening Program (SCDNBSP)

Data will be collected using two different instruments for SCDNBSP: the Minimum Dataset Project (MDP) Sickle Cell Disease Questionnaire and the MDP Sickle Cell Trait Questionnaire (see section 2). The total burden estimate per participant is shown below in Table 3. Wage rates were determined based on the 2009 National Occupational Employment and Wage Estimates from the Bureau of Labor Statistics for all occupations.

Table 3. Estimated Hour and Cost Burden of the Data Collection

Questionnaires	No. of Respondents	Responses per Respondent	Total Responses	Average Hours per Response	Total Hour Burden	Wage Rate	Total Hour Cost
MDP SCD Questionnaire	140	2	280	.45	126	$20.90	$2633.4
MDP SCT Questionnaire	1400	1	1400	.30	420	$20.90	$8778
Total	1540		1680		546		$11,411.4

II. Sickle Cell Disease Treatment Demonstration Program (SCDTDP)

Table 4 summarizes the estimated hour burden and cost of data collection. Data will be collected using the following instruments for SCDTDP: Utilization Questionnaire, the SF-36 for adults aged 18 and over; the PedsQL for adolescents and children and their parents; the Medical Home Family Index and the Hemoglobinopathies Emerging Populations (Family Communication) forms. Wage rates were determined based on the 2009 National Occupational Employment and Wage Estimates from the Bureau of Labor Statistics for all occupations.

Table 4. Estimated Burden Hours

Questionnaires		No. of Respondents	Responses per Respondent	Total Responses	Average Hours per Response	Total Hour Burden
SCDTDP	Utilization Questionnaire (pre-demonstration)	900	1	900	.75	675
	Utilization Questionnaire (post demonstration)	900	1	900	.50	450
	SF-36 Health Survey for adults over 18 years of age	630	2	1260	.25	315
	PedsQL for parents of children & adolescents 18 years or younger*	270	2	540	.25	135
	PedsQL for children & adolescents 18 years or younger*	225	2	450	.25	112.5
	The Medical Home Family Index (Health Care Satisfaction)	900	2	1800	.25	450
	QI Instrument	9	12	108	4	432
	Hemoglobinopathies Emerging Populations Form (Client Family Communication)	900	2	1800	.20	360
Total		4734		7758		2929.5

* Only one form is completed by respondent based on age and responder.

The estimates of burden for the SF-36, the PedsQL, and the Medical Home Family Index were derived from published estimates of administering these instruments.[2] The Utilization Form was pre-tested with 9 respondents and the estimates of burden are based on the results of those assessments. We are in the process of developing similar measures that have similar data collection burden as these measures detailed in this application. We will pay particular attention that the data collection burden for these new measures will be the same or less as the current measures for both programs.

III. Combined Table

Table 5 represents the total burden from both the Sickle Cell Disease and Newborn Screening (SCDNBSP) and the Sickle Cell Disease Treatment Demonstration Program (SCDTDP) Measurement and Quality Improvement Activities.

Table 5. Estimated Hour and Cost Burden of the Data Collection

Questionnaires	No. of Respondents	Responses per Respondent	Total Responses	Average Hours per Response	Total Hour Burden	Wage Rate	Total Hour Cost
MDP SCD Questionnaire	140	2	280	.45	126	$20.90	$2633.4
MDP SCT Questionnaire	1400	1	1400	.30	420	$20.90	$8778
Utilization Questionnaire (pre-demonstration)	900	1	900	.75	675	$20.90	$14,107.5
Utilization Questionnaire (post demonstration)	900	1	900	.50	450	$20.90	$9,405
SF-36 Health Survey for adults over 18 years of age	630	2	1260	.25	315	$20.90	$6,583.5
PedsQL for parents of children & adolescents 18 years	270	2	540	.25	135	$20.90	$2,821.5

[2] SF-36 : http://www.rand.org/health/surveys_tools/mos/mos_core_36item.html; PedsQL: http://www.pedsql.org/about_pedsql.html; Medical Home Family Index: http://www.medicalhomeimprovement.org/outcomes.htm

or younger*							
PedsQL for children & adolescents 18 years or younger*	225	2	450	.25	112.5	$20.90	$2,351.25
The Medical Home Family Index (Health Care Satisfaction)	900	2	1800	.25	450	$20.90	$9,405
The QI Instrument	9	12	108	4	432	$20.90	$9,028.80
Hemoglobinopathies Emerging Populations Form (Client Family Communication)	900	2	1800	.20	360	$20.90	$7,524
Total	6,274		9,438		3,475.5	$20.90	$72,637.95

13. Estimates of Annualized Cost Burden to Respondents

There are no capital or startup costs associated with data collection.

14. Estimates of Annualized Cost to the Government

I. Sickle Cell Disease and Newborn Screening Program (SCDNBSP)

The National Coordinating and Evaluation Center is a cooperative agreement with HRSA. The estimated cost to the Government for collecting these data is based on the portion of the cooperative agreement that is devoted to the data collection and analysis efforts that includes personnel, supplies and other resources. The estimated cost to the government for three years is $1,011,000.

II. Sickle Cell Disease Treatment Demonstration Program (SCDTDP)

The cost of the contractor to gather data as part of the Sickle Cell Disease Treatment Program is approximately $200,000 annually as well as the cost for one FTE GS-13 at 20% time at $20,000 to monitor the project. The total annual costs for this collection of information are approximately $220,000. The estimated cost for three years is $660,000.

The total estimated costs for both measurement strategies to the government for three years are $1,671,000.

15. Changes in Burden

This is a new collection activity.

16. Time Schedule, Publication, and Reporting Plans

The proposed schedule for the information collection is shown below in Table 6.

Table 6: Estimated Time Schedule for Data Collection, Analysis and Publication

Activity	Time Schedule
Receipt of OMB Approval	Estimated January 2012
SCDNBSP and SCDTDP Patient Enrollment and Field Questionnaires	January /February 2012
Implementation of NCEC MDP Data Collection Protocols	January/February 2012
Data Analysis and Reporting	Bi-Annually (April and October) through the funded period 2011-2015
Final Report to HRSA/MCHB	Annual (June) through the funded period 2011-2015

17. Exemption for Display of Expiration Date

The expiration date will be displayed.

18. Certifications

This information collection fully complies with the guidelines in 5 CFR 1320.9.