Part I. Overview Information

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to CDC-RFA-DD15-1507. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC)

B. Funding Opportunity Title:

Public Health Surveillance for the Prevention of Complications of Bleeding Disorders

C. Announcement Type: New - Type 1

This announcement is only for non-research domestic activities supported by CDC. If research is proposed, the application will not be considered Research for this purpose is defined at http://www.cdc. gov/od/ science / integrity/ docs/cdc- policy- distinguishing- public- health- research- nonresearch. pdf.

D. Agency Funding Opportunity Number:

CDC-RFA-DD15-1507

E. Catalog of Federal Domestic Assistance (CFDA) Number:

93.080

F. Dates:

1. Due Date for Letter of Intent (LOI):	**05/01/2015**
2. Due Date for Applications:	**05/20/2015**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.
3. Date for Informational Conference Call:	**04/13/2015**

April 13, 2015 3pm-4pm Eastern Time; (855) 644-0229, Conference ID: 2963605

G. Executive Summary:

1. Summary Paragraph:

Hemophilia, von Willebrand disease and other congenital bleeding disorders that decrease normal blood clotting cause significant disease burden and reduced quality of life. The purpose of this FOA is to build upon the work currently ongoing in the United States Hemophilia Treatment Center Network (USHTCN) under DD11-1103/DD14-1409 to prevent and reduce the complications of bleeding disorders by supporting the collection, aggregation and use of nationally representative data and specimens for surveillance for inhibitors and other complications of bleeding disorders. The awardee or awardees are required to collaborate with hemophilia treatment centers that are part of the USHTCN and are expected to build or model upon the structures, processes and instruments implemented under DD11-1103/DD14-1409. The awardee or awardees (should USHTCN regions choose to collaborate with different applicants) are expected to implement these five strategies and their corresponding activities: 1) establish collaborations with HTCs; 2) data collection and transfer; 3) specimen collection and transfer; 4) data evaluation; and 5) disseminate information (see Part 11.A.2.a.iii. Strategies and Activities), in order to achieve the following project outcomes: data collection legally and financially enabled; HTCs provide administrative input on existing capacity and barriers for project implementation; HTCs provide multidisciplinary input on project content based on professional practice and research expertise; HTCs contribute uniform data on bleeding disorders complications to a pooled national dataset; HTCs provide data for refinement of project processes and content; researchers and other stakeholders have access to more comprehensive evidence base for inhibitors and other complications; researchers, providers and other stakeholders: a) monitor trends in, b) identify

potential disparities between subpopulations in the rates of, c) identify high risk populations for interventions to reduce or prevent, and d) assess gaps in data collection on inhibitors and other complications of bleeding disorders. Applicants are encouraged to propose methods for maximizing national inhibitor surveillance.

a. Eligible Applicants:	Open Competition
b. FOA Type:	Cooperative Agreement
c. Approximate Number of Awards:	1
d. Total Project Period Funding:	$21,500,000
e. Average One Year Award Amount:	$4,300,000
f. Number of Years of Award:	5
g. Estimated Award Date:	08/31/2015
h. Cost Sharing and / or Matching Requirements:	N

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this FOA exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

Hemophilia, von Willebrand disease (VWD) and other congenital bleeding disorders that decrease normal blood clotting cause significant disease burden and reduced quality of life. About 20,000 people in the United States (US) (mostly males) have hemophilia, with healthcare costs approaching $3 billion annually. People with hemophilia have spontaneous internal bleeding and prolonged bleeding after injury or surgery that can lead to long-term damage and chronic conditions such as disabling joint disease. VWD occurs in about 1% of the population. Severe VWD causes symptoms like those of hemophilia in men and women. With other forms, women are more likely to have symptoms because VWD increases bleeding during menstrual periods and after childbirth. VWD increases risk for miscarriage, bleeding during pregnancy and maternal death. Historically, persons with bleeding disorders have also suffered infection with blood-borne viruses due to contaminated treatment products.

Patients with bleeding disorders are largely treated at specialized hemophilia treatment centers (HTCs) which provide comprehensive care. The federal HTC system (the US Hemophilia Treatment Center Network or USHTCN) includes 132 centers throughout the US and its territories. From January 2012 through December 2014, the USHTCN provided care to more than 16,200 patients with hemophilia, 11,000 with VWD and 5,700 with other bleeding disorder diagnoses.

Since the 1980s, CDC has collaborated with the USHTCN to reduce the complications of bleeding disorders and their treatment. This began with programs to reduce the secondary spread of HIV to partners of infected patients. In 1991, in response to requests from constituents, Congress authorized CDC to expand its activities to the prevention of other complications. CDC collaborated with the USHTCN to design and implement the Universal Data Collection (UDC) project (1998-2011). The UDC was designed to monitor the complications of bleeding disorders over time, especially joint disease and blood-borne infections. UDC demonstrated that some complications related to joint disease had decreased over time. The proportion of patients on treatment to prevent bleeding episodes (prophylaxis) increased. Overweight and obesity were shown to increase and accelerate the loss of joint range of motion, leading to programs to help patients maintain or achieve healthy weight. No new hepatitis or HIV infections from contaminated treatment products were found. The

percentage of youth with severe hemophilia using prophylaxis varied widely across HTCs and evidence suggested other viruses may still be transmitted in plasma-derived treatment products.

In 2010 CDC hosted a stakeholder meeting to identify ongoing and new areas of concern to the bleeding disorders community. Stakeholders individually identified numerous health indicators that should be monitored in order to protect the health of persons with bleeding disorders, including inhibitors. An inhibitor is an antibody created by the patient's immune system that inactivates clotting factor concentrate, making treatments ineffective and increasing complications and hospitalization rates. A single patient with complications and an inhibitor can have over $1 million in treatment costs annually. Widely cited as the most serious complication of hemophilia treatment, approximately 15-20% of hemophilia patients develop an inhibitor. Numerous risk factors for inhibitor development have been identified yet the causes are not completely understood, including whether specific treatment products play a role. Nationally representative data on inhibitor development in the US bleeding disorders population are not available. Determining the incidence and prevalence of inhibitors in this group and better understanding the risk factors associated with their development and their consequences is a priority for the Division of Blood Disorders, as are joint disease, intracranial hemorrhage and complications of treatment product use. In 2011, under cooperative agreement DD11-1103/DD14-1409, CDC and the USHTCN substantially revised data collection to reflect revised priorities. Data collection under the revised project, Community Counts, began in 2012.

b. Statutory Authorities

Sections 301(a) [42 USC 241(a)] and 317 (C) of the Public Health Service Act [42 U.S.C. Section 247b-4] as amended.

c. Healthy People 2020

This program addresses the "Healthy People 2020" focus area(s) of Blood Disorders and Blood Safety.
BDBS-11(Developmental) Increase the proportion of persons with bleeding disorders who receive recommended vaccinations.
BDBS-15 Increase the proportion of females with von Willebrand disease (VWD) who are timely and accurately diagnosed.
BDBS-16 Reduce the proportion of persons with hemophilia who develop reduced joint mobility due to bleeding into joints.
http://www.healthypeople.gov/2020/topics-objectives/topic/blood-disorders-and-blood-safety

d. Other National Public Health Priorities and Strategies

N/A

e. Relevant Work

This FOA builds on previous projects for the surveillance of complications of bleeding disorders, Prevention of the Complications of Bleeding Disorders through Hemophilia Treatment Centers (DD06-005, Universal Data Collection) and Public Health Surveillance for the Prevention of Complications of Bleeding and Clotting Disorders (DD11-1113/DD14-1409, Community Counts). Awardees are expected to build or model upon the structures, processes and instruments implemented under DD11-1103/DD14-1409.

2. CDC Project Description

a. Approach

The logic model below describes the expected approach to and outcomes of this program. Awardees will be responsible for accomplishing the outcomes marked with an asterisk (*).

CDC-RFA-DD15-1507 Logic Model: Public Health Surveillance for the Prevention of Complications of Bleeding Disorders

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-term Outcomes
Strategy 1: Establish collaborations with HTCs	1. Data collection legally and financially enabled* 2. HTCs provide administrative input on existing capacity and barriers for project implementation* 3. HTCs provide multi-disciplinary input on project content based on professional practice and research expertise* 4. HTCs invested in implementation and success of project	Researchers, providers and other stakeholders: • have increased awareness of inhibitors and other complications, treatment practices and patterns • monitor trends* • identify potential disparities* • identify high risk populations for interventions* • assess gaps in data collection* • generate hypotheses for research	Reduce and prevent inhibitors and other complications of bleeding disorders
Strategy 2: Data collection and transfer Strategy 3: Specimen collection and transfer	1. HTCs contribute uniform data on bleeding disorders complications to a pooled national dataset* 2. Patients receive regular inhibitor screening 3. Patients receive regular screening for HCV and HIV		
Strategy 4: Data evaluation	1. Researchers and other stakeholders have confidence in the quality of data 2. HTCs provide data for refinement of project processes and content* 3. HTCs committed to implementation and success of project		
Strategy 5: Disseminate information	1. HTCs monitor progress towards participation and data quality expectations 2. Researchers and other stakeholders have access to more comprehensive evidence base for inhibitors and other complications*		

i. Purpose

The purpose of this FOA is to build upon the work currently ongoing in the USHTCN under DD11-1103/DD14-1409 to prevent and reduce the complications of bleeding disorders by supporting the collection, aggregation and use of nationally representative data and specimens for surveillance for inhibitors and other complications of bleeding disorders. These data will be used to increase awareness of inhibitors and other complications among stakeholders; monitor trends in complications; identify disparities among subpopulations of bleeding disorder patients; identify high risk populations for interventions; assess gaps in data collection; generate hypotheses for research; and, ultimately, prevent the complications of bleeding disorders.

ii. Outcomes

Awardees are expected to achieve the following outcomes during the 5-year FOA project period:

1. Data collection legally and financially enabled (maintain or put in place)
2. HTCs provide administrative input on existing capacity and barriers for project implementation (maintain or put in place)
3. HTCs provide multidisciplinary input on project content based on professional practice and research expertise (maintain or put in place)
4. HTCs contribute uniform data on bleeding disorders complications to a pooled national dataset (increase)
5. HTCs provide data for refinement of project processes and content (maintain or put in place)
6. Researchers and other stakeholders have access to more comprehensive evidence base for inhibitors and other complications (increase)
7. Researchers, providers and other stakeholders:
   i. monitor trends in;
   ii. identify potential disparities between subpopulations in the rates of;
   iii. identify high risk populations for interventions to reduce or prevent; and
   iv. assess gaps in data collection on inhibitors and other complications of bleeding disorders (increase)

iii. Strategies and Activities

Awardees are expected to implement the following strategies and activities in order to achieve the project outcomes:

<u>Strategy 1: Establish collaborations with HTCs</u>

- Activity 1: Identify and execute needed business agreements with HTCs
- Activity 2: Establish process for regular input from HTCs on implementation of project

<u>Strategy 2: Data collection and transfer</u>

Awardees must coordinate and facilitate data collection and transfer from HTCs to CDC for inclusion in a pooled national data set such that the number of patients represented in the data set at Activity 2 is maintained or increased and the number at Activity 3 increases relative to the number enrolled at the close of DD11-1103/DD14-1409 in September 2015. Additional information regarding the acceptance testing and data elements referred to in activities 1-4 below can be found in *CDC-RFA-DD15-1507 Supporting Information*.

- Activity 1: Choose data collection and transfer methods and processes

CDC has developed a web-based data entry application (DBD Gateway) for use by sites collecting data for DBD surveillance projects. Applicants must indicate whether HTCs will use DBD Gateway for data submission or whether the applicant will provide another method of transferring data from the HTCs to CDC electronically. Awardees that choose not to use DBD Gateway will be required to participate in acceptance testing of data files, including submission of associated documentation.

- Activity 2: Coordinate collection and transmission of annual minimal patient-level data on all patients with agreed-upon bleeding disorder diagnoses at HTCs

- Activity 3: Coordinate enrollment of patients and collection and transmission of longitudinal, patient-level data on health indicators, including seroconversion follow-up, at the HTCs
- Activity 4: Coordinate collection and transmission of patient-level data on deaths of bleeding disorder patients at the HTCs

Strategy 3: Specimen collection and transfer from participants of Strategy 2, Activity 3 (longitudinal patient-level health indicator data)

- Activity 1: Coordinate at HTCs the collection and transfer of plasma specimens from participants enrolled in Activity 3 of Strategy 2 for inhibitor testing and seroconversion follow-up
- Activity 2: Coordinate at HTCs the collection and transfer of serum specimens from participants enrolled in Activity 3 of Strategy 2 for evaluation of treatment product safety and seroconversion follow-up

Strategy 4: Data evaluation

Awardees must maintain, or put in place, a process for gathering and analyzing data from the HTCs for the purpose of assessing and refining project processes and content.

- Activity 1: Develop and implement process to ensure collection of accurate data
- Activity 2: Evaluate feasibility of data collection at HTCs

Strategy 5: Disseminate information

- Activity 1: Collaborate with CDC to develop and provide internal reports to HTCs
- Activity 2: Collaborate with CDC to develop public information reports/materials (for example, key findings)
- Activity 3: Collaborate with CDC to plan, develop and produce peer-reviewed publications
- Activity 4: Collaborate with CDC and the USHTCN to use the data collected to:
    i. monitor trends in;
    ii. identify potential disparities between subpopulations in the rates of;
    iii. identify high risk populations for interventions to reduce or prevent; and
    iv. assess gaps in data collection on inhibitors and other complications of bleeding disorders

Applicants may propose additional strategies and activities.

1.Collaborations

Please see below for expected collaborations for this FOA.

a. With CDC-funded programs:

Awardees are required to collaborate with CDC Division of Blood Disorders. In the event that more than one award is made under this cooperative agreement, awardees will be required to collaborate with each other to produce and disseminate public information reports and materials and peer-reviewed manuscripts using the nationally pooled data. Awardees are not expected at this time to collaborate with CDC-funded programs other than those funded by this cooperative agreement to achieve these outcomes.

b. With organizations external to CDC:

Awardees are required to collaborate with HTCs that are part of the USHTCN for data and specimen collection. The USHTCN is regionally organized (see *CDC-RFA-DD15-1507 Supporting Information*) and receives funds through Special Projects of Regional and National Significance (SPRANS) administered by the Health Resources and Services Administration (HRSA). The hemophilia regional core centers, the grantees for HRSA SPRANS funds, determine which treatment centers within their geographic region are included in the USHTCN. This determination includes an assessment of whether each center meets the criteria set for HTCs by the Medical and Scientific Advisory Committee of the (US) National Hemophilia Foundation (MASAC). These criteria are stated in MASAC Recommendation # 132- Standards and Criteria for the Care of Persons with Congenital Bleeding Disorders (Revised April 2002), which may be found at: http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=57&;contentid=220.

In the event that different regions of the USHTCN agree to collaborate with different applicants, CDC will consider making up to three awards under this cooperative agreement to preserve geographic and demographic representativeness. The HTCs of any single region may not be funded by more than one award under this cooperative agreement. Applicants must specify whether they are collaborating with all of the regions of the USHTCN, or a subset of the regions. If collaborating with a subset of the regions, applicants must specify which regions those are.

Awardees may also collaborate with treatment centers that are not currently part of the USHTCN supported by HRSA SPRANS funds if:

• The non-USHTCN center meets the criteria stated in MASAC Recommendation # 132- Standards and Criteria for the Care of Persons with Congenital Bleeding Disorders (Revised April 2002), which may be found at: http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=57&;contentid=220; and

• Participation of the non-USHTCN center will not reduce the funds that would otherwise be directed to USHTCN centers for use on project activities; and

• The core center for the region in which the non-USHTCN center is located agrees that the non-USHTCN center may participate.

Applicants must document that each non-USHTCN center meets all three criteria for participation. Applicants may provide evidence of fulfillment of each of the criteria set out in MASAC Recommendation # 132, or provide a written statement from the regional core center confirming that the non-USHTCN center meets the criteria. Documentation indicating that the core center for the region in which the non-USHTCN center is located agrees that the non-USHTCN center may participate must be signed by the Regional Coordinator and Regional Director.

Applicants must provide documentation that HTCs have agreed to collaborate with the awardee and CDC to carry out the strategies and activities relevant to the HTCs that are proposed for this project. This documentation may be in the form of letters of support, letters of agreement, memoranda of understanding, memoranda of agreement, or contracts from or with collaborating HTCs (hereafter referred to collectively as "letters of support"). Documentation from the regional core center on behalf of the participating HTCs within its region may be provided in place of individual documentation from each HTC. Documentation that any non-USHTCN centers fulfill the criteria for participation may be provided in the same attachment as the letters of support from USHTCN HTCs.

2. Target Populations

The target populations are people of all ages with congenital bleeding disorders, primarily those due to factor deficiencies such as hemophilia A and B, von Willebrand disease and other clotting factor deficiencies. However, since inhibitor surveillance is a CDC priority, those patients at risk for development of an inhibitor to factor VIII or factor IX (patients with a diagnosis of hemophilia A, hemophilia B or type 3 VWD, especially racial and ethnic minorities) are considered to be of highest priority for enrollment in Strategy 2, Activity 3 (longitudinal patient-level health indicator data). Applicants should describe the geographic catchment area and demographic make-up (number and diagnoses, gender, race, ethnicity, age: 0-10 years; 11-19 years; 20 years and older) of the patient population of the HTCs with which it proposes to collaborate, as well as the percentage of all USHTCN bleeding disorder patients represented at its collaborating HTCs.

a. Inclusion

Applicants should strive to include people with disabilities; non-English speaking populations; lesbian, gay, bisexual, and transgender (LGBT) populations; people with limited health literacy; and/or populations that may otherwise be overlooked by the program.

iv. Funding Strategy (for multi-component FOAs only)

N/A

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

Evaluation and performance measures are directly linked to the program outcomes and strategies. Evaluation findings will be used to refine and improve program activities. Process evaluation methods will be used to assess the extent to which planned program activities have been implemented and have led to desired programmatic outcomes. Short and intermediate-term outcome evaluation will assess whether the project activities are leading to the intended long-term outcomes. All evaluation activities will support the logic model and approach presented earlier. Audiences for performance measures and evaluation findings include CDC, HTC leadership and staff and the public. Results are expected to be disseminated as technical notes and findings in public presentations and as reports to HTC leadership and staff.

Process Measures

Strategy 1- Establish collaborations with HTCs

Activity 1- Identify and execute needed business agreements with HTCs

- # of HTCs with business and financial agreements in place within 3 months of beginning of project period (reported to CDC quarterly until completion)

Activity 2- Establish process for regular input from HTCs on implementation of project

- Documented process for gathering input on administrative/business issues (reported to CDC once, upon completion)
- Documented process for gathering multidisciplinary input on professional practice and scientific issues (reported to CDC once, upon completion)
- Written agreement between the awardee, CDC and the HTCs on data use by the parties and sharing or release for public use, and implementation thereof (reported to CDC once, upon completion)

Strategy 2- Data collection and transfer

Activity 1- Choose data collection and transfer methods and processes

- Timely receipt of correct data files at CDC*
  - Timely: Percent of data files received at CDC within the agreed-upon timeframe
  - Correct: Percent of data files conforming to the file structure and data field content specified by CDC

Activities 2-4- Coordinate collection and transmission of minimal, longitudinal and mortality data

- # of HTCs obtaining institutional approval within 6 months of beginning of project period (reported to CDC quarterly until completion)
- Written regional plans to assess HTC participation and address barriers on an on-going basis within 6 months of beginning of project period (reported to CDC semiannually)
- # of HTCs submitting timely and complete longitudinal patient level health indicator data*
  - Timely: Percent of initial submissions made within the agreed-upon timeframe; percent of data queries resolved within the agreed-upon timeframe
  - Complete: Percent of non-missing responses

Strategy 3- Specimen collection and transfer

On a per HTC basis:

Activity 1- Coordinate collection and transfer of plasma specimens

- Percent of expected specimens submitted for inhibitor screening (# of specimens appropriately

submitted for inhibitor screening ÷ # of participants eligible for inhibitor screening)*

Activity 2- Coordinate collection and transfer of serum specimens

- Percent of expected specimens submitted for infectious disease and/or biomarker screening (# of specimens appropriately submitted for infectious disease and/or biomarker screening ÷ # of participants eligible for infectious disease and/or biomarker screening)*

Activities 1 & 2- Coordinate collection and transfer of plasma and serum specimens

- Percent of specimens prepared and shipped according to agreed-upon protocols. Includes collecting correct specimen, appropriate processing, notification to serum bank, completed specimen form (see *CDC-RFA-DD15-1507 Supporting Information*) and proper shipping*

Strategy 4- Data evaluation

Activity 1- Develop and implement process to ensure collection of accurate data

- Written plan for periodic evaluation and documentation of the accuracy of data collected and any indicated refinements (reported to CDC once, upon completion)

Activity 2- Evaluate feasibility of data collection at HTCs

- Written plan for periodic evaluation of the process and ease of data collection at HTCs (reported to CDC once, upon completion)

Strategy 5- Disseminate information

Activity 1- Collaborate with CDC to develop and provide internal reports to HTCs

- Provision of HTC-level quarterly progress reports on participation to HTCs (reported to CDC annually)
- Provision of recurrent HTC-level reports of clinically relevant measures to HTCs (reported to CDC annually)
- Provision of reports to HTCs on findings from periodic evaluations of data accuracy and the data collection process, as completed (reported to CDC annually)
- Notification to HTCs about materials under production for public and scientific community, at least semiannually (reported to CDC annually)

Activity 2- Collaborate with CDC to develop public information reports/materials

- Process measures to be developed in collaboration with CDC

Activity 3- Collaborate with CDC to plan, develop and produce peer-reviewed publications

- Process measures to be developed in collaboration with CDC

Activity 4- Collaborate with CDC and the USHTCN to use the data collected to monitor trends in; identify potential disparities between subpopulations in the rates of; identify high risk populations for interventions to reduce or prevent; and assess gaps in data collection on inhibitors and other complications of bleeding disorders

- Process measures to be developed in collaboration with CDC

Outcome Measures

Outcome 1: Data collection legally and financially enabled

- # of HTCs with completed business and financial agreements in place (reported to CDC annually)

Outcome 2: HTCs provide administrative input on existing capacity and barriers for project implementation

- Evidence of implementation of process such as call schedules, agendas, minutes, communications, etc. (reported to CDC annually)

Outcome 3: HTCs provide multidisciplinary input on project content based on professional practice and research expertise

- Evidence of implementation of process such as call schedules, agendas, minutes, communications, etc. (reported to CDC annually)

Outcome 4: HTCs contribute uniform data on bleeding disorders complications to a pooled national dataset

- # of HTCs submitting annual minimal patient-level data, on an annual basis*
- # of HTCs submitting longitudinal health indicator data, on a quarterly basis*
- # of HTCs submitting mortality data, on an annual basis*

Outcome 5: HTCs provide data for refinement of project processes and content

- Written findings from evaluation(s) of data accuracy, including # and representativeness of HTCs participating in data quality assessment (reported to CDC upon completion)
  - Representativeness includes USHTCN region; characteristics of patient population (number, pediatric vs. adult, diagnoses); resources available for data collection/project activities
- Written findings from evaluation(s) of data collection process, including # and representativeness of HTCs participating in evaluation of project processes (reported to CDC upon completion)
  - Representativeness includes USHTCN region; characteristics of patient population (number, pediatric vs. adult, diagnoses); resources available for data collection/project activities

Outcome 6: Researchers and other stakeholders have access to more comprehensive evidence base for inhibitors and other complications

- Dissemination of at least one public information product per year targeting participants and other consumers (reported to CDC annually)
- Dissemination of at least one public information product per year targeting researchers, providers or policy-makers (reported to CDC annually)
- Production of at least one peer-reviewed manuscript explaining methods and data results (reported to CDC annually)

Outcome 7: Researchers, providers and other stakeholders:

i. monitor trends in;
ii. identify potential disparities between subpopulations in the rates of;
iii. identify high risk populations for interventions to reduce or prevent; and
iv. assess gaps in data collection on inhibitors and other complications of bleeding disorders.

- Documentation of discussion and review with CDC, the USHTCN and other partners (if applicable) of trends, disparities, high risk populations, potential interventions and gaps in data collection on inhibitors and other complications of bleeding disorders (reported to CDC annually beginning with project year 4)

Measures marked with an asterisk (*) can be evaluated directly by CDC and do not require additional reporting by the awardee. The data collected relative to performance measures are limited to that which will be analyzed and used for this purpose.

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that is consistent with the CDC evaluation and performance measurement strategy. In this plan, applicants must:

1. Affirm their ability to collect the data for the performance measures
2. Describe how the applicant's key project staff, USHTCN regional core center staff, HTC staff and other key partners if applicable (for example, other federal agencies, consumer-based organizations, professional organizations, etc.) will be engaged in the evaluation and performance measurement process
3. Describe key evaluation questions to be answered, ensuring that the relevant outcomes, as displayed in the logic model, are included
4. Describe strategies for appropriate collection of performance evaluation data
5. Describe how evaluation findings will be used for quality improvement

c. Organizational Capacity of Awardees to Execute the Approach

Applicants must have the organizational structure and capacity to execute the CDC strategies and activities and meet project period outcomes. Applicants should address their collaboration with USHTCN regional core center staff, HTC staff and other key partners if applicable (for example, federal agencies other than CDC, consumer-based organizations, professional organizations, etc.); their ability to carry out evaluation, performance monitoring, financial reporting, subcontracting, budget management and administration; and their expertise and experience related to the surveillance of conditions among persons with congenital bleeding disorders. For those capacities that involve collaboration with other organizations (including the USHTCN regional core centers, HTCs and other key partners), existing capacity may be documented within letters of support.

Key capacity considerations to address in the application:

- Applicants must describe their experience related to the surveillance of conditions among persons with congenital bleeding disorders.
- Applicants must specify which HTCs are anticipated to participate in the project.
- Applicants must describe the roles and expertise of their key project staff, USHTCN regional core center staff, HTC staff and other key partners if applicable (for example, other federal agencies, consumer-based organizations, professional organizations, etc.), and their ability to collaboratively implement the FOA.
- Applicants must provide a staffing plan, describing in detail their own resources and staffing levels for this project, including an organizational chart and resumes/CVs.
- Applicants must describe, generally, the resources and staffing levels of the participating HTCs.
- If proposed collaboration with non-USHTCN or non-HTC partners (for example, federal agencies other than CDC, consumer-based organizations, professional organizations, etc.) is key to the success of this project, applicants must include each non-USHTCN or non-HTC partner's organizational chart and resumes/CVs of the partner's key project staff.
- Applicants must provide regional data collection projections for the first year of the project for Strategy 2, Activity 3 (Data collection and transfer, longitudinal patient level health indicator data), accounting for both expected initial enrollments and subsequent episodes of participation by patients enrolled previously. These projections should be based on the expectation that any HTC funded under this cooperative agreement will also participate in Activities 2 and 4 of Strategy 2, as well as Activities 1 and 2 of Strategy 3 (Specimen collection and transfer). Projections should be commensurate with available resources and the cost of carrying out the project at each HTC. CDC is interested in maximizing national surveillance for inhibitor development, characterizing its risk factors and monitoring the outcomes of patients at risk of inhibitor development. To that end, applicants may propose reductions to the set of elements collected for Strategy 2, Activity 3 under DD11-1103/DD14-1409 (see *CDC-RFA-DD15-1507 Supporting Information*) that would reduce the

amount of data collected on each participant, freeing resources for the enrollment of additional participants at risk for inhibitor development. Proposed reductions to the set of elements should preserve elements describing inhibitor-related risk factors (patient characteristics, treatment products, treatment regimen) and outcomes (bleeds, joint disease, ability to control bleeding episodes with routine doses and frequency of factor). Applicants must specify the elements they propose to remove from the set by item number and text of item and provide the rationale for removal; this information may be provided in the budget narrative under contractual costs. Applicants proposing a reduction to the set of elements must provide data collection projections based on both the complete set of elements and the proposed reduced set. Applicants are welcome to submit multiple scenarios. If the applicant wishes to provide data collection projections based on a reduced set of elements but is unable to provide such projections at the time of application, it must provide a plan for developing such projections and a timeline for accomplishing this before the beginning of the project period. Applicants that do not propose reductions to the set of elements should justify why no change is needed. Final decisions on whether and how to alter the set of elements will be made jointly by CDC, the awardee and the USHTCN.

- Applicants must demonstrate that they have adequate technical resources to meet the project's goals, including informational technology (IT) infrastructure. Applicants must describe how data will be collected and submitted to CDC. If the applicant chooses to provide a method of submitting data from the HTCs to CDC electronically other than DBD Gateway, it must describe the current status of the application and the estimated amount of time before the application can be used for this project.

d. Work Plan

A work plan aids in monitoring progress towards expected project outcomes. Applicants must provide a high-level work plan that covers the duration of the project, with more detail for the first year of the project period. The first year details should include program strategies, activities, performance measures, person(s) responsible, timeframe and activity completion date. The high-level work plan should include a description of intended strategies, activities, outputs, and outcomes for the entire five-year project period.

A work plan template using Outcome 5 as an example is shown below; such a table should be completed for each project period outcome.

Outcome 5: **HTCs provide data for refinement of project processes and content**		**Outcome Measure(s):** 1. Written findings from evaluation(s) of data accuracy, including # and representativeness of HTCs participating in data quality assessment 2. Written findings from evaluation(s) of data collection process, including # and representativeness of HTCs participating in evaluation of project processes		
Strategies/Activities	**Process Measure**	**Person(s) Responsible**	**Time-frame**	**Activity Completion Date**
Strategy 4- Data Evaluation *Activity 1- Develop and implement process for collection of accurate data*	Written plan for periodic evaluation and documentation of the accuracy of data collected and any indicated refinements			

Strategy 4- Data Evaluation *Activity 2- Evaluate feasibility of data collection at HTCs*	Written plan for periodic evaluation of the process and ease of data collection at HTCs			

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and awardees, site visits, and awardee reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking awardee progress in achieving the desired outcomes.
- Ensuring the adequacy of awardee systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities:

- Ensuring that work plans are feasible based on the budget and consistent with the
- intent of the award.
- Ensuring that awardees are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with awardees on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Other activities deemed necessary to monitor the award, if applicable.

These activities may include monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk grantees.

f. CDC Program Support to Awardees (THIS SECTION APPLIES ONLY TO COOPERATIVE AGREEMENTS)

In a cooperative agreement, CDC and awardees share responsibility for successfully implementing the award and meeting identified outcomes. CDC will:

1. Collaborate with awardee(s) and the USHTCN to balance priorities, and provide technical assistance, in finalization of data collection instruments;
2. Provide technical support for collection of data including data collection instruments, data cleaning and a secure interface for data submission;
3. Work with awardee(s) to assess training needs;
4. Obtain Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) Information Collection Clearance if necessary;
5. Serve as host and steward of data aggregated from HTCs;
6. Prepare surveillance reports and other public health practice reports of data aggregated from HTCs;
7. Provide technical assistance to awardee(s) and USHTCN for analysis of their data as requested;
8. Participate in project site visits and scheduled conference calls as appropriate;
9. Work with awardee(s) to disseminate findings;

10. Coordinate information sharing between awardees (if applicable);
11. Provide guidance for ethical conduct of non-research data collection and patient authorization;
12. Provide guidance on appropriate collection, processing and shipping of blood specimens;
13. Perform, or arrange for, laboratory tests called for by the project;
14. Report test results to the contributing HTC; and
15. Serve as host and steward of specimen repository for future use.

B. Award Information

1. Funding Instrument Type: Cooperative Agreement

CDC's substantial involvement in this program appears in the CDC Program Support to Awardees Section.

2. Award Mechanism: U27

Surveillance of Complications of Hemophilia Cooperative Agreements

3. Fiscal Year: 2015

Estimated Total Funding: $4,300,000

4. Approximate Total Fiscal Year Funding: $4,300,000

5. Approximate Project Period Funding: $21,500,000

6. Total Project Period Length: 5 year(s)

7. Expected Number of Awards: 1

8. Approximate Average Award: $4,300,000 Per Budget Period

9. Award Ceiling: $4,300,000 Per Budget Period

10. Award Floor: $100,000 Per Budget Period

11. Estimated Award Date: 08/31/2015

Throughout the project period, CDC will continue the award based on the availability of funds, the evidence of satisfactory progress by the awardee (as documented in required reports), and the determination that continued funding is in the best interest of the federal government. The total number of years for which federal support has been approved (project period) will be shown in the "Notice of Award." This information does not constitute a commitment by the federal government to fund the entire period. The total project period comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

12. Budget Period Length: 12 month(s)

13. Direct Assistance

Direct Assistance (DA) is not available through this FOA.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category: Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

2. Additional Information on Eligibility

Applicants must provide documentation that HTCs have agreed to collaborate with the awardee and CDC to carry out the strategies and activities relevant to the HTCs that are proposed for this project. This documentation may be in the form of letters of support, letters of agreement, memoranda of understanding, memoranda of agreement, or contracts from or with collaborating HTCs (hereafter referred to collectively as "letters of support"). Documentation from the regional core center on behalf of the participating HTCs within its region may be provided in place of individual documentation from each HTC. If letters of support are not provided, the applicant will be considered non-responsive.

The award ceiling for this FOA is $4,300,000. CDC will consider any application requesting an award higher than this amount as non- responsive and it will receive no further review. If a pre-application is required, then specify here and include it in the special eligibility requirements section. (http:// www.hhs.gov/ asfr/ ogapa/ aboutog/ hhsgps107.pdf)

3. Justification for Less than Maximum Competition

N/A

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement: No

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this FOA exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D.1. Required Registrations

Additional materials that may be helpful to applicants: http://www.cdc.gov/od/pgo/funding/docs/FinancialReferenceGuide.pdf.

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

a. Data Universal Numbering System: All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements.

The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or Internet athttp:// fedgov.dnb.com/webform/displayHomePage.do. The DUNS number will be provided at no charge.If funds are awarded to an applicant organization that includes sub-awardees, those sub-awardees must provide their DUNS numbers before accepting any funds.

b. System for Award Management (SAM): The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as an awardee. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process usually requires not more than five business

days, and registration must be renewed annually. Additional information about registration procedures may be found at www.SAM.gov.

c. Grants.gov: The first step in submitting an application online is registering your organization through www.grants.gov, the official HHS E-grant website. Registration information is located at the "Get Registered" option atwww.grants.gov.

All applicant organizations must register with www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants must start the registration process as early as possible.

2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC PGO staff at 770-488-2700 or e-mail PGO PGOTIM@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the FOA, it will not be processed. PGO personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by PGO.

a. Letter of Intent Deadline (must be emailed or postmarked by)

Due Date for Letter of Intent: **05/01/2015**

b. Application Deadline

Due Date for Applications: **05/20/2015**, 11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which grants.gov operations resume.

Date for Informational Conference Call: 04/13/2015

April 13, 2015 3pm-4pm Eastern Time; (855) 644-0229, Conference ID: 2963605

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at http://www.cdc.gov/grants/interestedinapplying/applicationprocess.html.

- Complete the applicable assurances and certifications on an annual basis, name the file "Assurances and Certifications" and upload it as a PDF file at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://wwwn.cdc. gov/grantassurances/(S(mj444mxct51lnrv1hljjjmaa))/ Homepage.aspx

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications submitted to CDC by the applicant within one year of the submission date.

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

Applicants are requested, but not required, to submit an LOI.
The LOI should include the following information:
• Descriptive title of proposed project
• Name, address, telephone number, and email address of the Principal Investigator or Project Director, or both
• Name, address, telephone number, and e-mail address of the primary contact for writing and submitting this application
• Number and title of this FOA

LOI must be sent via U.S. express mail, delivery service, fax, or email to:
Brandi Cooke Dupervil
CDC/NCBDDD/DBD
1825 Century Blvd., Room 2132
Atlanta, GA 30345
Telephone number: 404-498-6879
Fax: 404-498-6799
Email: bcooke@cdc.gov

An LOI is not required, is not binding, and does not enter into the review of a subsequent application. The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.

8. Table of Contents

(No page limit and not included in Project Narrative limit): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package.

Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF file under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

(Maximum 1 page)

A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative

(Maximum of 20 pages, single spaced, Calibri 12 point, 1-inch margins, number all pages. Content beyond 20 pages will not be considered. The 20 page limit includes the work plan. For a multi-component FOA, maximum page limit is 25.)

The Project Narrative must include all of the bolded headings shown in this section. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire project period as identified in the CDC Project Description section. Applicants must submit a Project Narrative with the application forms. Applicants must name this file "Project Narrative" and upload it at www.grants.gov.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the project period. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (e.g., increase, decrease, maintain). (See the logic model in the Approach section of the CDC Project Description.)

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the project period outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance Measurement Plan, how these strategies will be evaluated over the course of the project period. (See CDC Project Description: Strategies and Activities section.)

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC.

Applicants must file letters of support, as appropriate, name the file "Letters of Support", and upload it as a PDF file at www.grants.gov.

Documentation that any non-USHTCN centers fulfill the criteria for participation may be provided in "Letters of Support." Refer back to the CDC Project Description section– Approach: Collaborations of this FOA for required collaborations.

2. Target Populations

Applicants must describe the specific target population(s) in their jurisdiction and explain how such a target will achieve the goals of the award and/or alleviate health disparities. Refer back to the CDC Project Description section – Approach: Target Population.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an overall evaluation and performance measurement plan that is consistent with the CDC Evaluation and Performance Measurement Strategy section of the CDC Project Description of this FOA. Data collected must be used for ongoing monitoring of the award to evaluate its effectiveness, and for continuous program improvement.

The plan must:

- Affirm the ability to collect the performance measures and respond to the evaluation questions specified in the CDC strategy. (For guidance regarding the Paperwork Reduction Act, please visit http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html)
- Describe how key program partners will participate in the evaluation and performance measurement planning processes.
- Describe how evaluation findings will be used for continuous program quality improvement.

Where the applicant chooses to, or is expected to, take on specific evaluation studies:

- Describe the type of evaluation(s) (i.e., process, outcome, or both) to be conducted.
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information relevant to the evaluation (e.g., measures, data sources)

Pursuant to the second bullet above, be sure to include as "key program partners" the applicant's key project staff, USHTCN regional core center staff, HTC staff and other key partners (for example, federal agencies other than CDC, consumer-based organizations, professional organizations, etc.), as applicable.

Awardees will be required to submit a more detailed evaluation and performance measurement plan within the first 6 months of the project, as outlined in the reporting section of the FOA.

d. Organizational Capacity of Applicants to Implement the Approach

Applicant must address the organizational capacity requirements as described in the CDC Project Description.

Applicants must submit CVs/Resumes of key project staff; name this file "CVs/Resumes" and upload it at www.grants.gov. Applicants must submit an organizational chart or charts; name this file "Organizational Charts" and upload it at www.grants.gov.

11. Work Plan

(Included in the Project Narrative's 20 page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the awardee plans to carry out achieving the project period outcomes, strategies and activities, evaluation and performance measurement.

Applicants must name this file "Work Plan" and upload it as a PDF file at www.grants.gov.

12. Budget Narrative

Applicants must submit an itemized budget narrative, which may be scored as part of the Organizational Capacity of Awardees to Execute the Approach. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

Indirect costs will not be reimbursed under grants to foreign organizations, international organizations, and foreign components of grants to domestic organizations (does not affect indirect cost reimbursement to the domestic entity for domestic activities). The CDC will not reimburse indirect costs unless the recipient has an indirect cost rate covering the applicable activities and period.

For guidance on completing a detailed budget, see Budget Preparation Guidelines at:http://www.cdc.gov/grants/interestedinapplying/applicationresources.html .

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this FOA to meet national standards or seek health department accreditation through the Public Health Accreditation Board (see: http://www.phaboard.org). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the FOA. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Applicants must name this file "Budget Narrative" and upload it as a PDF file at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Grantees under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

If the applicant is proposing reductions to the data collection instrument developed under DD11-1103/DD14-1409 in order to reduce the amount of data collected on each participant and free resources for the enrollment of additional participants at risk for inhibitor development, it may specify and justify the items proposed for removal within the budget narrative under contractual costs.

13. Tobacco and Nutrition Policies

Awardees are encouraged to implement tobacco and nutrition policies.

Unless otherwise explicitly permitted under the terms of a specific CDC award, no funds associated with this FOA may be used to implement the optional policies, and no applicants will be evaluated or scored on whether they choose to implement these optional policies.

CDC supports implementing evidence-based programs and policies to reduce tobacco use and secondhand smoke exposure, and to promote healthy nutrition. CDC encourages all awardees to implement the following optional recommended evidence-based tobacco and nutrition policies within their own organizations. The tobacco policies build upon the current federal commitment to reduce exposure to secondhand smoke, specifically The Pro-Children Act, 20 U.S.C. 7181-7184, that prohibits smoking in certain facilities that receive federal funds in which education, library, day care, health care,or early childhood development services are provided to children.

Tobacco Policies:

1. Tobacco-free indoors: Use of any tobacco products (including smokeless tobacco) or electronic cigarettes is not allowed in any indoor facilities under the control of the awardee.
2. Tobacco-free indoors and in adjacent outdoor areas: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the awardee.
3. Tobacco-free campus: Use of any tobacco products or electronic cigarettes is not allowed in any indoor facilities or anywhere on grounds or in outdoor space under the control of the awardee.

Nutrition Policies:

1. Healthy food-service guidelines must, at a minimum, align with HHS and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations. These guidelines apply to cafeterias, snack bars, and vending machines in any facility under the control of the awardee and in accordance with contractual obligations for these services (see: http://www.gsa.gov/ graphics/pbs/Guidelines_for__Federal__Concessions_and_Vending__Operations.pdf).
2. Resources that provide guidance for healthy eating and tobacco-free workplaces are:

http://www.cdc.gov/ nccdphp/dnpao/hwi/ toolkits/ tobacco/index.htm

http://www. thecommunityguide.org/ tobacco/index.html

http:// www.cdc.gov /obesity /strategies /food-serv-guide.html

14. Health Insurance Marketplaces

A healthier country is one in which Americans are able to access the care they need to prevent the onset of disease and manage disease when it is present. The Affordable Care Act, the health care law of 2010, creates new Health Insurance Marketplaces, also known as Exchanges, to offer millions of Americans affordable health insurance coverage. In addition, the law helps make prevention affordable and accessible for Americans by requiring health plans to cover certain recommended preventive services without cost sharing. Outreach efforts will help families and communities understand these new options and provide eligible individuals the assistance they need to secure and retain coverage as smoothly as possible. For more information on the Marketplaces and the health care law, visit: www.HealthCare.gov.

15. Intergovernmental Review

Executive Order 12372 does not apply to this program.

16. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

17. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Awardees may not use funds for research.
- Awardees may not use funds for clinical care.
- Awardees may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, awardees may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs is not allowed.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
    - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
    - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See http:// www.cdc.gov /grants /additional requirements /index.htm l#ar12 for detailed guidance on this prohibition and http://www. cdc.gov/ grants /documents/Anti- Lobbying_Restrictions_for_CDC_Grantees_July_2012.pdf

- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

18. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically at www.grants.gov. The application package can be downloaded at www.grants.gov. Applicants can complete the application package off-line and submit the application by uploading it at www.grants.gov. All application attachments must be submitted using a PDF file format. Directions for creating PDF files can be found at www.grants.gov. File formats other than PDF may not be readable by PGO Technical Information Management Section (TIMS) staff.

Applications must be submitted electronically by using the forms and instructions posted for this funding opportunity at www.grants.gov.

If Internet access is not available or if the forms cannot be accessed online, applicants may contact the PGO TIMS staff at 770- 488-2700 or by e-mail at pgotim@cdc.gov, Monday through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are available to PGO TIMS staff for processing from www.grants.gov on the deadline date.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the FOA. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Applicant User Guide, Version 1.1, page 102.

http:// www.grants.gov /documents /19/18243 /Grantsgov ApplicantUserGuide .pdf /ce754626 -c2aa-44bc- b701 -30a75bf428c8

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@www.grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@www.grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail or call CDC GMO/GMS, before the deadline, and request permission to submit a paper application. Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be postmarked at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered. If a paper application is authorized, PGO will advise the applicant of specific instructions for submitting the application (e.g., original and two hard copies of the application by U.S. mail or express delivery service).

E.1. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases.

a. Phase I Review

All applications will be reviewed initially for completeness by CDC PGO staff and will be reviewed jointly for eligibility by the CDC NCBDDD and PGO. Incomplete applications and applications that do not meet the eligibility criteria will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility or published submission requirements.

b. Phase II Review

A review panel will evaluate complete, eligible applications in accordance with the criteria below.

i. Approach
ii. Evaluation and Performance Measurement
iii. Applicant's Organizational Capacity to Implement the Approach

Approach	**Maximum Points: 35**

Evaluation Criteria:

Background

• Does the applicant provide relevant background information that includes the context of the problem? (2 points)

Purpose

• Does the applicant's 2-3 sentence purpose describe specifically how their application will address the problem as described in the CDC Background Section? (2 points)

Outcomes

• Does the applicant clearly identify the outcomes they expect to achieve by the end of the project period? For each outcome, do they indicate the intended direction of change (e.g. increase, decrease, maintain) (4 points)

Strategies and Activities

• Does the applicant describe strategies and activities that align with the CDC logic model, that are achievable, and that will allow for achievement of the outcomes of the project? (16 points, distributed as

indicated below)

o Does the applicant describe strategies and activities consistent with the logic model that are appropriate, achievable and will establish collaborations with HTCs? (4 points)

o Does the applicant describe strategies and activities consistent with the logic model that are appropriate, achievable and will enable collecting and transferring data, including the proposed method of data collection and submission? (4 points)

o Does the applicant describe strategies and activities consistent with the logic model that are appropriate, achievable and will enable collecting and transferring specimens? (4 points)

o Does the applicant propose strategies and activities consistent with the logic model that are appropriate and achievable for information dissemination to a) participating HTCs and b) other stakeholders and the public? (4 points)

Collaboration

• Does the applicant provide letters of support, letters of agreement, memoranda of understanding, memoranda of agreement, or contracts from or with the USHTCN HTCs or regional core centers they propose to work with? If proposing to collaborate with non-USHTCN centers, do they provide documentation that the non-USHTCN centers meet all 3 criteria for participation (meets MASAC HTC standards for HTCs; will not utilize funds that would otherwise be directed towards USHTCN centers; has the support of the regional core center)? If the applicant proposes to collaborate with a subset of the regions of the USHTCN rather than the entire USHTCN, does the applicant describe how they will collaborate with other awardees under this cooperative agreement? (4 points)

Target Population

o Does the applicant describe the geographic catchment area of the collaborating HTCs? (1 point)

o Does the applicant describe the demographic make-up (number and diagnoses, gender, race, ethnicity, age: 0-10 years; 11-19 years; 20 years and older) of the target population within their area of geographic catchment, as well as the percentage of all USHTCN patients represented? (2 points)

Work plan

• Does the applicant present a work plan that is aligned with the strategies/activities, outcomes, and performance measures in the approach? Is the work plan consistent with the content and format proposed by CDC? Are the timeframes proposed for the activities feasible? (4 points)

Evaluation and Performance Management	**Maximum Points: 25**

Evaluation Criteria:

• Does the applicant show or affirm the ability to collect data on the process and outcome performance measures specified by CDC in the project description as well as those presented by the applicant in their approach? (4 points)

• From the applicant's description, are the monitoring and evaluation procedures clear? Is it clear how evaluation and performance measurement will be incorporated into planning, implementation, and reporting of project activities? (11 points)

• Does the applicant describe how performance measurement and evaluation findings will be reported to the relevant audiences, and used to demonstrate the outcomes of the FOA and for continuous program quality improvement? (10 points)

Applicants Organizational Capacity to Implement the Approach	**Maximum Points: 40**

Evaluation Criteria:

• Does the applicant specify which HTCs are expected to participate in the project? (2 points)

• Does the applicant demonstrate experience that is relevant to implementation of the proposed activities and achievement of the project outcomes? (3 points)

• Does the applicant describe the roles and expertise of its own staff; the USHTCN regional core center staff; HTC staff; and the staff of any other key partners (if applicable)? Is it clear how the collaborators will collectively implement the project activities? Are the resources and staffing levels of the participating HTCs described? (5 points)

• Does the applicant provide a staffing plan for its own organization? Is this staffing plan sufficient to implement the activities and achieve the project outcomes? Are staff roles clearly defined? Is the staffing plan consistent with the work plan? (4 points)

• Is the applicant's project management structure sufficient to implement the activities and achieve the project outcomes? (4 points)

• Does the applicant demonstrate the administrative capacity to implement the activities and achieve the project outcomes? (4 points)

• Does the applicant provide its own organizational chart and resumes/CVs of its staff as well as (if applicable) those for other non-USHTCN or non-HTC key partners? (2 points)

• Does the applicant demonstrate the technical capacity to implement the activities and achieve the project outcomes, including (if applicable) the current status of any proposed data collection and submission application and when it can be used for this project? (4 points)

• Does the applicant demonstrate the experience and capacity to implement the evaluation plan? (4 points)

• Does the applicant provide regional data collection projections for the first year of the project for Strategy 2, Activity 3 (longitudinal patient-level health indicator data)? (8 points, distributed as indicated below)

o Does the applicant provide regional data collection projections based on the current set of data elements (see *CDC-RFA-DD15-1507 Supporting Information*)? (2 points)

o Does the applicant either:

a) Provide regional data collection projections based on a reduced set or sets of the elements? (2 points)

• Does the applicant specify which elements are to be removed and explain why? (2 points)

• Does the applicant demonstrate that removal of these elements will free up resources to allow enrollment of additional participants at risk for inhibitor development? (2 points)

OR

b) Provide a feasible plan and timeline for providing data collection projections based on a reduced set of elements prior to the beginning of the project period? (6 points)

OR

c) Justify that project resources are sufficient to maximize national inhibitor surveillance without reduction of the current set of elements? (6 points)

• Is the budget prepared according to the CDC Budget Preparation Guidelines? Is the budget aligned with the proposed work plan? Is the proposed use of funds an efficient and effective way to implement the strategies and activities and attain the project period outcomes? If collaborating with non-USHTCN centers, does the budget demonstrate that this collaboration does not reduce the funds that would otherwise be directed to USHTCN centers for use on project activities? (not scored)

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

c. Phase III Review

The following factors also may affect the funding decision: Geographic diversity; the number of patients with diagnoses of hemophilia A or B, von Willebrand disease or other clotting factor deficiencies in the geographic catchment area (greater than or less than 5,000); inclusion of populations with diagnoses at risk for FVIII and FIX inhibitors (hemophilia A, hemophilia B, type 3 VWD); inclusion of racial and ethnic minorities; ability to implement data collection with minimal disruption of activities ongoing under DD11-1103/DD14-1409.

2. Announcement and Anticipated Award Dates

Applicants will be notified whether they are to be awarded funds via email. Awards are anticipated to be made by August 29, 2015. Applicants can get award information from the Grants Staff Contact listed in Section G. Agency Contacts.

F. Award Administration Information

1. Award Notices

Awardees will receive an electronic copy of the Notice of Award (NOA) from CDC PGO. The NOA shall be the only binding, authorizing document between the awardee and CDC. The NOA will be signed by an authorized GMO and emailed to the Awardee Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this FOA will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.

2. Administrative and National Policy Requirements

Awardees must comply with the administrative and public policy requirements outlined in 45 C.F.R. Part 74 or Part 92 and the HHS Grants Policy Statement, as appropriate.

Brief descriptions of relevant provisions are available at http://www.cdc.gov/grants/additionalrequirements/index.html

The HHS Grants Policy Statement is available at http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf.

*Note that 2 CFR 200 will supersede the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

The following Administrative Requirements (AR) apply to this project:
Generally applicable ARs:
• AR-7: Executive Order 12372
• AR-9: Paperwork Reduction Act http://www.hhs.gov/ocio/policy/collection/infocollectfaq.html
• AR-10: Smoke-Free Workplace
• AR-11: Healthy People 2020
• AR-12: Lobbying Restrictions
• AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities
• AR-14: Accounting System Requirements
• AR-16: Security Clearance Requirement
• AR-21: Small, Minority, And Women-owned Business
• AR-24: Health Insurance Portability and Accountability Act
• AR-25: Release and Sharing of Data
• AR-26: National Historic Preservation Act of 1966

• AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving,” October 1, 2009
• AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
• AR-33: Plain Writing Act of 2010
• AR-34: Patient Protection and Affordable Care Act (e.g., a tobacco-free campus policy and a lactation policy consistent with S4207)
• AR-35: Nutrition Policies

Organization-specific ARs:
• AR-8: Public Health System Reporting (community-based, nongovernment organizations)
• AR-15: Proof of Non-profit Status (nonprofit organizations)
• AR 23: Compliance with 45 C.F.R. Part 87 (faith-based organizations)]

For more information on the C.F.R. visit http://www.ecfr.gov/cgi-bin/ECFR?page=browse.

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that awardees encounter throughout the project period. Also, reporting is a requirement for awardees who want to apply for yearly continuation of funding. Reporting helps CDC and awardees because it:

- Helps target support to awardees;
- Provides CDC with periodic data to monitor awardee progress toward meeting the FOA outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the project period and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the FOA.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the “Agency Contacts” section of the FOA copying the CDC Project Officer.

Report	When?	Required?
Awardee Evaluation and Performance Measurement Plan	6 months into award	Yes
Annual Performance Report (APR)	120 days before end of budget period. Serves as yearly continuation application.	Yes
Data on Performance Measures	CDC program determines. Only if program wants more frequent performance measure reporting than annually in APR.	No
Federal Financial Reporting Forms	90 days after end of calendar quarter in which budget period ends	Yes
Final Performance and Financial Report	90 days after end of project period.	Yes

DBD does require reporting of some performance measures more frequently than annually in the APR. See the CDC Evaluation and Performance Measurement Strategy section of this FOA for the reporting frequencies of specific measures.

Any activities involving information collection (i.e., surveys, questionnaires, etc.) from 10 or more non-Federal individuals or entities are subject to OMB PRA requirements and may require the CDC to coordinate an OMB Information Collection Clearance.

a. Awardee Evaluation and Performance Measurement Plan (required)

With support from CDC, awardees must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; awardees must submit the plan 6 months into the award.

This plan should provide additional detail on the following:

- The frequency that evaluation and performance data are to be collected.
- How data will be reported.
- How evaluation findings will be used for continuous quality and program improvement.
- How evaluation and performance measurement will yield findings to demonstrate the value of the FOA (e.g., improved public health outcomes, effectiveness of FOA, cost-effectiveness or cost benefit).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

b. Annual Performance Report (APR) (required)

The awardee must submit the APR via www.grants.gov 120 days before the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but weblinks are allowed.

This report must include the following:

- **Performance Measures:** Awardees must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Awardees must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Awardees must update work plan each budget period to reflect any changes in project period outcomes, activities, timeline, etc.
- **Successes**
    - Awardees must report progress on completing activities and progress towards achieving the project period outcomes described in the logic model and work plan.
    - Awardees must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
    - Awardees must describe success stories.
- **Challenges**
    - Awardees must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the project period outcomes.
    - Awardees must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Awardees**
    - Awardees must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving project period outcomes.

- **Administrative Reporting** (No page limit)
    - SF-424A Budget Information-Non-Construction Programs.
    - Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
    - Indirect Cost Rate Agreement.

The awardee must submit the Annual Performance Report via www.grants.gov 120 days before the end of the budget period.

c. Performance Measure Reporting (optional)
CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for awardees at the beginning of the award period.

Information on reporting frequency, format and data fields is provided in the CDC Evaluation and Performance Measurement Strategy section of this FOA.

d. Federal Financial Reporting (FFR) (required)
The annual FFR form (SF-425) is required and must be submitted through eRA Commons 90 days after the end of the calendar quarter in which the budget period ends. The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, awardees are required to submit a letter of explanation to PGO and include the date by which the Grants Officer will receive information.

Effective October 1, 2012, CDC grantees are required to submit their upcoming FFR (SF 425) electronically through eRACommons, per Federal Register Notice published Monday, June 11, 2012. http://www/gpo.gov/fdsys/pkg/FR-2012-06-11/pdf/2012-14049.pdf

e. Final Performance and Financial Report (required)
This report is due 90 days after the end of the project period. CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire project period and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Awardees must report final performance data for all process and outcome performance measures.
- Evaluation Results – Awardees must report final evaluation results for the project period for any evaluations conducted.
- Impact/Results/Success Stories – Awardees must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the project period, and can include some success stories.
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

The FFATA and Public Law 109-282, which amends the FFATA, require full disclosure of all entities and organizations that receive federal funds including awards, contracts, loans, other assistance, and payments. This information must be submitted through the single, publicly accessible website, www.USASpending.gov.

Compliance with these mandates is primarily the responsibility of the federal agency. However, two elements of these mandates require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through SAM; and 2) similar information on all sub-awards, subcontracts, or consortiums for greater than $25,000. For the full text of these requirements, see: http://www.gpo.gov /fdsys/browse/ collection.action?collectionCode= BILLS.

G. Agency Contacts

CDC encourages inquiries concerning this FOA.

Program Office Contact

For programmatic technical assistance, contact:

Meredith Oakley, Project Officer
Department of Health and Human Services
Centers for Disease Control and Prevention
1600 Clifton Rd. NE, MS E64
Atlanta, GA 30329
Telephone: (404) 498-6729
Email: moakley@cdc.gov

Grants Staff Contact

For **financial, awards management, or budget assistance,** contact:

Kenya Anderson, Grants Management Specialist
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS E09
Atlanta, GA 30341
Telephone: (770) 488-2487
Email: KAnderson4@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

For all other **submission** questions, contact:
Technical Information Management Section
Department of Health and Human Services
CDC Procurement and Grants Office
2920 Brandywine Road, MS E-14
Atlanta, GA 30341
Telephone: 770-488-2700
E-mail: pgotim@cdc.gov

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348.

H. Other Information

Following is a list of acceptable attachments **applicants** can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- CDC Assurances and Certifications
- Table of Contents for Entire Submission

Applicants are permitted to use all optional attachments as applicable.

The following are questions asked about CDC-RFA-DD15-1507 on the informational call of April 13, 2015 and received via email through Thursday, May 7, and the corresponding answers.

Question 1: In relation to the regional organization of HTCs, is it required that we utilize current regional organization of HTCs in the 8 region pattern?
Answer 1: For purposes of applying for the Cooperative Agreement and for supplying documentation such as, letters of intent (LOI) required by the application for which a regional core center is empowered to act on behalf of its constituent HTCs, the 8 region HRSA regional structure must be used. For example, we would not fund previous regions four south and four north under separate awards because now they are considered to be a single region, the Southeast region, under HRSA. However, if the current HRSA regions are themselves in the practice of subdividing duties, jurisdictions and administrative functions within their own boundaries and prefer their subdivision to be represented separately, for example in budgets presented in the application or on project related committees, then we do not object to them being represented in that fashion.

Question 2: In relation to the 8 regions, say for example, that the current awardee applies as they have done in the past and then they are going to send out their subcontracts. Do there now have to be 8 subcontracts?
Answer 2: No, how an awardee subcontracts with its subcontractors is up to that awardee and its subcontractors.

Question 3: What is the actual implication of the 8 regions?
Answer 3: As we have stated in the FOA, it is possible that the USHTCN regions might decide to collaborate separately from each other- we do not know how they are going to apply- in which case there might be more than one award made under this FOA. However, any single region would not be funded under more than one award. That is the primary place where the HRSA 8 region structure comes in. As in the example in question 1, we would not fund part of a particular region under hypothetical awardee A and another part of that region under hypothetical awardee B.

Question 4: Do you mean fund directly, because there is supposed to be one grantee?
Answer 4: There may be more than one awardee (grantee) under this FOA, depending upon how the 8 regions apply for this FOA. An HTC could apply directly or a regional core center could apply directly. Funds would go to the awardee and then the awardee would subcontract. CDC will not fund different parts of a single region under separate awards, either directly or indirectly.

Question 5: If they [one or more HTCs] were to apply directly they would have to be a HRSA region not a separate region?
Answer 5: The requirement of this FOA is that the awardee collaborate with the HRSA funded HTCs. So, the

applicant itself does not have to be HRSA-funded (directly or indirectly) but it must collaborate with HRSA funded HTCs.

Question 6: Are the current data elements sufficient to monitor persons at highest risk for inhibitors? If not, what new data elements are needed?
Answer 6: CDC does not have in mind additional data elements to add. Assessment of gaps in data collection is a planned activity under DD15-1507. If such assessment indicates that additional or different elements are called for, new elements may be incorporated into the data collection.

Question 7: Will CDC consider a targeted recruitment approach to promote enrollment of persons at highest risk for inhibitors? This would likely result in improved data quality, remove unrealistic registry enrollment expectations, and allow for funding to be shifted to the new inhibitor enrollment priority.

Question 8: Can the Registry be an optional surveillance component as one method of ensuring that there are adequate resources to accomplish CDC's new highest priority area - inhibitors?

Question 9: The RFA states: "These projections should be based on the expectation that any HTC funded under this cooperative agreement will also participate in Activities 2 and 4 of Strategy 2, as well as Activities 1 and 2 of Strategy 3 (Specimen collection and transfer)."
In discussions with the regional coordinators there is the feeling that a subset of HTCs simply do not have the infra-structure to participate in the Registry portion of this project (Strategy 2, Activity 3, Data collection and transfer, longitudinal patient level health indicator data; and Strategy 3, Activities 1 and 2, Specimen collection and transfer). Would CDC allow regions to use a stratified approach to funding where we provided a smaller amount of funding to some HTCs to participate only in Activities 2 and 4 of Strategy 2 but not expect them to do the Registry? This would allow those HTCs who are capable of doing the Registry additional funds and they would be able to provide data on more individuals so the total population that CDC received information on would not decrease.
Not allowing this approach will likely lead to the defunding of these HTCs and loss of their Patient Profile (Strategy 2, Activity 2) and Mortality (Strategy 2, Activity 4) data.
Answer 7, 8, 9: Applicants must respond to the FOA as directed in Part II.D.10.d on page 19. This section refers applicants to Part II.A.2.c. Organizational Capacity of Awardees to Execute Approach on page 11, the 7th bullet under which is relevant to the questions posed above (applicants may also wish to review the scoring criteria under Part II.E.1.b, especially the 10th bullet on page 25). Applicants may, in addition, propose other strategies for CDC's consideration that would maximize national surveillance for inhibitor development commensurate with available resources (and resource constraints) and the cost of carrying out the project at each HTC. Enrollment expectations are based on information provided by applicants. Applicants should provide the rationale and evidence for how the alternative strategy (or strategies) will affect surveillance as compared to what's requested by the FOA, including how the alternative strategy would affect participation of HTCs and projected regional data collection projections for the first year of the project for Strategy 2, Activity 3 (Data collection and transfer, longitudinal patient level health indicator data, including its companion activities 1 and 2 of Strategy 3, Specimen collection and transfer).

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements (ARs): Administrative requirements found in 45 CFR Part 74 and Part 92 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the FOA; awardees must comply with the ARs listed in the FOA. To view brief descriptions of relevant provisions, see http://www.cdc.gov/grants/additional requirements/index.html. Note that 2 CFR 200 will supersede the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the project period.Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Catalog of Federal Domestic Assistance (CFDA): A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

CFDA Number: A unique number assigned to each program and FOA throughout its lifecycle that enables data and funding tracking and transparency.

CDC Assurances and Certifications: Standard government-wide grant application forms.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established project period (i.e., extends the "life" of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the awardees. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the awardee.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. http:// www.cdc.gov /grants

/additionalrequirements /index.html.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/ webform/displayHomePage.do.

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The FOA evaluation plan is used to describe how the awardee and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Healthy People 2020: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list: http://www.whitehouse.gov/omb/ grants_spoc/.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically

given in terms of meeting a previous base-year dollar amount.

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activites; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Plain Writing Act of 2010: Requires federal agencies to communicate with the public in plain language to make information more accessible and understandable by intended users, especially people with limited health literacy skills or limited English proficiency. The Plain Writing Act is available at www.plainlanguage.gov.

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Program Official: Person responsible for developing the FOA; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Project Period Outcome: An outcome that will occur by the end of the FOA's funding period.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation http://www.phaboard.org.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of project period outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.