

Centers for Disease Control and Prevention

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office

Interstitial Cystitis Epidemiologic Study, Translation, and Education
RFA-DP-15-010
Application Due Date: 02/24/2015

Interstitial Cystitis Epidemiologic Study, Translation, and Education

RFA-DP-15-010

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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control and Prevention

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion Extramural Research Program Office (NCCDPHP ERPO)
National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)

Funding Opportunity Announcement (FOA) Title

Interstitial Cystitis Epidemiologic Study, Translation, and Education

Activity Code

U01 Cooperative Agreement

AMENDMENT 2: QUESTIONS FROM POTENTIAL APPLICANTS AND CDC RESPONSES added to Section VIII. Other Information, Cleared on February 13, 2015

Funding Opportunity Announcement Type

New

Funding Opportunity Announcement Number

RFA-DP-15-010

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.068

Category of Funding Activity:

Health

FOA Purpose

AMENDMENT 1: Title change, budget, and description changes.

The purpose of this funding opportunity is to support research that will expand on preliminary findings on interstitial cystitis (IC) in the United States and enhance our understanding of the demographic and clinical characteristics of IC, variation in clinical practices, and the impact of the disease. The FOA also includes development of a national surveillance model for IC. The results from this study will provide a better understanding of the epidemiology of the disease and be used to target interventions for groups at high risk for IC and inform best clinical practices.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-DP-15-010, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**
Letter of Intent Due Date:	**01/23/2015**
Application Due Date:	**02/24/2015**

On-time submission requires that electronic applications be error-free and made available to CDC for processing from eRA Commons on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov/eRA Commons no later than 5:00 PM U.S. Eastern Time. Note: HHS/CDC grant submission procedures do not provide a period of time beyond the application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review: **04/01/2015**

Secondary Review: **05/01/2015**

Estimated Start Date: **09/30/2015**

Expiration Date: **02/25/2015**

Due Dates for E.O. 12372: **Executive Order 12372 does not apply to this program.**

Required Application Instructions

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this FOA. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

Executive Summary

- **Purpose.** This FOA solicits applications for conducting an epidemiological research study to obtain estimates of the prevalence and incidence of Interstitial Cystitis (IC) in adult populations, and to define the demographic and clinical characteristics of IC and its impact on the health from a population perspective. The FOA also includes development and recommending a model for national surveillance of IC. The results from this study will provide a better understanding of the epidemiology of the disease and be used to improve approaches for gathering information on those affected by IC in order to better target interventions for groups at high risk for IC and to inform best clinical practices.
- **Mechanism of Support.** This funding opportunity will use the cooperative agreement funding mechanism (CDC U-01).
- **Funds Available and Anticipated Number of Awards.** Total funding available for this cooperative agreement is expected to be $ 3,000,000 over the five year project period. It is anticipated that one award will be made to a single recipient for approximately $450,000 in FY 2015.
- Awards issued under this FOA are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period.** Total estimated funding (direct and indirect) for the first year (12 month budget period) is approximately $450,000 for one award. The total funding expected to be available for the project period will be $ 3,000,000. The project period will run from September 30, 2015 to September 29, 2020.
- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information of this announcement.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1 are eligible to

apply.

- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** Applications may contain more than one PI, however, the first PI listed will be the "contact PI" for all correspondence.
- **Number of Applications.** Only one application per institution (normally identified by having a unique Data Universal Numbering System [DUNS] number).
- **Application Type.** New
- **Special Date(s).** None
- **Application Materials.** See Section IV.1 for application materials.
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: (770) 488-2783.
- This FOA will be posted at http://www.cdc.gov/chronicdisease/about/foa.htm

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Section 301(a) of the Public Health Service, 42 U.S.C. 241(a), 317(k)(2) of the Public Health Service Act, 42 U.S.C. 247b(k)(2).

1. Background and Purpose

The CDC seeks research to expand knowledge of the incidence (new cases), prevalence (existing cases), and demographic and clinical characteristics of interstitial cystitis (IC) in the general population, the variations in clinical practice, and the impact of the disease. This announcement will build on previous epidemiology studies. The results from this study will provide a better understanding of the epidemiology of the disease and be used to identify groups at high risk for IC and inform best clinical practices.

At least 4 million people in the United States are estimated to have IC based on small clinical patient studies and registries.1 Three to eight million women may be affected2 and one to four million men may be affected.3 Little is know about the burden of IC within geographic or racial groups. However IC has not been extensively measured in the general population; therefore, it is unknown whether these numbers over – or under-estimate the actual IC burden. Estimates of healthcare utilization, diagnosis, and treatment in the US population are also unknown. Therefore, research to find latest IC incidence and prevalence is essential for informing public health practice.

Research Goals and Objectives:

The purpose of the project is to obtain population based estimates of the prevalence and incidence of Interstitial Cystitis (IC) in adult populations, define the demographic and clinical patterns of IC, document its impact on the health of affected persons and adapt and expand current population-based studies to capture an increasingly socio-economically, racially and geographically diverse population.

Historically, two kinds of data have been used to study disease outcomes in IC and the factors associated with these outcomes. These include:

1. Administrative data collected in insured populations in the course of routine healthcare, and co-opted for outcomes studies; and
2. More detailed, direct, and occasionally prospective data of health outcomes and risk factors for these

outcomes in cohorts arising from tertiary care centers. This FOA is focused on prospective data collection and the use of direct methods to contact and follow up individuals with IC in order to determine disease outcomes and associated risk factors for these outcomes.

Applications fully responsive to this FOA will incorporate elements of prospective data collection through direct contact with and follow up of individuals with IC to determine disease outcomes and associated risk factors for these outcomes. Such factors may include:

1. Detailed demographic, socioeconomic, and familial factors;
2. Healthcare resource utilization, including medication use, imaging, pathology, hospitalization and surgery;
3. Patient-reported outcomes, including generic and health-related quality of life; sexual and reproductive function; work productivity and impairment and disability; outcomes related to specific therapies; and psychosocial factors, including depression; and
4. Biological determinants of disease that may include genetic, serologic, and other qualitative and quantitative biologic factors that may be predictors of disease outcomes.

The successful applicant is expected to propose an appropriate population-based study that will collect data necessary to achieve the project research goals and objectives. Registries of all new cases or longitudinal cohort studies would be appropriate tools to capture this information. The study is expected to achieve the following research goals:

1. Conduct a population-based study to describe the incidence, prevalence, demographic and clinical characteristics of persons with IC; assess the impact of the disease; and examine variations in clinical practices in the management of IC
2. Adapt and expand on results of prior population-based studies to capture an increasingly socio-economically, racially and geographically diverse population.
3. Conduct feasibility of scaling up the proposed project in order to recommend an IC national surveillance program to gather national prevalence and incidence data, potentially based on utilizing an existing surveillance system.

Scientific Knowledge to be achieved through this Funding Opportunity

Findings from this epidemiological study are expected to add to the understanding of the:

- Prevalence and incidence of IC at a state or regional level.
- Impact of the disease on the health of affected persons.
- Practice variations in the management of IC.
- Impact of various clinical practices on outcome of the disease.
- Feasibility of scaling to a national level.

Healthy People 2020 and other National Strategic Priorities

This program addresses the “Healthy People 2020” focus areas of: Access to Health Care Services and Health-Related Quality of Life and Well-Being.www.healthypeople.gov

Division/Center priorities: This program addresses following Division/Center priorities:

- Collect, analyze, and disseminate surveillance data to document the burden of IC.
- Monitor, prevent, delay, detect, and control chronic diseases.
- Collaborate with partners from all sectors of society to increase the reach and effectiveness of public health programs.

Public Health Impact

The results from this study will provide a better understanding of the epidemiology and treatment of the disease. It will describe risk factors which may be affected by variations in clinical practice. The finding from this study will contribute to advancing our understanding of the epidemiology of IC in the United States. Further, the study findings will be used to target interventions for groups at high risk for IC, inform best clinical practices, and explore new approaches to improve the availability of data on those affected by IC.

Relevant Work

2. Approach

The approach is expected to include a plan that:

Defines the geographic population to determine the estimated population prevalence of IC in that population. IC patients must be selected from multiple clinical sources to help provide diversity in treatment outcomes and to achieve a sufficient sample size with patient diversity.

- Specifies a process for developing the protocol, methods, and quality assurance to be used for this study that includes an Advisory Committee.
- Identifies the data to be collected and methodology.
- Specifies how the study would be implemented, including plans for acquiring the needed data, the number and type of project staff that would be involved, and potential barriers (e.g., IRB, patient consent, resistance/inability of primary care and other providers to share needed data) to be addressed.

Objectives/Outcomes

Using a population-based approach in population area that is large enough to capture a sufficient sample size (large city, metropolitan area, region, state, etc.), the objectives of this research program are:

I. Establish an advisory or multidisciplinary workgroup

a) Create a multidisciplinary workgroup of 10 or more expert IC partners, collaborators, and stakeholders with clinical, research, academic and public health backgrounds to define research activities and provide expert assistance to implement work plan activities.

b) Workgroup will define specific studies conducted and guide technical approaches that will be used.

II. Design study for prevalence/characteristics

a) Using evidence-based strategies, design a population-based study to assess the incidence and prevalence and demographic characteristics of IC and its impact on general health.

b) Obtain population-based estimates of IC through a population-based study.

c) Describe the demographic and clinical characteristics of persons with IC through population-based studies.

d) Assess the impact of IC on the health of the population.

e) Develop the methodology to assess the demographic and clinical characteristics of IC and its impact on the health of persons with IC.

f) Develop the methodology to assess variation in clinical practice in the management of IC patients.

g) Assess the impact of various clinical practices in the management of IC.

h) Describe stakeholder engagement in the research activities.

III. Develop and recommend a national survey program

a) Using evidence-based strategies, develop and recommend a model national surveillance program for IC to gather national prevalence and incidence data.

IV. Disseminate findings

a) Establish a dissemination plan for study findings targeting professional and general audiences through journal articles, fact sheets, conference presentations and training programs.

b) Describe the role of the multidisciplinary workgroup and other external partners in the dissemination and translation of the research findings.

V. Evaluate project activities and report on findings

a) Develop a realistic and focused evaluation plan. The evaluation plan should include:

I. A logic model,

II. Broad goals, objectives, and activities that are Specific, Measurable, Achievable, Realistic, and Time-limited (SMART),

III. A description of mechanisms for engaging stakeholders in evaluation activities,

IV. Key local-level or activity-specific evaluation questions,

V. Evaluation methods, and

VI. A description of how evaluation results are intended to be used to overcome any barriers identified and improving efficiencies

b) Identify and describe participating clinical/research sites and their roles/responsibilities in the evaluation.

Target Population

The target population is a large US-based, population area (e.g., large city, metropolitan area, region, state, etc.) that is large enough to capture a sufficient adult sample size of people of all ages with IC. Population-based is defined as a general population delineated by geopolitical boundaries, e.g., state or region. Diversity of the selected population with sufficient study sample size will augment the ability to determine racial/ethnic-specific prevalence and incidence rates.

Collaboration/Partnerships

In order to target a population area that is large enough to capture a sufficient adult sample size (large city, metropolitan area, region, state, etc.), collaboration or partnerships will be needed. Partners or collaborators will help provide access to the required data (both existing and follow-up data), and to those individuals with the requisite expertise in lC, data management, and longitudinal data analysis needed to achieve the objectives of this FOA. Collaboration/partnerships with other funding sources may promote achievement of the core objectives of the FOA more quickly. Applicants are expected to recruit and partner with IC experts and hospital systems to effectively develop and implement work plan activities. Recruitment of 10 or more members for an IC advisory group to help guide research activities and inform development of recommended actions for a national surveillance program for IC to gather national prevalence and incidence data perhaps by utilizing a new or an existing surveillance system is expected.

Evaluation/Performance Measurement

The applicant is expected to monitor and document the success of the various stages of follow-up activities, monitor and document the quantity and quality of the follow-up data obtained, and identify and quantify any gaps in these measures. The evaluation plan should include:

I. A logic model,

II. Broad goals, objectives, and activities that are Specific, Measurable, Achievable, Realistic, and Time-limited (SMART),

III. A description of mechanisms for engaging stakeholders in evaluation activities,

IV. Key local-level or activity-specific evaluation questions, and

V. Evaluation methods

Budget MUST include up to 10% of requested funding for evaluation of activities on yearly basis.

Letters of commitment from partners and/or collaborating sites with specifics of technical expertise volunteered are expected.

Translation Plan

A detailed dissemination plan that demonstrates how data and information collected will serve as a resource to key public health practitioners, academic researchers, governmental agencies, private organizations, and the public is expected. Describe how target population will be identified and activities to increase education and awareness about the study findings particularly effective strategies to increase IC awareness in general population, targeted subgroups and health care providers. The plan for dissemination and translation of research findings should be developed with input from the multidisciplinary advisory workgroup and other external partners. The plan should also include a variety of approaches for increasing IC education and awareness (website, webinars, an electronic chart book, conference presentations, reports/ fact sheets, and manuscripts submitted to peer-reviewed journals). It is estimated that at least two scientific or professional products should be developed and disseminated each year. At least one peer reviewed scientific product should be developed and published every year.

OMB/PRA may apply.

References:

1. Interstitial Cystitis Association retrieved at: http://www.ichelp.org/page.aspx?pid=917
2. Sandra H. Berry, Marc N. Elliott, Marika Suttorp, Laura M. Bogart, Michael A. Stoto, Paul Eggers , Leroy Nyberg, J. Quentin Clemens. Prevalence of Symptoms of Bladder Pain Syndrome/Interstitial Cystitis among Adult Females in the United States. *The Journal of Urology*, 186 (2011), pp. 540-544.

J.Q. Clemens, C.L. Link, P.W. Eggers, et al. Prevalence of painful bladder symptoms and effect on quality of life in black, Hispanic and white men and women. *The Journal of Urology*, 177 (2007), p. 1390.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding: $3,000,000

Anticipated Number of Awards: 1

Total estimated funding (direct and indirect) for the first year (12 month budget period) is $450,000 for one award.

Estimated total funding for the entire five year project (09/30/2015 to 09/29/2020) will be $3,000,000 (direct and indirect).

Applications with budget requests greater than the ceiling will be considered non-responsive and will not be reviewed. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

The floor (minimum amount) of this award will be $300,000 (direct and indirect) for the first 12 month budget period.

Awards issued under this FOA are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling: $600,000 Per Budget Period

Award Floor: $300,000 Per Budget Period

Total Project Period Length: 5 year(s)

Throughout the project period, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC's determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category:

State governments
County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses

Small businesses
Others (see text field entitled "Additional Information on Eligibility" for clarification)

The following types of Higher Education Institutions are always encouraged to apply for CDC support as Public or Private Institutions of Higher Education:

Hispanic-serving Institutions
Historically Black Colleges and Universities (HBCUs)
Tribally Controlled Colleges and Universities (TCCUs)
Alaska Native and Native Hawaiian Serving Institutions

Nonprofits Other Than Institutions of Higher Education:

Nonprofits (Other than Institutions of Higher Education)

Governments:

Eligible Agencies of the Federal Government
U.S. Territory or Possession

Other:

Native American tribal organizations (other than Federally recognized tribal governments)
Faith-based or Community-based Organizations
Regional Organizations
Bona Fide Agents: a Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If applying as a bona fide agent of a state or local government, a legal, binding agreement from the state or local government as documentation of the status is required. Attach with "Other Attachment Forms" when submitting via www.grants.gov.
Federally Funded Research and Development Centers (FFRDCs): FFRDCs are operated, managed, and/or administered by a university or consortium of universities, other not-for-profit or nonprofit organization, or an industrial firm, as an autonomous organization or as an identifiable separate operating unit of a parent organization. A FFRDC meets some special long-term research or development need which cannot be met as effectively by an agency's existing in-house or contractor resources. FFRDC's enable agencies to use private sector resources to accomplish tasks that are integral to the mission and operation of the sponsoring agency. For more information on FFRDCs, go to http:// ecfr.gpoaccess.gov /cgi/t/text/ text-idx?c=ecfr& sid=512ff78311f427c00454772dcf21523a&rgn=div8 &view=text&node=48:1.0.1.6.34.0.1.18& idno=48

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

Foreign components of U.S. Organizations are not eligible to apply.

For this announcement, applicants may include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

Eligible applicants must meet the following criteria:

A. Access to a large diverse U.S. patient population (for example one which includes a variety of race/ethnic groups) with IC and/or related conditions.

B. The research team must have experience in conducting and analyzing population based research as well as clinically oriented research on IC and/or related conditions.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

A. Access to a large diverse U.S. patient population (for example one which includes a variety of race/ethnic groups) with IC or related conditions, as evidenced by letters of commitment or other documents granting access from source controlling access to the patient population. Patient population characteristics, including race/ethnicity, should be included in the letter(s)

B. Experience in conducting and analyzing population based research as well as clinically oriented research on IC and/or related conditions must be demonstrated by publications or reports of such research as evidenced in the Research & Related Senior/Key Person Section of the SF424(R&R).

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https://eportal.nspa.nato. int/AC135Public/Docs/US%20Instructions%2 0for%20NSPA%20NCAGE.pdf
- System for Award Management (**SAM**) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/#1.
- Grants.gov
- eRA Commons

All applicant organizations must register with **Grants.gov**. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The "one-time" registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Program Directors/Principal Investigators (PD/PIs) **must** also work with their institutional officials to register with the **eRA Commons** or ensure their existing eRA Commons account is affiliated with the eRA Commons account of the applicant organization. **All registrations must be successfully completed and active before the application due date**. Applicant organizations are strongly encouraged to start the

registration process at least four (4) weeks prior to the application due date.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number.

Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.

If an award is granted, the grantee organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its DUNS number to the grantee organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (http:// www.hhs.gov/ asfr/ ogapa/ aboutog/ hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf), applications received in response to the same funding opportunity announcement generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this FOA that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Section IV. Application and Submission Information

1. Address to Request Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity from www.Grants.gov.

If access to the Internet is not available or if the applicant encounters difficulty accessing the forms on-line, contact the HHS/CDC Procurement and Grants Office Technical Information Management Section (PGO TIMS) staff at (770) 488-2700 or pgotim@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time. CDC Telecommunications for the hearing impaired or disabled is available at: TTY 1-888-232-6348.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/ 424/SF424_RR_Guide_General_VerC.pdf), except where instructed in this Funding Opportunity Announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

The forms package associated with this FOA includes all applicable components, mandatory and optional. Please note that some components marked optional in the application package are required for submission of applications for this FOA. Follow the instructions in the SF 424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.

In conjunction with the SF424 (R&R) components, CDC grants applicants should also complete and submit additional components titled "PHS398." Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components.

3. Letter of Intent

Due Date for Letter of Intent: **01/23/2015**

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CIO staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the applicant Institution

Descriptive title of the proposed research

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel and institutional affiliations

Other participating institutions Number and title of this funding opportunity

The letter of intent should be sent to:

Michael A. Brown, M.P.H.

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Hwy, NE

Mailstop F-80

Atlanta, GA 30341

Telephone: (770) 488-5118

E-mail: mab5@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this FOA in Grants.gov includes all applicable components for this FOA, required and optional.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of 16 components. Not all 16 components of the Research Plan apply to all Funding Opportunity Announcements (FOAs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See Part I, Section 5.5 of the SF 424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Funding Opportunity Announcement Description).

Follow the page limits stated in the SF 424 unless otherwise specified in the FOA. As applicable to and specified in the FOA, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. Introduction to Application (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the FOA.
2. Specific Aims – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. Research Strategy – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and timeline.
4. Inclusion Enrollment Report (Renewal and Revision applications ONLY)
5. Progress Report Publication List (for Continuation ONLY)

Human Subjects Section

6. Protection of Human Subjects
7. Inclusion of Women and Minorities
8. Targeted/Planned Enrollment Table (for New Application ONLY)
9. Inclusion of Children

Other Research Plan Sections

10. Vertebrate Animals
11. Select Agent Research
12. Multiple PD/PI Leadership Plan.
13. Consortium/Contractual Arrangements
14. Letters of Support
15. Resource Sharing Plan(s)
16. Appendix

Component 4 (Inclusion Enrollment Report) applies only to Renewal and Revision applications for clinical research. Clinical research is that which is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies). Follow the page limits in the SF 424 **unless otherwise specified in the FOA.**

All instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf) must be followed along with any additional instructions provided in the FOA.

Research Plan:

The applicant's research plan should address activities that will be conducted over the entire 5 year project period and should include at least the following items:

1. A staffing plan that defines the roles, responsibilities and qualifications of team and expected contributions of key/collaborative partners.
2. Provide evidence of demonstrated partnerships and proposed or existing collaborations to address the goals, objectives, and intent of the FOA.
3. Describe the approach for convening a multidisciplinary workgroup of experts to develop and implement a prototype for a national surveillance system to collect national estimates of the disease.
4. Describe the methodologic approach for designing and implementing a population-based study to assess the prevalence and incidence of IC, impact of disease on affected persons, and variations in clinical practice at the state or regional level.
5. Describe the analytic process for IC identification and inclusion and exclusion criteria for numerators (IC cases) and denominators of the populations at risk. Include a rationale for selection of identification or tracking criteria.
6. Describe access to existing and new data sources and patient populations with IC. Include any letters of support defining access to the data source and/or population.
7. Describe the coordination and communication approach for working with CDC.
8. Describe the approach to be used to compile and analyze data and information and disseminate research findings.
9. Provide detailed timeline including realistic and measurable milestones for proposed project activities and include a budget plan that is linked to activities and milestones.
10. Describe plans for producing reports: interim progress reports and a final report, as well as technical reports, professional presentations, and publications that will be produced collaboratively with CDC.
11. Document the institution's leadership in identifying and supporting research that could lead to understanding the causes, pathology, and complications of IC. This includes effective and well-defined working relationships with any organization and/or outside entities expected to participate in the proposed research that will ensure implementation of the proposed activities, goals, and objectives.
12. Describe the infrastructure and work environment to be used to access existing data sources or to create new data sources to accomplish the research goals and objectives in this funding opportunity announcement.
13. Describe the existing or new data sources that will be used in the proposed research activities. Include any descriptions or reports from existing data that describe the incidence, prevalence, or other descriptors of persons with IC disease for the state or region under study.
14. Describe the project team's expertise, including:

    a. Leadership in coordinating a network of IC researchers in studies of IC epidemiology and surveillance;

    b. Subject matter expertise in designing epidemiologic studies, case definitions, disease registries, and surveillance systems relating to IC; and

    c. Track record of coordinating efforts which have led to publication of studies in major peer reviewed journals.

15. Describe the partnership's or collaborator's expertise, including:

a. Role in supporting research activities proposed by the applicant

b. Partner or collaborator's subject matter expertise in designing epidemiologic studies, case definitions, disease registries, and surveillance systems relating to IC, and

c. Track record of supporting or coordinating similar research efforts which have led to publication of studies in scientific journals.

16. Describe plan to participate in monthly program monitoring, technical assistance (TA) calls, and providing information as requested by CDC.
17. Describe plans to evaluate funded activities and report on findings, including plans to:

a. Track process, outcome, and the impact of supported activities, focusing on outcomes and stated goals;

b. Report process and outcome data on activities and evaluation findings using written report(s), and peer-reviewed journals.

c. Provide evaluation plan on monitoring outcomes of proposed activities

17. Identify and describe the proposed study population. Include demographic and other characteristics of the population and describe how this population will enable the calculation of population-based rates. Also provide the case definition or other defined approach to identifying IC.

18. Budget MUST include up to 10% of requested funding for evaluation of activities on yearly basis.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

7. Page Limitations

All page limitations described in this individual FOA must be followed. For this specific FOA, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 35 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide (Part I, Section 2) (http://grants.nih.gov/ grants/funding/424/ SF424_RR_Guide_General_VerC.pdf).

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit in advance of the deadline to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications via Grants.gov (http://www.grants.gov), the online portal to find and apply for grants across all Federal agencies. The eRA Commons systems retrieve the application from Grants.gov and check the application against CDC business rules. If no errors are found, the application will

be assembled in the eRA Commons for viewing by the applicant before moving on for further CDC processing.

If errors are found, the applicant will be notified in the eRA Commons. They must make required changes to the local copy of their application and submit again through Grants.gov.

Applicants are responsible for viewing their application in the eRA Commons to ensure accurate and successful submission.

Once you can see your application in the Commons, be sure to review it carefully as this is what the reviewer will see. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http:// grants.nih. gov/grants /guide/url_redirect .htm? id=11123).

Information on the submission process is provided in the SF424 (R&R) Application Guide.

Note: HHS/CDC grant submission procedures do not provide a period of time beyond the grant application due date to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).

The application package is not complete until it has passed the Grants.gov/eRA Commons validation process. This process and email notifications of receipt, validation or rejection may take two (2) business days.

Applicants are strongly encouraged to allocate additional time prior to the submission deadline to submit their applications and to correct errors identified in the validation process. Applicants are encouraged also to check the status of their application submission to determine if the application packages are complete and error-free. Applicants who encounter system errors when submitting their applications must attempt to resolve them by contacting the Grants.gov Contact Center (1-800-518-4726; support@grants.gov). If the system errors cannot be resolved, applicants must contact CDC PGO TIMS at 770-488-2700; www.pgotim@cdc.gov for guidance at least 3 calendar days before the deadline date.

After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. This validation process may take as long as two (2) business days. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor has confirmed receipt of the application.

Unsuccessful Submissions:
If an application submission was unsuccessful, ***the applicant*** must:

1. Track his/her submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "***rejected***," do #2a or #2b.

2. Check his/her emails from both Grants.gov and eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grant Management Specialist listed in the FOA (pgotim@cdc.gov) explaining why the submission failed.

b. If there is time before the deadline, he/she should correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **02/24/2015**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (http:// www. whitehouse.gov/ omb/ grants_spoc).

11. Funding Restrictions

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.

For more information on expanded authority and pre-award costs, go to: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf.

Applicants are advised that any activities involving standard information collection (i.e, surveys, questionnaires, data requests, etc.) from 10 or more non-federal individuals/entities are subject to Paperwork Reduction Act (PRA) requirements and may require the CDC to coordinate an OMB/PRA approval request.

12. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144).

Important reminders: All PD/PIs must include their eRA Commons ID in the Credential fieldof the Senior/Key Person Profile Component of the SF 424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC. The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the Central Contractor Registration (CCR). Additional information may be found in the SF424 (R&R) Application Guide. Applicants are reminded to enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number. Do not enter the FWA before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of this Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http

://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm or http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants Office (PGO) and responsiveness by PGO and the Center, Institute or Office of the CDC. Applications that are incompleteand/or nonresponsive will not be reviewed.

Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_redirect.htm? id=11144).

Important reminders:
All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications: http:// grants.nih. gov/grants/ Electronic Receipt /avoiding_errors.htm or http:// grants. nih.gov/grants/ Electronic Receipt/submit _app.htm

Upon receipt, applications will be evaluated for completeness by the CDC Procurement and Grants Office (PGO) and responsiveness by PGO and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (http:// www.cdc.gov/ about/ organization/ mission.htm), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact
Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- What is the potential or actual impact of the research on public health in the US?
- Will the work be influential in that it will lead others to investigate the problem, open new areas of research, or change the scientific approach or public health practice, and how will this improve and be of value to public health?
- If successful, do the research results have the potential to be scalable and reach a large portion of the population at risk?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

- Does the Principal Investigator have previous experience and success in leading complex projects?
- Do the investigators have a successful track record in public health research?
- Is there evidence of past collaborations with the proposed research team?
- Have previous research results provided high quality outputs and contributed to improvements in public health practice and population health?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

- Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to public health and the scientific community?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

- Does the application propose to use evidence-based interventions or strategies in the research plan?
- In the evaluation plan, are outputs identified and are measures/metrics to assess outcomes included?
- In the translation plan, does the application describe how the results from the research will be disseminated and how educational activities will be conducted to increase IC awareness in general population, among high risk groups and among health care providers ?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

- Does the project utilize critical partnerships or collaborations?
- Does the project support key stakeholder involvement throughout the research process?
- Does the applicant describe areas of expertise and involvement with partners and collaborators, including:
  - Role in supporting research activities proposed by the applicant;
  - Partner or collaborator's subject matter expertise in designing epidemiologic studies, case definitions, disease registries, and surveillance systems related to IC; and
  - Track record of supporting or coordinating similar research efforts that have led to publication of studies in scientific journals.

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 , the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For

additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements

(http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar1).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children
When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (http://www.cdc.gov/maso/Policy/Policy_women.pdf and http://www.gpo.gov/fdsys/pkg/FR-1995-09-15/pdf/95-22950.pdf#page=1) and the policy on the Inclusion of Persons Under 21 in Research (http://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section

(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards
Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

Resource Sharing Plans
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: http://www.cdc.gov/od/pgo/funding/grants/additional_req.shtm#ar25. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/od/pgo/funding/budgetguide.htm.

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.

As part of the scientific peer review, all applications:

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.
- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Diversity by race/ethnicity of study population.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this FOA will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (http:// www.hhs.gov/ asfr/ogapa/aboutog/ hhsgps107.pdf).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

All HHS/CDC grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the NoA. For these terms of award, see the HHS Grants Policy Statement Part II: Terms and Conditions of Award (http:// www.hhs.gov/ asfr/ogapa/ aboutog/ hhsgps107.pdf).

Awardees must comply with the administrative requirements (AR) outlined in 45 Code of Federal Regulations (CFR) Part 74 or Part 92, as appropriate, as well as any additional requirements included in the FOA.

Specific requirements that apply to this FOA are the following:

Generally applicable ARs:

AR-1: Human Subjects Requirements

AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

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-17: Peer and Technical Reviews of Final Reports of Health Studies –; ATSDR

AR-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Release and Sharing of Data

AR26: National Historic Preservation Act of 1966

AR-28: Inclusion of Persons Under the Age of 21 in Research

AR-29: Compliance with EO13513, "Federal Leadership on Reducing Text Messaging while Driving", October 1, 2009

AR 31 - Distinguishing Public Health Research and Public Health Non-research

AR 32 –; FY 2012 Enacted General Provisions

ARs applicable to Conference Awards:

AR-27: Conference Disclaimer and use of Logos

Organization Specific ARs:

AR-8: Public Health System Reporting Requirements

AR-15: Proof of Non-profit Status

AR 23: Compliance with 45 C.F.R. Part 87

3. Additional Policy Requirements

The following are additional policy requirements relevant to this FOA:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications

This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at:

http:// www.hhs.gov/ asfr/ogapa/acquisition/ effspendpol_ memo.html)

Federal Funding Accountability and Transparency Act of 2006

Public Law 109-282, the Federal Funding Accountability and Transparency Act of 2006 as amended (FFATA), requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single publicly accessible Web site, www.USASpending.gov (http:// www.usaspending. gov/). For the full text of the requirements, please review the following website: https:// www.fsrs.gov/.

Plain Writing Act

The Plain Writing Act of 2010 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: http:// www.plainlanguage.gov/ plLaw/index.cfm.

Tobacco and Nutrition Policies

The 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* evidence-based tobacco and nutrition policies within their organizations. These policies build on the current federal commitment to reduce exposure to secondhand smoke, which includes The Pro-Children Act, 20 U.S.C. 7181-7184 that prohibits smoking in certain facilities that receive federal funds.

Tobacco:

- Tobacco-free indoors – no use of any tobacco products (including smokeless tobacco) or electronic cigarettes in any indoor facilities under the control of the applicant.
- Tobacco-free indoors and in adjacent outdoor areas – no use of any tobacco products or electronic cigarettes in any indoor facilities, within 50 feet of doorways and air intake ducts, and in courtyards under the control of the applicant.
- Tobacco-free campus – no use of any tobacco products or electronic cigarettes in any indoor facilities and anywhere on grounds or in outdoor space under the control of the applicant.

Nutrition:

- Healthy food service guidelines that at a minimum align with Health and Human Services and General Services Administration Health and Sustainability Guidelines for Federal Concessions and Vending Operations for cafeterias, snack bars, and vending machines in any facility under the control of the

recipient organization and in accordance with contractual obligations for these services. The following are resources for healthy eating and tobacco free workplaces:

- http://www.gsa.gov/graphics/pbs/Guidelines_for_Federal_Concessions_and_Vending_Operations.pdf

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

- http://www.cdc.gov/chronicdisease/resources/guidelines/food-service-guidelines.htm

Applicants should state whether they choose to participate in implementing these two optional policies. However, no applicants will be evaluated or scored on whether they choose to participate in implementing these optional policies.

4. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officer are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and HHS/CDC as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

- Convening an advisory workgroup to define the research priorities
- Designing a population based study to assess the prevalence and demographic characteristics of IC and its impact on general health
- Developing the methodology to assess the demographic and clinical characteristics of IC and its impact on the health of persons with IC
- Developing the methodology to assess variation in clinical practice in the management of IC patients
- Developing the protocol for the project
- Obtaining the appropriate IRB approvals for research involving human subjects for all participating sites
- OMB/PRA requirements may apply. If OMB applies, develop OMB submission package and coordinate with CDC to obtain and maintain appropriate approvals through the life cycle of the award
- Coordinating and conducting data collection, editing, analyses, and reporting
- Preparing a report on the prevalence, demographic characteristics of IC and its impact on general health
- Conduct evaluation of activities and report on findings.

Awardees will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC

policies.

CDC staff has substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below. Additionally, an agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

There are two separate CDC roles – Scientific Collaborator and the Scientific Program Official (SPO). In this cooperative agreement, a CDC Scientist (Scientific Collaborator) within the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) provides scientific and programmatic assistance during the conduct of the project through technical assistance, advice and coordination. It is expected that CDC Project Scientists will have substantial programmatic involvement in this cooperative agreement.

CDC Scientific Collaborators will:

- Serve as technical advisor and scientific consultant for the project activities related to this cooperative agreement overall and to monitor its progress, including conducting site visits to recipient institutions.
- Serve as a technical and scientific consultant to the advisory workgroup in order to help the grantee achieve goals and objectives of this FOA.
- Provide scientific and technical advice as needed to assist the investigator in achieving the study objectives.
- Facilitate distribution and dissemination of results including presentations, publications and other products
- Contribute to analyses, publications and other products as co-authors, within the CDC authorship guidelines.
- Obtain Institutional Review Board approvals as required by CDC when CDC is engaged in research involving human subjects.

Additionally, an HHS/CDC NCCDPHP project officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of this project.

However, the CDC Scientist will not prescribe specific variables, participate in direct data collection, have access to identifiable data, or have contact with study participants.

The NCCDPHP Extramural Research Program Operations and Services (ERPOS) will appoint a Scientific Program Official (SPO), apart from the NCCDPHP Scientific Collaborator. The ERPOS SPO will be responsible for the normal scientific and programmatic stewardship of the award.

The SPO will:

- Be named in the Notice of Grant Award (NGA) as the Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award.
- Monitor performance against approved project objectives.
- Assure assessment of the public health impact of the research conducted under this funding opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research

Areas of Joint Responsibility include:

- Establish guidelines for presentations at scientific meetings and for writing and publishing manuscripts on the findings of the study.
- Participate in monthly teleconferences, with other sites if more than one award is made, to

consider general scientific, logistical and strategic issues.

5. Reporting

Awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590) annually and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients: **1) information on executive compensation when not already reported through the SAM Registration; and 2) similar information on all sub-awards/ subcontracts/ consortiums over $25,000.** It is a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (http:// www.hhs.gov/asfr/ ogapa/aboutog/ hhsgps107.pdf) for additional information on this reporting requirement.

A. Submission of Reports

The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, (use form PHS 2590, posted on the HHS/CDC website, http:// www. cdc.gov/ od/pgo/ funding/ forms.htm and at http:// grants.nih.gov/grants/ funding/2590/ 2590.htm, **is due 90 to 120 days prior to the end of the current budget period.** The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.
2. **Annual Federal Financial Report (FFR)** SF 425 is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends.**
3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the project period.**

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress report should include:

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the PHS 2590 (http:// grants1.nih.gov/ grants/funding/ 2590/2590.htm)

http:// grants.nih.gov/grants/ funding/2590/2590.htm: Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness included in the current budget period proposal.

- Research Aims: list each research aim/project

  a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned

  b) Leadership/Partnership: list project collaborations and describe the role of external partners.

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. *Questions to consider in preparing this section include*:

  - How will the scientific findings be translated into public health practice or inform public health policy?
  - How will the project improve or effect the translation of research findings into public health practice or inform policy?
  - How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
  - How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. *Questions to consider in preparing this section include*:

  - How will this project lead to improvements in public health?
  - How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
  - How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:

  - Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
  - Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget

period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate “Not applicable: No publications or presentations have been made."
- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

2. Annual Federal Financial Reporting

The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include 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 in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information. **All CDC Financial Expenditure data due on/after October 1, 2012 must be submitted using the FFR via the eFSR/FFR system in the eRA Commons.** All Federal Reporting in the Payment Management System is unchanged. All new submissions should be prepared and submitted as FFRs.

CDC's implementation of the FFR retains a financial reporting period that coincides with the budget period of a particular project. However, **the due date for annual FFRs will be 90 days after the end of the calendar quarter in which the budget period ends**. Note that this is a change in due dates of annual FFRs and may provide up to 60 additional days to report, depending upon when the budget period end date falls within a calendar quarter. For example, if the budget period ends 1/30/2012, the annual FFR is due 6/30/2012 (90 days after the end of the calendar quarter of 3/31/2012). Due dates of final reports will remain unchanged. The due date for final FFRs will continue to be 90 days after the project period end date.

Grantees must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, grantees must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC grantees are now available at http:// grants.nih.gov/ grants/forms.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: http://www. cdc.gov/od/pgo/ funding/grants/eramain. shtm.

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

Organizations may verify their current registration status by running the “List of Commons Registered Organizations” query found at: http://era.nih.gov/commons/. Organizations not yet registered can go to https:// commons. era.nih.gov/ commons/ registration/ registration Instructions. jsp for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must

hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: http:// era.nih.gov/ commons /index.cfm.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.
- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the project period. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.
- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.
- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts
Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

CDC Technical Information Management Section (TIMS)
Procurement and Grants Office
Telephone 770-488-2700
Email: PGOTIM@cdc.gov

Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact(s)
Michael A. Brown, M.P.H.
Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Hwy, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770) 488-5118

E-mail: mab5@cdc.gov

Peer Review Contact(s)
Moises (Chris) Langub, PhD

National Center for Chronic Disease and Health Promotion (NCCDPHP)

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE M/S F-80

Atlanta, GA 30341

Telephone: (770) 488-3585
Email: eeo6@cdc.gov
Financial/Grants Management Contact(s)

LaKasa Wyatt, MPA,

Grants Management Specialist,

Centers for Disease Control and Prevention

Procurement and Grants Office

Chronic and Birth Defects Services Branch

2920 Brandywine Rd.

Atlanta, GA 30341

lgw5@cdc.gov

770 488-2728

Section VIII. Other Information

Other CDC funding opportunity announcements can be found at www.grants.gov.

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations
Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.

Awards are made under the authorization of Section 301(a) of the Public Health Service, 42 U.S.C. 241(a), 317(k)(2) of the Public Health Service Act, 42 U.S.C. 247b(k)(2).

Q&As RFA-DP-15-010

Interstitial Cystitis Epidemiologic Study, Translation and Education

Question 1: For budget: NIH salary cap is applied, correct?

Answer: CDC does not set its own salary cap but follows the requirements of the Consolidated and Further Continuing Appropriations Act, 2015. OPM publishes the salary rates, and the NIH issues guide notices to its grantee community on the current salary cap.

http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/15Tables/exec/html/EX.aspx

http://grants.nih.gov/grants/policy/salcap_summary.htm

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-049.html

Question 2: All other formatting including page limits are same as NIH guideline, correct?

Answer: Yes, there are page limits to be aware of when completing your application. Please refer to the SF424(R&R) Application Guide for application instructions, including information on page limits. The link for the Guide is found in the FOA Part I. Overview Information, Required Application Instructions. Helpful sections of the Guide are 5.0 Completing PHS 398 Forms and 5.5 PHS 398 Research Plan Form.

Question 3: Can you tell me how many LOIs that you have received for this funding mechanism?

Answer: We are not allowed to indicate how many LOIs come in for a FOA.

Question 4: that will only award 1 grant?

Answer: In the Executive Summary, Funds Available and Anticipated Number of Awards. The FOA states: "It is anticipated that one award will be made to a single recipient…"

Question 5: I am just wondering how many members are recommended to be on the advisory committee. I assume that 10 (or so) including all investigators (PI and co-I) and advisory committee members would sound okay. Please advise.

Answer: We cannot comment on specific topics or approaches or make eligibility determinations. The design and approach is determined by the applicant. However, the FOA under Approach, Goals and Objectives, indicates "Create a multidisciplinary workgroup of 10 or more expert IC partners, collaborators, and stakeholders with clinical, research, academic and public health backgrounds to define research activities and provide expert assistance to implement work plan activities. Also under Collaboration/Partnerships it states "Recruitment of 10 or more members for an IC advisory group to help guide research activities and inform development of recommended actions for a national surveillance program for IC to gather national prevalence and incidence data perhaps by utilizing a new or an existing surveillance system is expected.