Centers for Disease Control

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

Etiology and Outcome of Inflammatory Bowel Disease
RFA-DP-18-001
Application Due Date: 02/09/2018

Etiology and Outcome of Inflammatory Bowel Disease
RFA-DP-18-001
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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

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)

Notice of Funding Opportunity (NOFO) Title

Etiology and Outcome of Inflammatory Bowel Disease

Activity Code

U01

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DP-18-001

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

93.945

Category of Funding Activity:

Health

NOFO Purpose

To establish a surveillance program to obtain regional or state-level incidence of inflammatory bowel disease (IBD) to extrapolate to the U.S. population, and to determine the impact of demographic and clinical factors on the detection and management of IBD.

Key Dates

Publication Date:	**To receive notification of any changes to RFA-DP-18-001, 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:	**01/10/2018**
Application Due Date:	**02/09/2018**

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:	**04/04/2018**
Secondary Review:	**05/09/2018**
Estimated Start Date:	**09/30/2018**
Expiration Date:	**02/10/2018**
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 NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) 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

Apply Electronically

Executive Summary

- **Purpose.** The purpose of this Notice of Funding Opportunity (NOFO) is to establish a surveillance program to obtain regional or state-level incidence of inflammatory bowel disease (IBD) to extrapolate to the U.S. population, and to determine the impact of demographic and clinical factors on the detection and management of IBD.
- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** The estimated total funding (direct and indirect) for the 5-year period of performance is $3,250,000, to fund one award. Awards issued under this announcement 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 Period of Performance.** The estimated total funding (direct and indirect) for the first budget period, September 30, 2018 to September 29, 2019, is $800,000. The estimated total funding (direct and indirect) for the 5-year period of performance, September 30, 2018 to September 29, 2023, is $3,250,000.
- **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.A. 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 include more than one PI; however, the first PI listed on the application will be the "contact PI" for all correspondence. Any additional PIs are permitted, but would be referred to as Co-PIs.
- **Number of Applications.** Only one application per institution (normally identified by having a unique DUNS number) is allowed.
- **Application Type.** New
- **Special Date(s).** None
- **Application Materials**. See Section IV.1 for application materials. **Please note that the SF424 (R&R) Version E is to be used when downloading the application package** https://grants.nih.gov/grants/how-to-apply-application-guide.html

Hearing Impaired. Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

A link to this Notice of Funding Opportunity (NOFO) on the Grants.gov website may be found at Funding Opportunities Announcements | Chronic Disease Prevention and Health Promotion | CDC

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

Section 301(a) of the Public Health Service Act, 42 U.S.C. 241(a)

1. Background and Purpose

In 2015, approximately three million US adults reported having a diagnosis of inflammatory bowel disease (IBD) [1]. The estimated number has increased greatly from 1.8 million since 1999 [2] which does not include children who may be affected by IBD as well. Crohn's disease and ulcerative colitis are two common types of IBD that are characterized by chronic inflammation of the gastrointestinal tract. Some common symptoms include persistent diarrhea, abdominal pain, bloody stools, weight loss, and fatigue. The exact cause of IBD is not well understood. Genetic predisposition and environmental triggers may play a role. Additionally, diagnosis of IBD is not a straightforward process. A series of blood and stool tests, endoscopies, radiology scans or diagnostic imaging are usually performed to make a diagnosis of Crohn's disease or ulcerative colitis.

IBD is usually a lifetime chronic condition. The severity and progression of the disease largely impacts patients' quality of life through the ongoing symptoms. Furthermore, the disease also causes complications and is related to other comorbidities. For instance, hospitalization rate for Crohn's disease increased significantly when it was listed as a primary or any secondary diagnosis indicated by the ICD-9 diagnosis codes [3].

IBD is known to be more prevalent among the white population. However, incidence and prevalence of IBD is increasing among minorities [4]. Trends of hospitalizations showed that a discharge diagnosis of IBD increased from 1994 to 2006 among non-white populations in the US [5], which may suggest an increase of IBD burden among minorities. In addition, geographic variation was also detected in the prevalence of IBD for both children and adults. In a previous study reported by Kappelman et al [6], the prevalence of IBD was lower in the South and West compared to the rest of the U.S. regions. Geographic variation is usually associated with racial and ethnic disparity of disease detection and management [7, 8]. Understanding the racial difference in the prevalence of IBD helps elucidate the socio-environmental and genetic attributes related to the disease [9], as well as inform health policies aimed at addressing disparities in healthcare access.

Through this announcement, CDC seeks research proposals aimed at expanding knowledge of demographic and clinical characteristics of IBD in the general population. It is important to recruit minority races and ethnicities in the new IBD registry as the information in the current literature is fragmented. Comparing the clinical outcomes involving non-Hispanic white and other races and ethnicities helps understand genetic and socio-environmental factors accounting for the disease. Furthermore, although IBD is an uncommon disease, it imposes a huge financial burden to the US healthcare system resulting from the outcomes of the disease. For instance, the total annual direct costs attributable to Crohn's disease and ulcerative colitis in the US are estimated to be between $11 billion to $28 billion [10]. To address the important public health problem, the research findings will provide a better understanding of etiology of the disease, identify high-risk populations, help improve healthcare access among IBD patients, and inform better clinical practice.

This research will augment previous epidemiologic studies of IBD, by establishing and maintaining a surveillance program to obtain incidence of IBD, describing the natural history and outcomes of the disease, and assessing impact of IBD on minorities and affected people.

This NOFO is to address establishment and use of an IBD registry for conducting population-based studies. The project goals will be achieved by collecting patients' demographic and clinical data, extrapolating incidence to the U.S. population, disseminating study findings through peer-reviewed journals, conference presentations, training programs, and fact sheets.

The purpose of this research is to:

- Establish a new IBD registry to estimate incidence of IBD in the adult and pediatric populations from the IBD registry and extrapolate to the US population.
- Describe natural history and outcomes of IBD.
- Determine racial/ethnic variation in the detection and management of IBD.
- Identify evidence-based strategies to improve disease outcomes.
- Disseminate study findings to medical professionals, researchers, and public health

practitioners.

Healthy People 2020 and other National Strategic Priorities

This announcement supports Healthy People 2020 Objective, AHS-5 Access to Health Service, "Increase the proportion of persons who have a specific source of ongoing care." Since IBD requires an ongoing care, proper healthcare access among affected persons may improve disease outcomes.

Public Health Impact

The study is expected to add knowledge of the natural history of IBD to the existing literature. The results will enhance understanding of the impact of IBD on the overall health of affected persons (pediatric and adult patients) and the impact of various clinical practices and healthcare delivery approaches on the outcome of the diseases. The results will also inform healthcare professionals of evidence-based strategies that can be used to improve disease outcomes in terms of early diagnosis, proper treatment, and timely prevention of complications.

Relevant Work

Since 2005, CDC has collaborated with Crohn's & Colitis Foundation to develop a state registry, the Ocean State Crohn's and Colitis Area Registry (OSCCAR), which is a population-based cohort of newly diagnosed patients in Rhode Island. The study objective for that registry includes establishing and maintaining the prospective cohort of pediatric and adult IBD patients in the state of Rhode Island, determining the incidence rate of IBD and extrapolating to the U.S. population, defining the natural history of IBD, and identifying clinical and genetic factors associated with the disease [11]. The collaboration has resulted in numerous publications [12-15]. Additional information about the collaboration is available on the CDC website [16].

2. Approach

The purpose of this NOFO is to better understand the cause of the disease and how to improve diagnosis and clinical outcomes.

Objectives/Outcomes

1. Establish an IBD registry that will enable estimation of the incidence of IBD in adult and pediatric populations; describe the natural history and outcomes of IBD; determine racial/ethnic variation in the detection and management of IBD; and identify strategies to improve disease outcomes.
2. Create a multidisciplinary expert panel to provide consultation and advice on the surveillance program. The panel should include at least 15 experts with backgrounds in medicine and epidemiology specific to IBD or gastroenterology from both clinic and academic settings.
3. Develop a strategic plan to enroll patients with newly diagnosed IBD in the registry. The plan should include strategies to ensure diverse racial/ethnic groups to be enrolled. The plan should also ensure a sufficient number of newly diagnosed IBD patients to be enrolled into the registry in order to obtain estimation of the incidence of IBD and key

risk factors.

4. The study should be designed to characterize IBD incidence, to determine etiology and risk factors (e.g., biological plausibility of the genetic causes, environmental risk factors, and health-risk behaviors), to evaluate healthcare utilization (e.g., receipt of preventive care), and to identify effective approaches of disease detection and management (e.g., clinical practice) in order to achieve optimal disease outcomes.
5. Develop a dissemination plan of study findings including publishing peer-reviewed journal articles, presenting at scientific conferences, and generating fact sheets and disseminating to the appropriate audience.

Target Population

The target population is children and adults newly diagnosed with IBD.

Collaboration/Partnerships

Applicants are expected to establish or enhance partnerships with experts with IBD background from clinic and academic settings to achieve the objectives in this announcement.

Evaluation/Performance Measurement

Applicants are expected to develop an evaluation plan that includes process evaluation of key milestones of the project, including providing a realistic and focused evaluation plan that demonstrates how the recipient will fulfill the requirements of this announcement.

The evaluation plan should include the following:

- A logic model describing the research plan;
- Specific research objectives and activities to be aligned with this NOFO purpose;
- Key research activity questions of evaluation;
- Mechanisms for engaging stakeholders in evaluation activities; and
- Manuscripts shared with CDC for comments before submitted to peer-reviewed journals.

Translation Plan

Develop a dissemination plan of study findings including publishing peer-reviewed journal articles, presenting at scientific conferences, and generating fact sheets and disseminating to the appropriate audience.

OMB/PRA is expected to apply.

References

1. Dahlhamer, J.M., et al., *Prevalence of Inflammatory Bowel Disease Among Adults Aged >/=18 Years - United States, 2015.* MMWR Morb Mortal Wkly Rep, 2016. 65(42): p. 1166-1169.

2. Nguyen, G.C., C.A. Chong, and R.Y. Chong, *National estimates of the burden of inflammatory bowel disease among racial and ethnic groups in the United States.* J Crohns Colitis, 2014. 8(4): p. 288-95.
3. Malarcher, C.A., et al., *Hospitalizations for Crohn's Disease - United States, 2003-2013.* MMWR Morb Mortal Wkly Rep, 2017. 66(14): p. 377-381.
4. Afzali, A. and R.K. Cross, *Racial and Ethnic Minorities with Inflammatory Bowel Disease in the United States: A Systematic Review of Disease Characteristics and Differences.* Inflamm Bowel Dis, 2016. 22(8): p. 2023-40.
5. Sewell, J.L., H.F. Yee, Jr., and J.M. Inadomi, *Hospitalizations are increasing among minority patients with Crohn's disease and ulcerative colitis.* Inflamm Bowel Dis, 2010. 16(2): p. 204-7.
6. Kappelman, M.D., et al., *Recent trends in the prevalence of Crohn's disease and ulcerative colitis in a commercially insured US population.* Dig Dis Sci, 2013. **58**(2): p. 519-25.
7. Nguyen, G.C., et al., *Racial and geographic variations in colectomy rates among hospitalized ulcerative colitis patients.* Clin Gastroenterol Hepatol, 2006. **4**(12): p. 1507-1513.
8. Semrad, T.J., et al., *Geographic variation of racial/ethnic disparities in colorectal cancer testing among medicare enrollees.* Cancer, 2011. **117**(8): p. 1755-63.
9. Sewell, J.L. and F.S. Velayos, *Systematic review: The role of race and socioeconomic factors on IBD healthcare delivery and effectiveness.* Inflamm Bowel Dis, 2013. **19**(3): p. 627-43.
10. Foundation, C.s.a.C. *The facts about inflammatory bowel diseases*. 2014 [cited 2017 August]; Available from: http://www.crohnscolitisfoundation.org/assets/pdfs/ibdfactbook.pdf.
11. Sands, B.E., et al., *OSCCAR: Ocean State Crohn's and Colitis Area Registry.* Med Health R I, 2009. **92**(3): p. 82-5, 88.
12. Kochar, B., et al., *Achieving Synergy: Linking an Internet-Based Inflammatory Bowel Disease Cohort to a Community-Based Inception Cohort and Multicentered Cohort in Inflammatory Bowel Disease.* J Med Internet Res, 2016. **18**(6): p. e124.
13. Grand, D.J., et al., *Risk factors for radiation exposure in newly diagnosed IBD patients.* Abdom Radiol (NY), 2016. **41**(7): p. 1363-9.
14. Shapiro, J.M., et al., *Corticosteroid Use in a Prospective, Community-Based Cohort of Newly Diagnosed Inflammatory Bowel Disease Patients.* Dig Dis Sci, 2016. **61**(6): p. 1635-40.
15. Shapiro, J.M., et al., *Incidence of Crohn's Disease and Ulcerative Colitis in Rhode Island: Report from the Ocean State Crohn's and Colitis Area Registry.* Inflamm Bowel Dis, 2016. **22**(6): p. 1456-61.
16. CDC. *Inflammatory Bowel Disease Projects & Partners*. 2017 [cited 2017 August 14]; Available from: https://www.cdc.gov/ibd/projects-partners.htm.

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: $3,250,000

The estimated total funding of $3,250,000 includes direct and indirect costs for the entire 5-year Period of Performance.

Anticipated Number of Awards: 1

The estimated total funding (direct and indirect costs) for the first budget period is $800,000.

If an applicant requests a funding amount greater than the $800,000 ceiling for the first year, HHS/CDC will consider the application non-responsive and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

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.

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

Award Ceiling: $800,000 Per Budget Period

Award Floor: $0 Per Budget Period

Total Period of Performance Length: 5 year(s)

Throughout the Period of Performance, 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 (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.

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

Additional Eligibility Category:

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.

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 not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

None

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

N/A

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 recipient 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 recipient 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/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement,(https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity 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 NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Only one application per institution (normally identified by having a unique DUNS number) is allowed.

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 Office of Grants Services (OGS) Technical Information Management Section (TIMS) staff at (770) 488-2700 or ogstims@cdc.gov for further instructions. Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern 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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and

here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf, except where instructed in this Notice of Funding Opportunity 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 NOFO 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 NOFO. 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. These forms can be downloaded from http://grants.nih.gov/grants/funding/424/index.htm.

Duplication of Efforts
Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.
Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

3. Letter of Intent

Due Date for Letter of Intent: **01/10/2018**
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 CDC staff to estimate the potential review workload and plan the review.

By January 10, 2018, prospective applicants are asked to submit a letter of intent that includes the following information:

- Name of the Applicant

- Descriptive title of proposed research
- Name, address, and telephone number of the PD(s)/PI(s)
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

The letter of intent should be sent to:

Sue Shaw, MPH
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE., Mailstop F-80
Atlanta, GA 30341
Telephone: (770) 488-6142
Email: zgx7@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, 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 Notices of Funding Opportunities(NOFOs). Specifically, some of the following 16 components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guidehttps://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).
Follow the page limits stated in the SF 424 (R&R) unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, 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 NOFO.
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 (R&R) Application Guide unless otherwise specified in the NOFO. All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf must be followed along with any additional instructions provided in the NOFO.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

RESEARCH PLAN

The research plan should address activities that will be conducted over the entire 5-year period of performance and should include the following items:

1. Management and Staffing

- Provide a staffing plan that defines the roles, responsibilities, and qualifications of the principal investigator and the team.
- Describe the organizational structure, key personnel, work environment, and infrastructural capacity to accomplish the research objectives in this NOFO.
- Describe the specific roles and responsibilities of staff including, but not limited to, establishing the registry, identification and recruitment of enrollees, identifying analysis priorities, developing analysis plans, analyzing data, and disseminating the results.
- Provide an organizational chart and identify the location of the research program within the organization.

2. Partnership and Collaboration

- Describe plans for developing partnerships, and proposed or existing collaborations to address the objectives and the intent of this NOFO. Include a description of the expected roles and responsibilities of proposed partners and collaborators.
- Provide letters of agreement, memoranda of understanding, or other official documentation from health care providers/practices indicating they will refer newly diagnosed IBD patients for inclusion in the registry and will provide access to identifiable patient information and necessary permission to contact patients. Include these documents in Appendix A of the application.
- Describe a strategic plan to enroll patients with newly diagnosed IBD into the registry. The plan should include strategies to ensure diverse racial/ethnic groups to be enrolled. The plan should also ensure a sufficient number of newly diagnosed IBD patients that can be recruited into the registry to enable estimation of the incidence of IBD and key risk factors.
- Describe plans for establishing and convening a multidisciplinary expert panel to provide consultation and advice on the surveillance program. Provide, at minimum, the panel structure, proposed membership, and the contribution of the panel to the surveillance program. Provide letters of commitment in Appendix A, from proposed panel members demonstrating their agreement to serve on the expert panel.
- Describe approach and plans for the overall coordination and communication with CDC.

3. Research Activities

- Describe and justify the selected geographic area identified for establishment of the IBD registry.
- Describe the approach for accessing health care providers for referral of newly diagnosed IBD patients to enroll in the registry.

- Describe the methodologic approach for designing and implementing the population-based study to identify patient characteristics and environmental and clinical factors associated with IBD, and to assess the incidence of IBD, impact of disease on affected persons, variations in clinical practice, and the innovative disease management to improve IBD outcomes.
- Describe the registry enrollment plan. Provide a power calculation that demonstrates the ability to achieve stable estimates for all enrollees, including minorities and children.
- Provide an estimation of annual registry enrollees, based on the current incidence rate of IBD, number of newly diagnosed patients from the healthcare providers, and the demographic distribution of the selected geographic region or state.

4. Translation Plan

- Describe plans for producing and disseminating results such as technical reports, scientific presentations, and peer-reviewed manuscripts.

5. Evaluation Plan

- Provide a logic model describing research objectives and activities.
- Describe a plan for the development of a full evaluation plan.

6. Project Timeline

- Provide a detailed timeline for key milestones to occur in the first 12 months of the project and provide key milestones for years 2 through 5. Include milestones that demonstrate progress toward having an Institutional Review Board (IRB) approved protocol and, if required, an OMB approved protocol.

7. Budget

- Provide a detailed budget and line-item justification of all operating expenses that are consistent with the planned activities and milestones of the project for the first 12-months.
- Include travel to CDC once per year to discuss the project.

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 NOFO must be followed. For this specific NOFO, 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 25 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 https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf
and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.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 (https://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 TIMS at 770-488-2700; ogstims@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 NOFO (ogstims@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: **02/09/2018**

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 federal regulations, 45 CFR 75, terms and conditions,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.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
For more information on expanded authority and pre-award costs, go to: https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants, cooperative agreements, and contracts. The cost of sharing or archiving public health data may

also be included as part of the total budget requested for first-time or continuation awards. Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please
see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html for revised AR-25.

Funds will be restricted until:

- IRB and OMB/PRA (if needed) approvals are obtained.
- Human subjects education required documentation is provided for key personnel or other significant contributors involved in the design or conduct of research involving human subjects.
- Federalwide Assurance is obtained.

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

Reimbursement of pre-award costs **is not allowed**. 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 or speak with the Grants Management Specialist (GMS).

12. Other Submission Requirements and Information

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 Office of Grants Services (OGS) and responsiveness by OGS 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?

1. Does the work address the IBD burden to public health research and clinical practice?
2. What is the potential or actual impact of the research on public health in the United States?
3. 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?
4. If successful, do the research results have the potential to be scalable and reach other geographic areas of affected persons?

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?

1. Does the staffing and management plan demonstrate the applicant's staff have the necessary knowledge and skills to implement the proposed research plan?
2. Do the investigators have a successful track record in IBD research?
3. Is there evidence of past collaborations with the proposed research team?
4. 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?

1. Is the proposed research innovative and yet offer reasonable potential for concrete applications of interest and value to CDC?
2. Does the project have the potential to increase efficiency or lead to cost savings?

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?

1. Is the proposed research plan adequate to carry out the major project components?
2. Has the applicant provided an adequate plan for establishing and convening an expert panel that includes experts with IBD or gastroenterology background for consultation on the surveillance program?
3. Has the applicant provided sufficient justification of the selected geographic region for the registry?
4. Has the applicant provided an adequate approach to demonstrate that a sufficient number of newly diagnosed IBD patients, with diverse racial/ethnic groups, will be enrolled into the registry?
5. Do the proposed project timeline and key milestones demonstrate the applicant's proposal will be successful?

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?

1. Do the expert panel members have a background knowledge of IBD?
2. Will the roles and responsibilities of the expert panel members demonstrate support the research plan?
3. Do the identified partnerships demonstrate that the applicant's proposal will be successful?
4. Is the perceived organizational support adequate to carry out the research activities?

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/grants/additionalrequirements/index.html).
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 (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research(https://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 (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

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.

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.
For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be

found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

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 Plan(s)
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: https://www.cdc.gov/grants/additionalrequirements/ar-25.html
New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.
Investigators responding to this notice of funding opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.
The DMP should include, at a minimum, a description of the following:
• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified.
Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

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/grants/interestedinapplying/applicationresources.html
The budget can include both direct costs and indirect costs as allowed.
Indirect costs could include the cost of collecting, managing, sharing and preserving data.
Indirect costs on grants awarded to foreign organizations and foreign public entities and

performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.
Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.
If requesting indirect costs in the budget, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.
The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: https://www.cdc.gov/grants/documents/Budget-Preparation-Guidance.docx

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 NOFO. 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.

- Racial and ethnic diversity of the registry.

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to

review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.
In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.
CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this notice of funding opportunity.
In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:
(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.
CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

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 NOFO 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 (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/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 recipient's business official.

Recipients 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

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. CDC programs must indicate which ARs are relevant to the NOFO. All NOFOs from the Center for Global Health must include AR-35. Recipients must then comply with the ARs listed in the NOFO. Do not include any ARs that do not apply to this NOFO. NOFO Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: http://www. access.gpo.gov/ nara/cfr/cfr-table- search.html.

Specific requirements that apply to this NOFO are the following:

Generally applicable Additional Requirements (AR):

AR-1: Human Subjects Requirements

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

AR-7: Executive Order 12372 Review

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: Data Management and Access ;- ;New

AR-26: 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-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

AR-33: United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

AR-34: Language Access for Persons with Limited English Proficiency

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

AR-25: Data Management and Access

CDC requires recipients for projects that involve the collection or generation of data with federal funds to develop, submit and comply with a Data Management Plan (DMP) for each collection or generation of public health data undertaken as part of the award and, to the extent appropriate, provide access to and archiving/long-term preservation of collected or generated data.

Data Management Plan

Consistent with the terms of and activities expected under the funding opportunity announcement (NOFO), recipients must develop and submit a DMP generally during the project planning phase, but in any event, prior to the initiation of generating or collecting public health data. Accordingly, the DMP may be evaluated during the application, study proposal, or project review process or during other times in the period of performance. For NOFOs that involve already defined projects which include data collection or generation at the time of application, applications submitted

without the required DMP may be deemed non-responsive for award. For NOFOs where CDC specifies that submission of the DMP is deferred to a later period, funding restrictions may be imposed pending submission and evaluation of the DMP. For awards where data collection or generation activities may become necessary during the period of performance, DMPs will be required to be submitted and evaluated during the period of performance of the award. These DMPs also will be required to comply with this AR. In all instances described above, the reviewing officials have to approve an acceptable DMP. Costs associated with developing and implementing a DMP, including costs of sharing, archiving and long-term preservation, may be included in the budget submissions for grants and cooperative agreements.

A DMP for each collection and/or generation of public health data funded by this award should include the following information:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for or limitations to providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights). This section should address access to identifiable and de-identified data (see below for additional information about access);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified. This section should address archiving and preservation of identifiable and de-identified data (see below for additional information regarding archiving).

Access to and Archiving of the Data

Recipients whose terms of award do not include submitting data to CDC are expected to plan and prepare for access to and archiving/long-term preservation of collected and/or generated data within the funding period, as set forth below. The final version of a collected and/or generated data set intended for release or sharing should be made available within thirty (30) months after the end of the data collection or generation, except surveillance data which should be made accessible within a year of the end of a collection cycle. In addition, recipients should ensure the quality of data they make accessible and seek to provide the data in a nonproprietary format. Recipients who fail to release public health data in a timely fashion may be subject to procedures normally used to address lack of compliance consistent with applicable authorities, regulations, policies or terms of their award.

For public use de-identified (removal of sensitive identifiable or potentially identifiable information) datasets, an accompanying data dictionary, and other documentation relevant to use of the data set should be deposited in a sustainable repository to provide access to the data. Data that cannot be de-identified can be provided on request under a data-use agreement.

Recipients will be required to inform the appropriate CDC point-of-contact identified in the award via an update to their DMP of the location of the deposited data. The DMP is a living document that should be updated throughout the life cycle of data.

For data underlying scientific publication, recipient should make the data available coincident with publication of the paper, unless the data set is already available via a release or sharing mechanism. At a minimum, release of the data set should consist of a machine-readable version of the data tables shown in the paper.

Requirements set forth in this policy are not intended to conflict with or supersede applicable grants regulations related to agency access to recipient data and records.

To view brief descriptions of relevant CDC requirements visit: http://www.cdc.gov/grants/additionalrequirements/index.html#ui-id-17

Either refer to the current Releasing and Sharing Data Policy AR-25 here (http://www.cdc.gov/grants/additionalrequirements/index.html#ar25) and/or replace it on the PGO website with the Data Access and Management policy and add the link above as an AR.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

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: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, 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 website, 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, Public Law 111-274 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.

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

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic

version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.
The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take the reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Recipients (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.
Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation.
If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.
Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent

with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)
CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.
This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).
The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

4. Cooperative Agreement Terms and Conditions

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 Part 75, 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 recipients 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 Officers 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 recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and HHS/CDC as defined below.

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

Overseeing of all management, administrative, and scientific aspects of the research project that includes but is not limited to:

- Establishing or enhancing collaborations and partnerships with experts and health care providers to support the purpose of the announcement;
- Ensuring a sufficient number of IBD patients are referred to and enrolled into the registry;
- Convening and facilitating the project advisory group;
- Developing protocols for the study;
- Designing a population-based study to assess the incidence and prevalence of IBD and its

impact on the public health burden;
- Developing methodologies to assess the demographic, clinical, and genetic, and environmental characteristics of IBD and its overall health of affected persons;
- Developing methodologies to assess variation in clinical practice and provider characteristics in the management of IBD;
- Overseeing all research activities, including but not limited to data collection, analyses, editing, and reporting;
- Obtaining the IRB approvals for research involving human subjects for all participating sites and other required documents;
- Conducting evaluation of activities and report on findings;
- Updating research findings to CDC and sharing with CDC the manuscripts that are ready to be submitted to peer-reviewed journals;
- Ensuring individuals involved in the design and/or conduct of the research complete human subjects training;
- Attending monthly conference calls with CDC; and
- Complying with the responsibilities for the Extramural Investigators as described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html.

Recipients 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 and regulations.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

- Provide day-to-day programmatic, administrative, and fiscal management in support of the project;
- Provide technical support to the recipients to ensure the success of the cooperative agreement;
- Share information through regular communication and teleconferences;
- Conduct site visits to discuss the recipient's progress, success, technical barriers, and challenges;
- Ensure that work plans are feasible and consistent with the aims of this NOFO;
- Track recipient progress in achieving the NOFO objectives;
- Assist translation of promising practices and research findings; and
- Assisting the PI, as needed, in complying with the Investigator responsibilities described in the Policy on Public Health Research and Nonresearch Data Management and Access https://www.cdc.gov/grants/additionalrequirements/ar-25.html

Additionally, an HHS/CDC agency Program Official 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; and

- 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: None; all responsibilities are divided between recipients and CDC staff as described above.

5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) 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 recipients 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 recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.

All recipients 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 (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

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** is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. 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 https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm 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 Period of Performance.**

B. Content of Reports

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

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.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.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project's data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

N/A

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.
The due date for final FFRs will continue to be 90 days after the Period of Performance end date. Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients 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 recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.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: https://grants.nih.gov/support/index.html
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: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://commons.era.nih.gov/commons/ 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: https://era.nih.gov/docs/Commons_UserGuide.pdf.
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 recipient'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 Period of Performance. 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.

- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

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)
Telephone 770-488-2700
Email: ogstims@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Time

Application Submission Contacts

Scientific/Research Contact
Sue Shaw, MPH
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE, Mailstop F-80
Atlanta, GA 30341
Telephone: (770) 488-6142
Email: zgx7@cdc.gov

Peer Review Contact
Jaya Raman, Ph.D.
Scientific Review Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE, Mailstop F-80
Atlanta, GA 30341
Telephone: (770) 488-6511
Email: kva@cdc.gov

Financial/Grants Management Contact
Lashanda Washington, MPH

Grants Management Specialist
Centers for Disease Control and Prevention
Telephone: (770) 488-2766
Email: LNWashington@cdc.gov ;

Section VIII. Other Information

Other CDC Notices of Funding Opportunities 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.

Section 301(a) of the Public Health Service Act, 42 U.S.C.
241(a)