

**Pregnancy Risk Assessment Monitoring
System (PRAMS)
Pre-Application Conference Call**

**Funding Opportunity Announcement (FOA)
Program Announcement #DP16-001**

October 14, 2015



Welcome and Overview of Agenda

**Brenda Colley Gilbert, PhD, MSPH
Extramural Research Program Operations
and Services (ERPOS)
NCCDPHP**



Agenda

- ❑ Overview of PRAMS
- ❑ PRAMS Methodology
- ❑ Program Announcement (FOA)
- ❑ Question and Answer Session 1
- ❑ Human Subjects Protection
- ❑ Research Review Process
- ❑ Grants Management
- ❑ Question and Answer Session 2
- ❑ Wrap-Up

Overview of PRAMS

Leslie Harrison, M.P.H.
Project Officer/Team Leader
PRAMS
Applied Sciences Branch
Division of Reproductive Health

What is PRAMS?

- Pregnancy Risk Assessment Monitoring System (PRAMS)
- Ongoing population-based surveillance system
- State-specific data
- Self-reported data on maternal behaviors and experiences
- Action oriented

PRAMS Background

- Established in 1987 as part of an Infant Health Initiative
- Congressional funding to CDC to establish state-based programs
- Initially 6 states awarded funding
- Data collection began in 1988

PRAMS Goal

- Reduce maternal and infant morbidity and mortality by impacting
 - maternal and infant health programs
 - health policies
 - maternal behaviors

PRAMS Objectives

- To promote the collection of population-based data of high scientific quality
- To conduct comprehensive analyses
- To translate results into useable information
- To assist states in building capacity

PRAMS Methodology

Brian Morrow, M.A.
Statistician

PRAMS Basics

- Population-based surveillance of new mothers
- Cooperation between Vital Statistics, MCH groups
- Sample drawn from birth certificates
- Self-administered, mailed survey with telephone follow-up
- Use of a standard protocol and methods by all states

Protocol

- Standard protocol
 - Ensures comparable data
- Model protocol
 - Some flexibility for states
 - State-specific parts such as stratification variables and analysis plans are completed by states
- CDC provides technical assistance for protocol development

Sampling

- Target population: women who have had a recent live birth
- Frame: file of birth certificate records
- Stratified samples
 - High-risk groups oversampled
 - Annually, $n = 1400 - 3200$
- CDC advises on sample design

Data Collection in States

- CDC supplies software for tracking respondents, mail and telephone data entry
- Monthly samples from birth certificate files are drawn
- Series of mailings
- Telephone follow-up
- Data cleaning & editing, submission

PRAMS Integrated Data Collection System (PIDS)

- Integrated web-based system
- Centralized database with high level of security
 - minimal personally identifiable information temporarily entered to contact mothers
- Minimal system maintenance at state sites
- Real-time monitoring of data collection operations
- Potential for more frequent survey revisions
- Web survey module under development

Ongoing vs. Point-in-Time Data Collection

- Core Methodology
 - Ongoing surveillance of women with recent live births
 - Monthly sampling of women
- Point-in-time Methodology
 - One-time surveillance of women with recent live births
 - 4–6 month sampling period

Weighting of Data

- CDC processes data to perform consistency checks
- States clean and edit data
- State sends birth tape to CDC
- CDC weights data
 - Nonresponse and noncoverage adjustments

Analysis Data Sets

- Analysis files
 - Responses to questionnaire
 - Covariates from birth certificates
 - Operations data
 - Additional analysis variables
 - Weighting variables
 - Comments

PRAMS Program Announcement 2016 Funding Opportunity Announcement (FOA)

Denise D'Angelo, M.P.H.
Health Scientist/ Program Manager

Leslie Harrison, M.P.H.
Project Officer/Team Leader

PRAMS, Applied Sciences Branch
Division of Reproductive Health

PRAMS 2016 FOA

- Letter of Intent Due **October 26, 2015**
- Applications due **November 20, 2015**
- Anticipated award date is **May 1, 2016**

Overview of Components in FOA

- Component A: Core Surveillance
- Component B: Point-in-Time (PIT) Surveillance
- Component C: Stillbirth Surveillance Pilot
- Component D: Family History of Breast and Ovarian Cancer Survey

Objectives: Component A-Core

- Implement state-specific population-based surveillance
- Collect data using the CDC PRAMS protocol
- Analyze data based on a written analysis plan to inform public health programs and practice
- Disseminate and translate data into action in collaboration with a steering committee
- Have the capability to respond to post-disaster or pandemic surveillance needs that may arise

Objectives: Component B-PIT

- Establish **one time, one birth year** surveillance for entities with a small birth population (<20,000 annually), a lack of electronic birth records, or inadequate resources to maintain ongoing surveillance
- Collect data using the CDC PRAMS Point-in-Time protocol
- Analyze data based on a written analysis plan to inform public health programs and practice
- Disseminate and translate data into action in collaboration with a steering committee

Objectives: Component C-Stillbirth

- Collect data on maternal attitudes, behaviors and experiences **among women who experienced a stillbirth** (i.e. fetal death at 20 weeks gestation or more)
- Pilot test **existing stillbirth survey questions** and methods based on formative research
- Analyze data based on a written analysis plan to inform public health programs and practice related to stillbirth
- Disseminate and translate data into action in collaboration with a steering committee

Objectives: Component D-Cancer History

- Implement a **survey supplement of CDC-developed questions** on family history of breast and ovarian cancer, cancer screening referrals, and provision of genetic counseling
- Collect data using the CDC PRAMS protocol
- Analyze data based on a written analysis plan to inform public health programs and practice related to breast and ovarian cancer
- Disseminate and translate data into action in collaboration with a steering committee

Funding Estimates for Components

- Component A: **Core Surveillance**
- Estimated Awards: 50
- Award ceiling: \$175,000
- Budget period: 12 months
- Project period: 5/01/16 - 4/30/21

Funding Estimates for Components

- Component B: **Point-in-time surveillance**
- Estimated Awards: 4
- Award ceiling: \$125,000
- Budget period: 12 months
- Project period: 5/01/16 - 4/30/19

Funding Estimates for Components

- Component C: **Stillbirth Surveillance Pilot**
- Estimated Awards: 2
- Award ceiling: \$40,000
- Budget period: 12 months
- Project period: 5/01/16 - 4/30/19

Funding Estimates for Components

- Component D: Family History of Breast and Ovarian Cancer Survey
- Estimated Awards: 5
- Award ceiling: \$30,000
- Budget period: 12 months
- Project period: 5/01/16 - 4/30/21

Overview of Eligibility Criteria for Components

Component A, B, C & D - Eligibility

- Official State, local or territorial public health agencies designated as registration areas for vital statistics
- Federally or state recognized American Indian or Alaska Native Tribal (AI/AN) governments (with at least 1,000 births annually)
- Tribal Epidemiology Centers (TEC), as a **Bona Fide Agent** for a tribal government
- Applicants whose jurisdiction includes a TEC are encouraged to work with the TEC on surveillance of AI/AN populations

Component A, B, C & D - Eligibility

- Terms “state” or “site” apply to any local, state, territory, or tribe that meets the eligibility requirements
- 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.**

Component A – Additional Eligibility Information

- Open to all states
- Applicants may apply for Component A or B, not both
- Only applicants applying for Component A may apply for Component C or D

Component B – Additional Eligibility Information

- Applicable to entities with a small birth population (<20,000 annually), a lack of electronic birth records, or inadequate resources to maintain ongoing surveillance
- Applicants may apply for Component A or B, not both

Component C & D – Additional Eligibility Information

- To be funded for Component C or D, applicants must have a responsive application for Component A and receive Component A funding

Special Eligibility Requirements: Documentation of Support

Required Documentation of Support Components A & B

- Written assurance, signed by the head of the state's Vital Statistics unit, that:
 - They will collaborate with organizational units housing PRAMS to support surveillance
 - PRAMS program will have timely access to edited birth certificate information for monthly sampling
 - They will commit a Vital Statistics liaison to develop and maintain the sampling program

Required Documentation of Support Components A & B

- Written assurance, signed by the head of the state's Vital Statistics unit, that:
 - The final birth tape will be available to CDC by December 1 of the year following the year of data collection year
 - Birth tape will include all the elements required by CDC for data weighting
 - Any changes in the vital statistics system will be communicated in writing to the PRAMS program in a timely fashion

Required Documentation of Support Components A & B

- Joint letter of commitment from State Directors of the Maternal and Child Health (MCH), the Data Processing units and/or other organizational units housing PRAMS:
 - They will collaborate to support the PRAMS program
 - Identify which unit will lead implementation and what roles each unit will play
 - PRAMS questionnaire and operational variables are available to CDC without restriction for distribution via a proposal process

Required Documentation of Support Component C

- Written assurance, signed by the head of the state's Vital Statistics unit, that
 - They will collaborate with organizational units housing PRAMS to support the stillbirth sampling
 - PRAMS program will have access to edited fetal death certificate information at least 9-12 months after death for sampling
 - They will commit a Vital Statistics liaison to develop and maintain the sampling program
 - Final fetal death file will be available to CDC by December 1 of the second year following year of data collection

Required Documentation of Support Component C

- Written assurance, signed by the head of the state's Vital Statistics unit, that
 - Any changes in the vital statistics system will be communicated in writing to PRAMS program in a timely fashion
 - They will collaborate with organizational units supporting PRAMS and the CDC to:
 - Identify and define acceptable groupings of select fetal death certificate variables for release to researchers by CDC as part of a standard PRAMS Analytic Research File
 - Develop and approve a data sharing agreement

Required Documentation of Support Component C

- Joint letter of commitment from State Directors of MCH, the Data Processing units and/or other organizational units housing PRAMS that:
 - They will collaborate to support the sampling of stillbirths from the fetal death file
 - PRAMS questionnaire and operational variables are available to CDC without restriction for distribution via a proposal process

Required Documentation of Support Component D

- Written assurance, signed by the head of the state's Vital Statistics unit, that:
 - They will collaborate with organizational units housing PRAMS to support data collection on family history of breast and ovarian cancer
 - PRAMS program will have timely access to edited birth certificate information for monthly sampling
 - They will commit a Vital Statistics liaison to develop and maintain the sampling program

Required Documentation of Support Component D

- Written assurance, signed by the head of the state's Vital Statistics unit, that:
 - The final birth tape will be available to CDC by December 1 of the year following the year of data
 - Any changes in the vital statistics system will be communicated in writing to the PRAMS program in a timely fashion

Required Documentation of Support Component D

- Joint letter of commitment from State Directors of the MCH, the Data Processing units and/or other organizational units housing PRAMS that:
 - They will collaborate to support the PRAMS program
 - PRAMS questionnaire and operational variables are available to CDC without restriction for distribution via a proposal process

Required Documentation of Support Components A, B, C & D

- Applicants who will be working with a TEC should include a letter of support from the TEC that describes the nature of the working relationship
 - Data sharing agreements, steering committee appointments, assistance in locating survey participants, or dissemination of data, etc.
- Applicants with projects that span more than one state or territory must provide all of the above listed supporting materials from each state and territory involved

Overview of Recipient [PD(s)/PI(s)] Responsibility

Recipient Responsibilities, Component A & B

- Adhere to CDC PRAMS surveillance protocol
- Maintain Institutional Review Board (IRB) approvals
 - Certify new staff completed human subjects educational program
- Maintain an adequate management and staffing plan to support all project activities
 - Staff should possess proper skills and education to implement PRAMS surveillance activities

Recipient Responsibilities, Component A & B

- Collaborate with participating organizational units such as MCH, Vital Records, and Data Processing units
- Assure vital records data linked to PRAMS analytic dataset are available for re-release via a proposal process
- Assure PRAMS questionnaire and operational variables are available to CDC for distribution via a research proposal process

Recipient Responsibilities, Component A & B

- Maintain a state-level steering committee
- Implement a written analysis plan
- Document & share data translation examples
- Attend key meetings with CDC
 - Site visits
 - National meetings
 - Other working meetings

Recipient Responsibilities, Component C

- Use CDC PRAMS stillbirth surveillance protocol
- Collaborate with vital records department to assure timely access to fetal death records
- Form a steering committee related to stillbirth surveillance activities
- Implement a written analysis plan specific to stillbirth surveillance activities

Recipient Responsibilities, Component C

- Ensure staff have proper skills & education to implement the PRAMS stillbirth surveillance activities
 - Recommended telephone interviewers receive specialized training to understand grieving process
- Document and share results of pilot research

Recipient Responsibilities, Component D

- Use CDC PRAMS survey supplement protocol
- Ensure staff have proper skills and education to implement supplement without compromising core surveillance activities
- Maintain steering committee including relevant subject matter experts
- Implement a written analysis plan specific to family history of breast and ovarian cancer

Overview of Research Plan

Research Plan

- Applicants must submit a separate application for each Component of funding
- Include in the title of your application the Component for which you are applying:
 - CAT A Core
 - CAT B Point-In-Time Surveillance
 - CAT C Stillbirth
 - CAT D Cancer History
- For each Component, applicant's research plan should address activities to be conducted over the entire project period

Research Plan Content Component A & B

- Background and Need
- Profile of State Birth Registration Process
 - Steps for registering births & schedule for sampling
 - Plan for addressing any restrictions on release of vital records data for surveillance purposes
 - Plan for addressing any restrictions on the upload of minimal personally identifiable information to the CDC certified software system

Research Plan Content

Component A & B

- Plan of Operation
 - How major project components will be implemented within the first year of funding
 - Capacity to implement a survey supplement
- Management and Staffing Plan
 - Minimum of 2 full-time equivalents should be committed to PRAMS operations and coordination (Comp A)
- Analysis and Translation plan
- Collaboration
 - Plans for collaboration including composition and function of steering committee

Research Plan Content

Component C

- Background and Need
 - Scope of stillbirth in the state, rationale for stillbirth surveillance, state legislative support to evaluate and assess stillbirths, etc.
 - Experience conducting surveillance of stillbirths or an active stillbirth registry
- Profile of State Fetal Death Registration Process
 - Steps for registering fetal deaths & schedule for sampling
 - Plan for addressing any restrictions on release of vital records data for surveillance purposes
 - Plan for addressing any restrictions on the upload of minimal personally identifiable information to the CDC certified software system

Research Plan Content

Component C

- Plan of Operation
 - How stillbirth surveillance activities will be implemented considering existing and/or new resources
- Management and Staffing Plan
 - A minimum of .5 full-time equivalents should be committed to stillbirth surveillance project
- Analysis and Translation Plan
- Collaboration
 - Planned Steering Committee composition and adjustments made to accommodate the stillbirth surveillance pilot
 - Membership should include relevant subject matter experts

Research Plan Content Component D

- Background and Need
 - Scope and severity of breast and ovarian cancer
 - Existing programs in recipient agency funded to help those at high risk for developing hereditary cancer
 - Any CDC-funded programs, such as those funded through the cooperative agreement, “Enhancing Cancer Genomic Best Practices through Education, Surveillance, and Policy”:
http://www.cdc.gov/cancer/breast/what_cdc_is_doing/genomics_foa.htm
- Plan of Operation
 - How the cancer surveillance activities will be implemented considering existing and/or new resources

Research Plan Content Component D

- Management and Staffing Plan
- Analysis and Translation plan
- Collaboration
 - Planned Steering Committee structure and adjustments to accommodate PRAMS family history of cancer surveillance project
 - Membership should include appropriate subject matter experts
 - Existing collaborations and activities related to genomics and cancer prevention among women of reproductive age

Research Plan Content Component A, B, C & D

- Timetable
 - Schedule of activities for first 12 months and time line of major milestones for project period
- Budget
 - Detailed budget and line-item justification of expenses consistent with planned activities for the first 12-months
 - Include at least one trip per year to Atlanta, GA
 - New states should budget for travel to orientation meeting in Atlanta in Summer 2016 (*Components A & B*)

Research Strategy

- Research strategy narrative must not exceed **25 pages**
- Appendix attachments are limited to **10 PDF files not to exceed 50 pages**
- If research strategy exceed page limitation, your application may be considered nonresponsive and ineligible for review

The following materials should be included in the Appendix:

Eligibility documentation	Indirect Cost Rate Agreement
Letters of Support	Publications (not publically available)
Organizational Charts	Data Use Examples
Charts/diagrams illustrating the Vital Records Registration Process	

Data Sharing

- Awardees are expected to comply with applicable CDC policies on public access to publications and data collected with federal funds
 - CDC/ATSDR Policy on Releasing and Sharing Data is available at <http://www.cdc.gov/maso/Policy/ReleasingData.pdf>
- Grantees must also agree to share a pre-determined, pre-approved list of variables with CDC for release via a proposal process without additional state approval requirements
- **CDC will provide a PRAMS Data Sharing Agreement at time of budget negotiations**
 - Compliance with this data sharing agreement is required

Non-responsive Applications

- Applications that are incomplete and/or nonresponsive will not be reviewed
- Applications that are **incomplete or non-responsive to the special eligibility** will not enter into the review process
 - Evidence of the Special Eligibility Requirements should be placed in Appendix A
- Applications that **request a funding amount greater than the award ceiling** will be considered non-responsive and will not enter the review process
- If **research strategy exceeds page limitation**, application may be considered nonresponsive and ineligible for review

QUESTIONS??

Maintaining Compliance: Human Subjects Protection

Human Subjects

- This is a research FOA
- Any institution awarded funding under this FOA will be considered engaged in research supported by Health and Human Services (HHS)
- Must comply with the *Code of Federal Regulations, 45 CFR 46, Protection of Humans Subjects*, including, subpart C of the HHS regulations for governing inclusion of prisoners in research
- HHS oversight is by the HHS Office for Human Research Protections (OHRP)

Basic Requirements for Protecting Human Participants

- Compliance with 45 CFR 46, including subpart C
- Maintain an Institutional Assurance of Compliance (Federal-wide Assurance-FWA)
- Obtain Institutional Review Board (IRB) certification
 - Insure adequate informed consent
 - Report changes and adverse events
 - Provide annual review
- Adhere to Human Subjects Education Requirement

Why do you need an assurance (FWA)?

- 45 CFR 46, the Federal Regulation for the protection of human subjects, requires that each institution “engaged in HHS-supported human subjects research” file a “Federal-wide Assurance” of protection for human subjects
- The assurance formalizes the institution’s commitment to protect human subjects

What is an IRB?

“A group of at least five individuals with varying backgrounds to promote complete and adequate review of research studies. An IRB conducts the initial and annual reviews of a research study.”

Source: 45 CFR 46.107

What is the purpose of IRB?

- To protect respondents by minimizing risk
- Safeguard privacy and confidentiality
- Ensure subject selection is equitable
- Seek, document informed consent

IRB Certification: PRAMS Awardees

- Must obtain/maintain a FWA and obtain and provide certification of IRB approval
- Data collection under this new FOA begins with births occurring in 2016 or 2017
- IRB approval required *before* starting data collection for the birth year
- Strongly encouraged to start IRB renewals in advance to prevent lapses in data collection

Maintaining Compliance

Continuing Review

- PRAMS protocol submitted annually for continuing review by the IRB
- States must provide written documentation of local IRB continuation approval to CDC
- Local IRB must include prisoner representative and certify review to OHRP
- Any changes to the protocol require submission of an amendment to the IRB

Maintaining Compliance Training and Adverse Events

- Report any adverse events to CDC and local IRB
- An adverse event is one in which the protection of the respondent may have been violated
 - Incorrect letters mailed (“baby deceased” letters sent to mothers of living infants)
 - Telephone interviewer reveals the purpose and topic of the survey to someone other than the study participant
- Providing certification for any new key personnel to protect against adverse events
 - Includes local and CDC specified educational program in the protection of human subjects

Summary

- All awardees must have a current Federal-wide Assurance (FWA) and need approval from a local federally assured IRB
- IRB approval is required before any data collection can be started
- All CDC sponsored survey instruments must obtain OMB approval and be marked appropriately

Websites for Additional Information

HUMAN SUBJECTS

- Office for Human Research Protections: <http://www.hhs.gov/ohrp>
- Assurance Information:
http://www.hhs.gov/ohrp/assurances/assurances_index.html
- List of Approved FWAs and IRBs:
<http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>

OMB/PRA

- <http://www.hhs.gov/ocio/policy/collection>

Extramural Research Peer Review Process

Brenda Colley Gilbert, Ph.D., MSPH
Director, Extramural Research Program
Operations and Services (ERPOS)

- **Stages of the Scientific Merit Review Process**
 - Initial Scientific Merit Review by a Special Emphasis Panel (SEP)
 - Secondary Review Committee (SRC)
- **Foci of Review Process:**
 - Scientific and Technical merit
 - Program priority and relevance

Initial Scientific Merit Review

- SEP members are recognized experts from a range of key disciplines in Public Health
- Goal: Fair, objective, and transparent
- Task:
 - Evaluate the scientific merit of each application against the intent and provisions in the FOA
 - Provide scientific and programmatic suggestions to the PIs
 - Review Human Subjects Protections, inclusion of minorities, and budget

Scientific Merit Review Evaluation Criteria

- Overall impact
- Significance
- Investigators
- Innovation
- Approach
- Environment
- Protections for human subjects
- Inclusion of women, minorities, and children
- Budget review
- Data Sharing Plan review

Secondary Review Committee (SRC)

- CDC senior staff and experts
- Examine Scientific Merit Review scores and Summary Statements
- Makes recommendations for funding based on:
 - Scientific and technical merit
 - Intent of the FOA
 - Alignment with CDC goals and priorities
 - Published funding preferences

Results of the Review Process

- Every applicant receives a Summary Statement
 - Priority score
 - Reviewer critiques with criterion scores
 - Panel roster
- Applicants selected for funding will receive a Notice of Award from PGO
- Applicants not selected for funding will be notified by letter

Office of Financial Resources (OFR)/Office of Grants Services (OGS)

Grants Management Process

**Atlanta, GA
October 14, 2015**

Presented by:

**Barry B. Gregory,
Grants Management Specialist
Pamela Render,
Grants Management Officer**

Discussion Topics

- **Roles and Responsibilities**
- **OMB Circulars and Administrative Regulations**
- **Useful Websites**
- **Contact Information**
- **Questions**

Roles and Responsibilities

The Office of Grants Services(OGS):

Business conduit for all Program Requirements

- Negotiate, award, administer, and close out all Grants and Cooperative Agreements.**
- Review and approve all financial requests and payments.**
- Ensure compliance with applicable Statutes, Regulations and Policies.**
- Serves as the Official Receipt Office for ALL official communications and contacts with Recipients.**

Roles and Responsibilities

- **Grants Management Officer (GMO) – sole approving official authorized to obligate funds for grant and cooperative agreement actions on behalf of the Government.**
- **Grants Management Specialist (GMS) - primary point of contact for all business management, funding, and regulatory/policy issues regarding a grant; receives and processes all official requests.**

Preparing Budget Justifications

- **Salaries and Wages**
- **Fringe Benefits**
- **Consultant Costs**
- **Equipment**
- **Supplies**
- **Travel**
- **Other Costs**
- **Contractual Costs**
- **Direct Costs**
- **Indirect Costs**

Preparing Budget Justifications

- **Salaries and Wages Category:**
 - **Name of Staff member**
 - **Annual Salary**
 - **Percentage of time budgeted for the program**
 - **Total months of salary budgeted**
 - **Total Salary requested**
 - **Justification/duties and responsibilities for position**

Preparing Budget Justification

Salary

Total \$ 77,5000

Position Title, Name Brief Position Description/Activities/Responsibilities	Annual Salary	FTE / Time	Months involved with project	\$ Amount
Project Director, _____ (All Funded interventions) <i>The Project Director directs the overall operation of the project; responsible for overseeing the implementation of project activities.....etc, etc.</i>	\$60,000	1.0	12 months [*] _*	\$60,000
HIV Counselor, _____ <i>Responsible for counseling and referral-- etc.</i>	\$35,000	.5	12 months	\$17,500

Preparing Budget Justifications

- **Fringe Benefits Category:**
- **Are usually applicable to direct salaries and wages.**
- **Provide information on the rate of fringe benefits used and the basis for their calculation.**
- **If a fringe benefit rate is not used, itemize how the fringe benefit amount is computed.**

Preparing Budget Justifications

- **Fringe Benefits Sample:**

Fringe Benefits

Total \$ _____

25% of Total salaries = Fringe Benefits

If fringe benefits are not computed by using a percentage of salaries, itemize how the amount is determined.

Example: Project Coordinator C Salary \$45,000

Retirement 5% of \$45,000 = \$2,250

FICA 7.65% of \$45,000 = 3,443

Insurance = 2,000

Workers= Compensation = _____

Total:

Preparing Budget Justifications

- **Consultant Costs – Written approval required**
 - **Name of Consultant**
 - **Organization affiliation**
 - **Services to be provided**
 - **Relevance of Service to Project**
 - **Number of Days of Consultation**
 - **Expected Rate of Compensation. If unknown, submit for approval later as a budget revision**
 - **Method of Accountability**

Preparing Budget Justifications

- **Equipment Category:**
- **Is defined as tangible, non-expendable personal property (including exempt property) that has a useful life more than one year and an acquisition costs of \$5,000 or more per unit.**
- **List each item requested, and provide the following information: 1.number needed, 2.unit cost of each item, and 3.total amount requested.**
- **Maintenance or rental fees for equipment should be shown in the *Other* category.**

Preparing Budget Justifications

- **Equipment Costs Sample:**
 - **Provide justification for each item**
 - **Relate to specific program objectives**
 - **Dollar value of equipment is defined by IDC**

Equipment

Total \$ 5,600

Item Description, Quantity Justification for the item and how it will be used in project	Cost per item	Total costs
<i>Computer Workstation, 2 ea. For new staff that are being hired for this project. Currently, we have no workstations for new staff.</i>	\$2,500	\$5,000
<i>Scanner, 1 Required for scanning reports to other sites, used for day to day business for the project</i>	\$600	\$600

Preparing Budget Justifications

- **Supplies Category:**
 - **List each item requested, and provide the following information: 1. specify the type of item, 2. number needed, 3. unit cost of each item, and 4. total amount requested.**
 - **General office supplies – may be shown by an estimated amount per month times the number of months in the budget category.**
 - **Also provide a justification for the use of each item and relate it to specific program objectives.**

Preparing Budget Justifications

E. Supplies

Individually list each item requested. Show the unit cost of each item, number needed, and total amount. Provide justification for each item and relate it to specific program objectives. If appropriate, General Office Supplies may be shown by an estimated amount per month times the number of months in the budget category.

Supplies

Total \$ 6,100

General office supplies (pens, pencils, paper, etc.)	
12 months x \$100/month x 2 staff	\$1,200
Educational Pamphlets (3,000 copies @) \$1 each	\$3,000
Educational Videos (10 copies @ \$150 each)	\$1,500
Word Processing Software (@ \$400Cspecify type)	\$ 400

Justification

General office supplies will be used by staff members to carry out daily activities of the program. The education pamphlets and videos will be purchased from XXX and used to illustrate and promote safe and healthy activities . Word Processing Software will be used to document program activities, process progress reports, etc.

Preparing Budget Justifications

- **Travel Category:**
 - **Dollars requested in the category should be for recipient staff travel only.**
 - **Travel for consultants should be shown in the Consultant category.**
 - **In state – provide a narrative justification for staff member travel - who, where, number of trips planned, approximate dates, mileage costs, estimated airfare, per diem.**
 - **Out of state – same as above; include CDC meetings, conferences, workshops, if required by CDC.**

Preparing Budget Justifications

Travel (in-State and out-of-State)

Total \$ _____

In-State Travel:

1 trip x 2 people x 500 miles r/t x .27/mile = \$ 270

2 days per diem x \$37/day x 2 people = 148

1 nights lodging x \$67/night x 2 people = 134

25 trips x 1 person x 300 miles avg. x .27/mile = 2,025

Total \$ 2,577

Justification

The Project Coordinator and the Outreach Supervisor will travel to (location) to attend AIDS conference. The Project Coordinator will make an estimated 25 trips to local outreach sites to monitor program implementation.

Out-of-State Travel:

1 trip x 1 person x \$500 r/t airfare = \$500

3 days per diem x \$45/day x 1 person = 135

1 night=s lodging x \$88/night x 1 person = 88

Ground transportation 1 person = 50

Total \$773

Justification

The Project Coordinator will travel to CDC, in Atlanta, GA, to attend the CDC Conference.

Preparing Budget Justifications

- **Other Cost Category:**
- **This category contains items not included in the previous budget categories.**
- **Individually list each item requested and provide appropriate justification related to the program objectives.**

Preparing Budget Justifications

- **Other Cost Sample :**

• Item Requested	Number of Months	Estimated Cost per Month	Number of Staff	Amount Requested
• <i>Telephone</i>		\$		\$
• <i>Postage</i>		\$		\$
• <i>Equipment Rental</i>		\$	N/A	\$
• <i>Internet Provider Services</i>		\$	N/A	\$
• Total Other Amount			\$	

Preparing Budget Justifications

- **Contractual Costs:**
- **Cooperative Agreement recipients must obtain written approval from CDC prior to establishing a third-party contract to perform program activities.**
 - **Name of Contractor**
 - **Method of Selection**
 - **Period of Performance**
 - **Scope of Work**
 - **Method of Accountability**
 - **Itemized Budget/Justification and itemization for consultant/contractual costs**

Preparing Budget Justifications

- **Direct Costs:**
- **Show the direct costs by listing the totals of each category, including salaries and wages, fringe benefits, consultants costs, equipment, supplies, travel, other, and contractual costs.**
- **Provide the total direct costs within the budget.**

Preparing Budget Justifications

- **Indirect Costs**
 - **Must have a CURRENT approved indirect cost rate agreement (IDC) or cost allocation plan.**
 - **IDC must be provided with the application.**
 - **Must be consistent with accounting practices.**
 - **Indirect costs cannot be awarded without an approved rate.**
- **Budget Guidelines can be viewed at:**
[Http://www.cdc.gov/grants/interested in applying/applicationresources.html](http://www.cdc.gov/grants/interested_in_applying/applicationresources.html)

Application Submission Contacts:

- **1. Grants.gov. Customer Support:**
- **Contact Center Phone: 800-518-4726**
- **Email: support@grants.gov.**
- **Hours: 24 hours a day, 7 days a week; closed on Federal holidays.**

Application Submission Contacts:

- **1. eRA Commons Help Desk:**
- **Phone: 301-402-7469 or 866-504-9552 (Toll Free).**
- **Email: commons@od.nih.gov**
- **Hours: Monday-Friday, 7am-4:30pm.
(U. S. Eastern Standard Time).**

Useful Websites

OMB Circulars and Administrative Regulations

OMB Circulars

Part 200—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl

Code of Federal Regulations

45CFR92 – Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local, and Tribal Governments.

<http://www.hhs.gov/opa/grants-and-funding/grant-forms-and-references/45-cfr-92.html>

Note: Each recipient and/or contractor is subject to the referenced regulations.

Additional Resources

<http://www.hhs.gov/grantsnet>

HHS

Grants Policy Statement



U.S. Department of Health and Human Services
Office of the Assistant Secretary for Resources and Technology
Office of Grants

January 1, 2007

Contact Information

Barry B. Gregory

Grants Management Specialist (GMS)

Chenega Government Contractor (CGC)

Office of Grants Services (OGS)

Office of Financial Resources (OFR)

Office of the Chief Operating Officer (OCOO)

Centers for Disease Control and Prevention (CDC)

Email: kvi3@cdc.gov | 770-488-3073 office |

Submitting to CDC Funding Opportunities

Presented by TIMS Staff

Grants Technical Information Management Section (TIMS)

Application Submission On Grants.gov For RFA-DP-16-001
October 14, 2015



Office of the Director
Office of Financial Resources (OFR)

Points of Contact

Scientific/ Research Contact

**Sue Shaw, MPH, Scientific Program
Official**

**Extramural Research
Program Office
(770) 488-6142**

zgx7@cdc.gov

Peer Review Contact

**Donald Blackman, Ph.D., c Peer Review
Contact**

Peer Review Contact

**Jayalakshmi Raman, PhD
Extramural Research Program Office
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kva5@cdc.gov

Technical Information/ Management Section

**L.C. Browning/Maryam Pyles
Office of Financial Resources (OFR)**

Office of Grants Services (OGS)

770-488-2700

pgotim@cdc.gov

Financial /Grants Management Contacts:

Barry Gregory,

Grants Management Specialist

**Office of Grants Services Procurement and
Grants Office**

(770) 488-3073

Kvi3@cdc.gov





Registration Process

New Applicant Organizations: Begin registration immediately.

September 20, 2015
Date POSTED to Grants.gov

EXAMPLE

November 20, 2015
Date CLOSED in Grants.gov

FOA is posted for 60 days unless prior approval has been received

DO NOT DELAY REGISTRATION – Approval could take up to 6-8 weeks

Registered Organizations: Update your organization's information with all systems (if needed) and **renew your SAM account**, per the expiration date.



Registration Process

- ✓ Begin as early as possible.
 - ✓ Allocate as many as 6-8 weeks to complete the registration process (**especially** for **newly** established organizations).
 - ✓ **AOR Authorization** (authorized organization representative)
 - ✓ **E-Biz POC approves your AOR status**, which allows submitting of applications on behalf of your organization
- ✓ Assign personnel to oversee that registration is completed.
- ✓ Ensure all organizational information is current and accurate.
- ✓ Maintain all record keeping for the organization.

Registering through Grants.gov

Requirements

Obtain DUNS number & Complete registration in SAM.

Once DUNS number is verified, submit registration to Grants.gov.

An e-mail will be generated to your organization's E-Business Point of Contact.

Once the E-Business Point of Contact has verified as an Authorized Organization Representative (AOR) & assigned the AOR rights, the AOR is authorized to submit grant applications through Grants.gov on behalf of your organization.

Tips for registering:

- Identify your organizations DUN #
- Determine if your organization is registered with the SAM.

DUNS Number, call Dun & Bradstreet at 1-866-705-5711 and follow the automated prompts to obtain this information.

SAM – if not registered

- apply by phone (1-866-606-8220) or register online at <http://www.sam.gov>.

Registering through Grants.gov

continued

Create a
Grants.gov
account

To register a username and password, enter the organization's DUNS OR DUNS+4 Number and then click the "Register" button below.

Step 1: Complete the DUNS OR DUNS+4 Number field

Step 2: Click the Register button.

DUNS or DUNS+4 Number

Register

Tips

- Must create a Grants.gov account to begin the process of applying for federal grants.
 - Grants.gov currently supports associating only one DUNS number per credential.
 - Help with Grants.gov registration - Tutorial, user guide, and Help section are on site.
- Can also click on the Applicant tab for further assistance.

#1: The Data Universal Number System (DUNS)

Requirements

From the website listed above, select: begin D-U-N-S Search/Request Process

- Select your country or territory and follow the instruction to obtain your DUNS 9-digit #
- Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number

Duration of Time

Web form request take 1 to 2 business days

Follow-Up:

The best way to confirm if DUNS & Bradstreet (D&B) has assigned your entity a new

D-U-N-S Number are:

- Going online at : <http://fedgov.dnd.com/webform>
- **Or by calling:**
 - 1-866-705-5711

What is a CAGE Code?

A Commercial and Government Entity (CAGE) Code is a five digit identifier for companies pursuing business with the Federal Government.

The only authorized source for obtaining CAGE codes is the DLA Logistics Information Service.

There is currently no fee, no subscription charge.

No expiration date.

What are CAGE Codes Used for?

Provides a standardized method of identifying a given facility at a specific location.

Prime contractors often require sub-contractors to have one.

How to Get a CAGE Code?

1. Visit: <https://www.sam.gov>
2. Register in SAM
3. CAGE is assigned to your company as part of SAM validation process
4. Once registration is active, log into SAM account
5. View your CAGE code



#3: Grants.gov

The Submitter

Must set up an individual account in Grants.gov using the organization's DUNS number to become an **Authorized Organization Representative (AOR)**.

The E-Biz P.O.C.

Is assigned during SAM registration process (**and should have a back-up E-Biz POC**).

- Is notified by e-mail after the submitter sets up Grants.gov account.
- Log-in to Grants.gov using received password, MPIN (Marketing Personal Identification Number) & DUNS (**will be prompted to create a new password**).
- **Authorizes the AORs**, enabling him/her to submit grant applications on behalf of the organization.

Requirements

- Submitters for the organization (the AOR's) must set up the profile and obtain a Grants.gov username & password
- E-Biz POC receives notification of the AOR's request
- E-Biz POC must log into Grants.gov to review the AOR's approval status

Duration of Time

Same day
(24 hours)

Follow-Up

- Inquire with Chief Financial Officer (CFO) and/or Grants Administrator about status of DUNS number
- Check AOR status until it shows approved.

REGISTER EARLY!

Registration at both [Grants.gov](https://www.grants.gov) and [eRA Commons](https://www.eRA Commons) is required, can take up to 8 weeks and MUST be completed before the submission deadline.

- Verify that your organization is registered with the new [System for Award Management \(SAM\)](https://www.sam.gov).
- Maintain an active entity registration.
 - [Registration must be renewed annually through the SAM.gov web site.](https://www.sam.gov)
- Use the SAM.gov "Manage Entity" function to manage your entity registrations.
- See the Grants Registrations User Guide at <https://www.sam.gov> for additional information.

Contributing Factors to Registration Errors

- ❑ **Failing to read the funding opportunity announcement**
- ❑ **Last minute registration**
- ❑ **Failing to complete all four registration steps**
 - Obtaining DUNS
 - Registering in SAM
 - Registering with Grants.Gov
 - Obtaining Approval to Submit for Organization
- ❑ **Unregistered submitters and submitters unapproved by E-Biz POC for the organization**
- ❑ **Technical problems (computer viruses, incompatible software, internet server problems, etc.)**





[Redacted text]

1

- **Carefully follow the requirements** found in the application guide and FOA.

2

- **Check your application** for errors before submission.

3

- **Correct any errors or warnings** before the submission deadline.

4

- **Verify that your application is viewable in the eRA Commons.** If you cannot view the application in the Commons, NIH can't review it!

5

- **Submit early.** The best way to reduce stress and ensure successful submission is to submit well ahead of the due date.

Applying to CDC Funding Opportunities

- ❑ Perform a search at www.grants.gov and select a funding opportunity announcement (FOA).
- ❑ Read the full announcement document in its entirety.
- ❑ Fully register and/or update registration for your organization with Dun & Bradstreet, CCR & Grants.gov.
- ❑ Download and complete the application package for the selected opportunity.
- ❑ Submit the application through www.grants.gov as early as possible.



Application Submission



- Save & Submit
- Back-up
- E-mail Confirmations

All applications must be submitted *electronically* through

www.Grants.gov

applications)



Commons (electronic research

Submissions are not accepted by:

- X Mail (neither regular or express delivery)
- X E-mail
- X Fax
- X As a printed paper copy
- X As a CD, portable drive or other electronic device

Save & Submit

File Edit View Document Comments Forms Tools Advanced Window Help

Create Combine Secure Sign Forms Multimedia Comment

Please fill out the following form. If you are a form author, choose Distribute Form in the Forms menu to send it to your recipients. Highlight F

Save & Submit Save Print Cancel Check Package for Errors

GRANTS.GOVSM Grant Application Package

Opportunity Title: Partnership for Surveillance Collaborative

Offering Agency: Centers for Disease Control and Prevention

CFDA Number: 99.289

CFDA Description: Centers for Disease Control and Prevention Investigatio

Opportunity Number: CDC-RFA-OE11-1104

Competition ID: OSELS-NR

Opportunity Open Date: 04/26/2011

Opportunity Close Date: 06/10/2011

Agency Contact: CDC
Procurement and Grants Office (PGO)
Technical Information Management Section (TIMS)
E-mail: pgotim@cdc.gov
Phone: 770-488-2700

This electronic grants application is intended to be used to apply for the specific Federal funding opportunity referenced here.

If the Federal funding opportunity listed is not the opportunity for which you want to apply, close this application package by clicking on the "Cancel" button at the top of this screen. You will then need to locate the correct Federal funding opportunity, download its application and then apply.

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

* Application Filing Name: [Redacted]

Mandatory Documents

Application for Federal Assistance (SF-424)

Project Abstract Summary

Disclosure of Lobbying Activities (SF-LLL)

Budget Information for Non-Construction Program

HHS Checklist Form PHS-5161

Project Narrative Attachment Form

Budget Narrative Attachment Form

Mandatory Documents for Submission

Move Form to Complete

Move Form to Delete

Optional Documents

Other Attachments Form

Optional Documents for Submission

Open Form

1. Check for errors and blank required fields.
2. Save, then save to a back-up/portable device.
3. Click "save & submit."
4. Enter Grants.gov account information.
5. A confirmation screen will appear quickly.

[View Burden Statement](#)

APPLICATION FOR FEDERAL ASSISTANCE SF 424 (R&R)

3. DATE RECEIVED BY STATE <input type="text"/>	State Application Identifier <input type="text"/>
4. a. Federal Identifier <input type="text"/>	<input type="text"/>
b. Agency Routing Identifier <input type="text"/>	
c. Previous Grants.gov Tracking ID <input type="text"/>	

1. TYPE OF SUBMISSION

Pre-application Application Changed/Corrected Application

2. DATE SUBMITTED

Applicant Identifier

5. APPLICANT INFORMATION

Organizational DUNS:

Legal Name:

Department: Division:

Street1:

Street2:

City: County / Parish:

State: Province:

Country: USA: UNITED STATES ZIP / Postal Code:

Person to be contacted on matters involving this application

Prefix: First Name: Middle Name:

Last Name: Suffix:

Position/Title:

Street1:



Notification E-Mails

Submitter will receive 3 notification e-mails from **Grants.gov**:



Initially, you will see a confirmation screen on the computer (print this screen for your records).

1. **Submission Receipt E-Mail** (Provides a submission tracking number "GRANT-----.") Confirmation of Receipt
2. Validation Status
3. Successful Download

You receive the "Successful Download" notification email from Grants.Gov after TIMS has downloaded your application

Quick Application Submission Tracking

Start from the Grants.gov homepage...

CONTACT US | MANAGE SUBSCRIPTIONS | REGISTER | LOGIN

SEARCH: Grant Opportunities ▾ Enter Keyword... GO

GRANTS.GOV > Applicants > Track My Application

TRACK MY APPLICATION

Track and check the status of your grant application submissions.

- The system will only return a status for VALID tracking numbers.
- Until the status is available for valid tracking numbers, the following message will be returned by the system: *Tracking number(s) entered currently being processed, please check back later.*
- For invalid tracking numbers entered, the system will return the following message: *The tracking number(s) entered are not valid. Please make sure you entered the correct tracking number(s).*

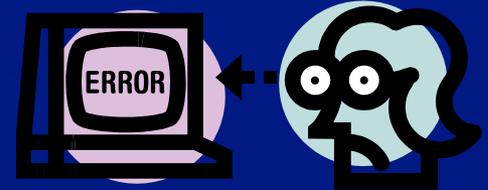
To Track Grants.gov submissions, enter up to five Grants.gov tracking numbers, one per line and click the "Submit Tracking Number(s)" button:

grant #

Submit Tracking Number(s)

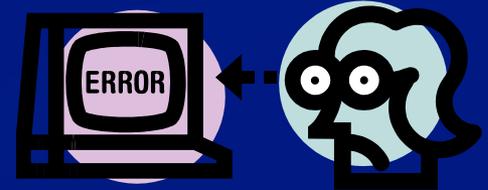
Common *User-Related* Difficulties

1. No account with Grants.gov
2. Unapproved AOR status (even if the AOR & E-Biz are the same)
3. The closing date has passed
4. Registration is incomplete
5. Invalid DUNS number (AOR's DUNS doesn't match organization's and/or DUNS on the application)
6. Expired SAM account status
7. Incompatible/outdated software
8. Special characters found in file names (&, -, *, %, /, #, ', --)



Common *User-Related* Difficulties

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7. Incompatible/outdated software
8. Special characters found in file names (&, -, *, %, /, #, ', --)



Key Dynamics For Successful Application Submission



- ✓ Start as early as possible.
- ✓ Complete the entire registration process in advance of the deadline date.
- ✓ Follow-up after each step to ensure submitted information is correct, up-to-date and moving forward successfully.
- ✓ Always have a "back-up!" 😊

Types of Registration Error Messages

- ❑ **Unregistered applicant**
- ❑ **Unapproved submitter for your organization**
 - Unapproved Authorized Organization Representative status
- ❑ **Incomplete registration**
 - With CCR, Grants.Gov and/or both
- ❑ **Invalid information provided**
- ❑ **Invalid DUNS number**
 - Applicant DUNS doesn't match organization DUNS



Why Are Registration Errors Are Important

- ❑ **Registration errors**
 - Are found after you submit your application, potentially causing you to miss the submission deadline
- ❑ **Indicate a problem was found with the information provided = application does not clear Grants.Gov validation**
- ❑ **Interrupt the validation process**
- ❑ **Must be corrected before your application is validated and made available to TIMS**



When you “Submit...”

- ❑ Your application is submitted to Grants.Gov, not CDC (TIMS)



The Technical Information Management Section (TIMS):

- ❑ CDC's receipt point for your applications.



Thank You!

For more information please contact:

Technical Information Management Section (TIMS)

Office of Grants Services (OGS)

Phone: (770) 488 – 2700

E-mail: pgotim@cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



Office of the Director

Office of Financial Resources (OFR)

QUESTIONS??