NATIONAL LUPUS OUTREACH AND CLINICAL TRIAL EDUCATION PROGRAM (LUPUS PROGRAM)

U.S. Department of Health and Human Services
Office of the Secretary
Office of Minority Health
February 7, 2017
NATIONAL LUPUS OUTREACH AND CLINICAL TRIAL EDUCATION PROGRAM (LUPUS PROGRAM)

FUNDING OPPORTUNITY ANNOUNCEMENT: CPI-MP-17-002
TECHNICAL ASSISTANCE WEBINAR

U.S. Department of Health and Human Services
Office of the Secretary
Office of Minority Health
February 7, 2017
3pm Eastern Time
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Programmatic Questions:
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Office of the Secretary
Office of Minority Health
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Office of Minority Health (OMH)
Mission Statement

The mission of the office is to improve the health of racial and ethnic minority populations through development of policies and programs that will help eliminate health disparities.
OMH expects the National Lupus Outreach and Clinical Trial Education Program (Lupus Program) will accomplish the following two goals (FOA page 3)

**Priority A:** Implement a national health education program on lupus

**Priority B:** Develop, pilot and assess clinical trial education interventions for health care providers and paraprofessionals focusing on improving recruitment and retention rates in clinical trials for minority populations affected by lupus.
National Lupus Outreach and Clinical Trial Education Program

Program Description: (FOA page 3-4)

Priority A  Improve culturally and linguistically appropriate outreach and education efforts among health care providers and paraprofessionals in the targeted community(ies).

Increase awareness and understanding of lupus and management of primary and secondary conditions.

Focus on primary care providers and practitioners to improve lupus diagnosis and treatment in minority populations.
Program Description: (FOA page 4)

Priority B

Requires applicants to identify an effective provider education model(s).

Tailors the model and educational contents to address health care provider knowledge, attitudes, and practices regarding minority participation in clinical trials.
National Lupus Outreach and Clinical Trial Education Program

Program Description: (FOA page 4)

Priority B  Test the model during the project period.

Pilot and assess model clinical trial education interventions for health care providers and paraprofessionals servicing in geographically diverse primary care settings.

Use an experimental design.

Develop an action plan for disseminating the education models to increase minority populations’ participation in lupus clinical trials.
National Lupus Outreach and Clinical Trial Education Program

Project Requirements Section
(FOA pages 8 – 12; page 18)
National Lupus Outreach and Clinical Trial Education Program

Project Requirements (FOA page 8):

The Lupus Program aims to remove the barriers to diagnosis, treatment and disease management for minority populations impacted by lupus.
For purposes of the Lupus Program:

1. Primary Care Providers (PCPs) refers to physicians providing direct patient care who practice principally in general or family practice, general internal medicine, pediatrics, or obstetrics and gynecology; and nurse practitioners, clinical nurse specialists, and physician assistants; and

2. Other health care providers and paraprofessionals including registered nurses, licensed practical nurses, allied health professionals, community health workers and promotores de salud.
National Lupus Outreach and Clinical Trial Education Program

Project Requirements (FOA page 9)

Priority A applications must propose projects with activities designed to:

1. Improve outreach and education efforts by PCPs and other health care providers and paraprofessionals in the target community(ies) to increase awareness and understanding of lupus and management of primary and secondary conditions related to lupus using culturally and linguistically appropriate materials and models; and

2. Engage PCPs in improving lupus diagnosis and treatment in minority and/or disadvantaged populations.
National Lupus Outreach and Clinical Trial Education Program

Project Requirements (FOA page 9)

Priority B applications must propose projects that will:

1. Develop public-private and community partnerships to address minority populations participation in clinical trials;

2. Design and test models for PCPs, other health care providers and paraprofessionals to assess attitudes, beliefs, and behavioral intentions associated with referral of minority populations to clinical trials
Project Requirements (FOA page 10)

Priority B applications must propose projects that will (continued):

3. Develop and test innovative model education programs

4. Implement educational interventions for PCP, other health care providers, and paraprofessional using the selected model during the project period and adapt the intervention(s) for clinical trial education to address lupus using a culturally and linguistically appropriate framework for minority populations;

5. Use experimental or quasi-experimental design in evaluating clinical trial education model(s) for PCPs, other health care providers and paraprofessionals;
National Lupus Outreach and Clinical Trial Education Program

Project Requirements (FOA page 10)

Priority B applications must propose projects that will (continued):

6. Design recruitment and participation initiatives for PCPs with the goal of increasing clinical trial participation and education among minority populations;

7. Develop and submit an action plan for disseminating a successful educational intervention; and

8. Prepare a manuscript for publication that reports the results of the educational intervention evaluation during the project period.
National Lupus Outreach and Clinical Trial Education Program

Project Requirements (FOA pages 10 and 18)

Priority A and Priority B

Metropolitan Statistical Areas (MSAs):

1. Priority A projects must target two to three MSAs or other clearly identified geographic areas.

2. Priority B projects must engage three MSAs or other clearly identified geographic areas.

3. A brief description of the proposed MSAs or other clearly identified geographic summaries must be included in the Project Abstract Summary and the Executive Summary.
National Lupus Outreach and Clinical Trial Education Program

Project Requirements (FOA pages 10 and 18)

Priority A and B

National CLAS Standards

All applicants are required to use the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care as a framework to develop Priority A and Priority B proposals.
Partnerships

1. Developing a structure for involvement, regularly engaging community and partnering organizations in the design and review of strategies, tools, resources and approaches needed to carry out the Lupus Program and leveraging the strengths of each partner organization without duplication of effort.

2. Community and partnering organization members shall represent a wide range of health partners including:
   Minority health professional associations, medical and nursing professional associations, and health care organizations such as federally qualified health centers.
Project Requirements (Page 11)

OMH Expections: Applicants have significant demonstrated expertise in:

1. Having knowledge regarding lupus epidemiology, diagnosis, treatment and disparity related issues.

2. Knowing the most effective strategies for achieving desired outcomes resulting from provider and paraprofessional education.

3. Designing and testing provider and paraprofessional education model(s).

4. Gaining access to representative samples of health care providers and paraprofessionals.
Applicant Expertise (continued)

5. Implementing a provider and paraprofessional education program.


7. Training providers and paraprofessionals in delivering culturally and linguistically appropriate care.

8. Applicants must have the necessary partnerships already in place to conduct the proposed intervention(s).
Application Responsiveness Criteria (FOA pages 17-18)

1. Letter of Commitment (LOC) between the applicant organization and each partner organization and agency.

2. Only one application under Priority A and one application under Priority B will be considered. If more than one application is submitted for the same priority areas, then only the last application submitted for that priority area will be considered.

3. The applicant must demonstrate the National CLAS Standards serves as a framework for project intervention, resources, and materials.
Application Responsiveness Criteria (FOA pages 17-18), continued

4. Applicant for Priority A must target two to three MSAs or other clearly identified geographic areas; applicants for a Priority B projects must target three MSAs or other clearly identified geographic areas.

5. A brief description of the proposed MSA or other clearly identified geographic areas must be included in the Project Abstract Summary and Executive Summary.
National Lupus Outreach and Clinical Trial Education Program

Application Deadline
(FOA page 1)

Due Date: March 31, 2017
Closing Time: 5:00 PM (ET)
National Lupus Outreach and Clinical Trial Education Program

Application Content (FOA pages 21-22)

Project Narrative:

1. Executive Summary
2. Problem Statement
3. Organizational Capability
4. Goals and Objectives
5. Outcomes
6. Program Plan
   6a. Proposed Intervention/Plan
   6b. Special Target Populations and Organizations
   6c. Project Management
7. Evaluation
8. Dissemination
9. Appendices
National Lupus Outreach and Clinical Trial Education Program

1. Executive Summary (FOA page 22)
   • A brief description of the proposed project, including: goal(s) objectives, outcomes, and products.

2. Problem Statement (FOA page 22)
   • Describe the nature and scope of the specific and particular problem or issue and the proposed intervention.
   • Detail how the project will potentially affect the targeted population, specific subgroups within those populations and other interested stakeholders as identified.
   • Must address the problem concerning lupus in each of the geographic areas selected.
3. Organizational Capability (FOA page 23)
   - Organizational capability statement

   - Document significant experience working on prior lupus projects.

   - Document any lupus project currently funded, or funded within the past five years, or projects with a similar scope.

   - Bios for key project personnel.
4. Goals and Objectives (FOA page 24)

• Description of the project’s goal(s) and major objectives. Unless the project involves multiple, complex interventions, we recommend you have only one overall goal.

• Objectives must follow the SMART approach (Specific, Measurable, Attainable/Achievable, Relevant, and Timely)

• Developing specific, measurable objectives requires time, orderly thinking, and a clear picture of the results expected from program activities.
5. Outcomes (FOA page 24)

• Must clearly identify the measurable outcome(s) that will result from your project. HHS/OASH will not fund any project that does not include measurable outcomes.

• In addition to discussion in the narrative, applicants must describe how they envision the project will benefit the field at large.
National Lupus Outreach and Clinical Trial Education Program

Program Plan

6a. Proposed Intervention/Plan (FOA page 25)

• Provide a clear and concise description of the intervention/plan to address the need identified in the program announcement and the problem described in the “Problem Statement” section.

• Explain the rationale for using a particular intervention/plan and present a clear connection between the identified system gaps and the needs and your proposed activities to be undertaken.

• How they address system gaps and identified issues, and how they will assist in achieving the overall project goals and objectives.
6b. Special Target Populations and Organizations

(FOA page 26)

• Describe how you plan to involve community-based organizations, network partners, and stakeholders in a meaningful way in the planning and implementation of the proposed project.

• Describe how your proposed intervention will target minority and/or disadvantaged populations, including limited English speaking populations and identify the languages spoken by the target populations.
National Lupus Outreach and Clinical Trial Education Program

Program Plan

6c. Project Management (FOA page 26-27)

- Clear delineation of the roles and responsibilities of project staff and subrecipients and how they will contribute to achieving the project’s objectives and outcomes.

- Identify who will have day-to-day responsibility for key tasks.

- Describe the approach that will be used to monitor and track progress on the project’s tasks and objectives.

- HHS/OASH expects that, throughout the grant period, the Principal Investigator or Project Director will have involvement in, and substantial knowledge about, all aspects of the project.
7. Evaluation (FOA page 27)

- Describe the methods you will use to evaluate whether or not the proposed intervention/plan achieve propose outcome(s) and assess and evaluate the impact of activities for which you are applying.

- These research and demonstration grants are not intended to fund ongoing program operations or replace existing or expiring funding, but rather to test modifications or new innovative programs grounded in and built upon successful evidence-based programs.

- Funded grants will propose rigorous tests of new programs or program innovations that are likely to significantly improve health outcomes over and above what current interventions or programs achieve.
7. Evaluation (FOA page 27)

- Clearly describe (narrative and logic model) existing or current evidence-based models/programs and the associated outcomes achieved. The theoretical basis of the model/program should be specified.

- Clearly describe (narrative and revised logic model) the novel components or execution of the revised logic model associated with an expected significant improvement in outcomes. Theoretical basis for the innovation should be specified.
7. Evaluation (FOA pages 27-28)

- Clearly describe the research design (i.e., experimental or quasi-experimental) that will be used to test the proposed intervention against a control group or data.

- Specify planned outcome measures that are specific, achievable, reliable and valid.

- Include a description of procedures to ensure compliance with 45 CFR Part 46 (Human Subjects Protections).

- Provide a power analysis on the key outcome measures that demonstrate that the proposed test will be able to detect a significant difference between the intervention group and control or comparison group at the alpha = .05 level.
8. Dissemination (FOA page 28)

- Describe the method that will be used to disseminate the project’s results and findings

- Timely manner and in easily understandable formats to the target audience, the general public, and other parties who might be interested in using the results of the project.
9. Appendices (FOA page 37-38)

These count toward the total page limit and include:

- Work Plan
- Letter of Commitment from Subsequent Organizations and Agencies (not “letters of support”)
- Information as to Other Funds for Lupus Projects
Budget Narrative (FOA page 29)

- One year Budget Narrative.

- Budget Narrative should detail all costs.

- Review Section D.6 Funding Restrictions for specific information on allowable, unallowable, and restricted costs.

- Staff listed by position with salary and percentage of full-time equivalent to be devoted to this project.

- Any participant incentives proposed to be provided should be fully justified.
# National Lupus Outreach and Clinical Trial Education Program

## Application Review Information Criteria (FOA pages 46 - 50)

<table>
<thead>
<tr>
<th>Factor 1</th>
<th>Executive Summary, Problem Statement and Organizational Capability</th>
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<tbody>
<tr>
<td>Factor 2</td>
<td>Goals and Objectives, and Outcomes</td>
<td>10 points</td>
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<tr>
<td>Factor 3</td>
<td>Program Plan including Proposed Intervention/Plan, Special Target Populations and Organizations, and Project Management</td>
<td>30 points</td>
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<tr>
<td>Factor 4</td>
<td>Evaluation, Innovation and Dissemination Plan</td>
<td>40 points</td>
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<tr>
<td>Factor 5</td>
<td>Budget</td>
<td>5 points</td>
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Award Information (FOA page 16)

- Funds Available: $2,000,000
- Anticipated No. of Awards:
  - Priority A: up to 4 awards
  - Priority B: up to 2 awards
- Range of Awards
  - Priority A: $250,000 - $325,000
  - Priority B: $450,000 - $550,000
- Anticipated Start Date: 07/01/2017
- Period of Performance: Not to exceed 1 year
- Budget Period Length: 12 months
- Type of Award: Grant
National Lupus Outreach and Clinical Trial Education Program

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NATIONAL LUPUS OUTREACH AND CLINICAL TRAIL EDUCATION PROGRAM (LUPUS PROGRAM) WEBINAR

OASH Office of Grants Management
Eric West
Senior Grants Management Specialist
NATIONAL LUPUS OUTREACH AND CLINICAL TRIAL EDUCATION PROGRAM (LUPUS PROGRAM)

U.S. Department of Health and Human Services
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February 7, 2017
Address to Request Application Package

- Obtain an application package electronically by accessing Grants.gov at [http://www.grants.gov/](http://www.grants.gov/). Find it by searching the CFDA number on page 1 of the FOA.

- CFDA Number is 93.137
Submission Dates and Times

• 5pm Eastern Time on the date indicated on page 1 of the FOA.

• Your submission time will be determined by the date and time stamp provided by Grants.gov when you complete your submission.

• Strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date.

• Grants.gov may take up to 48 hours to notify you of a successful submission.

• If you fail to submit your application by the due date and time, we will not review it, and it will receive no further consideration.

• OASH requires that all applications be submitted electronically via Grants.gov unless an exemption has been granted. If you submit an application via any other electronic communication, it will not be accepted for review.

• Access Grants.gov website portal. All funding opportunities and grant application packages are made available on www.Grants.gov.

• An Application will not be considered valid until all application components are entered in Grants.gov and received by HHS Office of Grants Management according to the deadlines specified in the “DATES” section on page 1 of the FOA.

• Contact Grants.gov with any questions or concerns regarding the electronic application process 1-800-518-4726.
Application Submission

To ensure successful submission of your application, carefully follow the step-by-step instructions provided at http://www.grants.gov/web/grants/applicants/apply-for-grants.html

These instructions are kept up-to-date and also provide links to Frequently Asked Questions and other troubleshooting information.
Application Submission

- Applications must be submitted as three (3) files
  - File 1: The ENTIRE project narrative
  - File 2: The ENTIRE budget narrative, including supporting documentation described in the Budget Narrative content section
  - File 3: All documents in the appendices

Exceptions: required standard forms do not apply to the submission requirements as stated in Disqualification Criteria
System for Award Management (SAM)

- Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations.

- Minimum timeframe to complete an initial SAM registration (30min).

- Timeframe for applicant’s registration to become active (up to 10 days).

- SAM registration **must** be renewed each year.

- Average timeframe for updates to take effect in Grants.gov (72hrs).
System for Award Management (SAM)

SAM Continued

- Recommend applicants check active registration in SAM well before application deadline.

- If successful and receive award must maintain an active SAM registration w/current info at all times during the active award.

- If you have not complied with these requirements, HHS/OASH
  1. May determine you are not qualified to receive .
  2. May use that determination as a basis for making an award to another applicant.

- Should you successfully compete and receive an award, all first-tier sub-award recipients must have a DUNS number at the time you fund the recipient -- make a sub-award.
Funding Restrictions

• Allowability, allocability, reasonableness, and necessity of direct expenses; indirect costs may be charged on HHS/OASH grants in accordance with Department regulations and current policy effective at the time of the award.

• Current requirements can be found online via 45 CFR part 75 “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards”

• Indirect costs may be included per 45 CFR 75.414. Applicants should indicate which method or rate is used for this application.

• 2017 Salary Limitation: $187,000
Application Disqualification Criteria

a) Submitted electronically via www.grants.gov by 5pm on due date (unless an exemption was granted 2 business days prior to the deadline)

b) An applicant organization’s last successfully submitted application that is received by the deadline will be reviewed.

c) Project Narrative double-spaced, on the equivalent of 8.5” X 11” page size with 1” margins on all sides and font size not less than 12 points.

d) Project Narrative must not exceed 50 pages.

e) Total Application including Project Narrative plus Appendices must not exceed 75 pages.

f) Proposed Budget does not exceed the maximum indicated in Range of Awards.

g) Application meets the Application Responsiveness Criteria.
Award Decisions

• Independent review panel will evaluate each successfully submitted application

• Federal staff will review each application for programmatic, budgetary and grants management compliance

• Geographic distribution

• All award decisions are final, including
  • level/amount of funding, if an award is made
  • number of awards, if an award is made.

• Information about individual applications is not released
Review of Risk Posed by Applicant

- HHS/OASH will evaluate each application in the fundable range for risks posed by the applicant before issuing an award in accordance with 45 CFR 75.205
- OASH will use a risk-based approach and may consider any items such as the following as stated in the FOA:
  - Applicant’s financial stability;
  - Quality of management systems and ability to meet the management standards prescribed in 45 CFR part 75;
  - History of performance – Applicants record in managing Federal awards including timeliness of compliance with applicable reporting requirement, conformance to the terms and conditions of previous Federal awards;
  - Reports and findings from audits performed; and
  - The applicant’s ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.
Funding Process

• We are not obligated to make any Federal award as a result of this announcement.

• Only the grants officer can bind the Federal government to the expenditure of funds.

• If you receive communications to negotiate an award or request additional or clarifying information, this does not mean you will receive an award; it only means that your application is still under consideration.

• All award decisions, including level of funding if an award is made, are final and you may not appeal.
Funding Process

Notice of Award (NOA)

• Notifies the successful applicant of the selection; award amount; project & budget periods

• Includes any conditions on the award (e.g., requirements that must be met as a condition of receiving the grant funds)

• Includes standard terms, reporting requirements and contact information for OGM and the Program Office
Funding Process

• OGM is the official contact for the grantee.

• All official communication related to the grant is between OGM and the successful applicant.
National Lupus Outreach and Clinical Trial Education Program

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