

FY2021 NOFO Technical Assistance Webinar: National Lupus Outreach and Clinical Trial Education Program

MP-CPI-21-005

May 5, 2021



OASH

Office of the
Assistant Secretary
for Health

Webinar Agenda

- Overview of the Notice of Funding Opportunity (NOFO)
- Grants and Acquisitions Management
 - Competitive Application Requirements
- Question and Answer Session

The Office of Minority Health (OMH)

OMH Mission

To improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities.

Statutory Authority:
Public Health Service Act §1707
[\(42 U.S.C. § 300u-6\)](#)

OMH Functions



Executive Summary (page 2-3)

The Lupus Program seeks to demonstrate the effectiveness of interventions for increasing minority participation in lupus-related clinical trials to help to reduce lupus-related health disparities experienced by racial and ethnic minority populations.

Projects will seek to develop public-private and community partnerships to support and/or sustain effective practices to increase racial and ethnic minority enrollment and retention in lupus clinical trials, and tailor existing outreach or education interventions that focus on health care providers/practitioners and/or racial and ethnic minority populations.

Target Population

Racial and ethnic minority populations experiencing lupus-related health disparities

Racial and ethnic minority communities within cities and/or counties where lupus clinical trials are recruiting patients

Award Information

- Estimated Federal Funds Available: \$2,000,000
- Anticipated Number of Awards: Up to 6
- Award Ceiling (Federal Funds including indirect costs): \$500,000
- Award Floor (Federal Funds including indirect costs): \$300,000
- Anticipated Start Date: September 1, 2021
- Estimated Period of Performance: Up to 2 years
- Anticipated Initial Budget Period Length: 12 months
- Type of Award: Grant

Program Description (pages 8 - 11)

- a. Develop and Implement a Disparity Impact Statement**
- b. Develop Public-Private and Community Partnerships**
- c. Use and Disseminate Existing Resources**
- d. Tailor Existing Intervention(s)**
- e. Implement a Process and Outcomes Evaluation**
- f. Document and Disseminate Project Findings**
- g. Develop a Sustainability Plan**

Develop and Implement a Disparity Impact Statement (page 8)

OMH expects recipients to develop a disparity impact statement using local data, whenever possible, to identify racial and ethnic minority populations at highest risk for health disparities relevant to this initiative.

Develop Public-Private and Community Partnerships (page 9)

OMH expects recipients to utilize standard practices necessary for establishing and sustaining effective collaborative partnerships, including public-private and community partnerships.

Projects should involve at least two partners, one of which must be a:

- Local hospital, health care system, Federally Qualified Health Center (FQHC), or community health center
- National, state or local professional organization that represents primary care physicians, other health care providers, and/or CHWs
- Tribe or tribal organization

Use and Disseminate Existing Resources (page 9)

OMH expects recipients to use and disseminate the resources developed as a result of previous OMH-supported lupus programs and projects to achieve expected program outcomes.

Tailor Existing Intervention(s) (page 10)

OMH expects recipients to tailor an existing intervention to increase minority participation in clinical trials for the intended population of focus, and to implement the tailored intervention.

Interventions may include:

- Provider education models trials
- Outreach and social media campaigns
- Capacity-building models for CHWs
- Lupus clinical trial education models

Implement a Process and Outcomes Evaluation (pages 11)

OMH expects projects to implement a rigorous evaluation to:

- assess the extent to which the intervention increased racial and ethnic minority referrals, enrollment, and/or retention in lupus clinical trials
- measure lupus clinical trial knowledge of healthcare providers/community health workers and measure attitudes, knowledge and beliefs gained using pre- and post-surveys.

Document and Disseminate Project Findings (page 11)

Recipients should document project knowledge and findings, to include implementation process, lessons learned, successes and challenges.

OMH expects recipients to communicate and disseminate project knowledge and findings, to include dissemination to federal, state, territorial and tribal public health agencies; policymakers; community organizations; community members; and other stakeholders.

Develop a Sustainability Plan (pages 11)

OMH expects the recipient to develop an effective plan to sustain successful interventions after the award period.

OMH expects successful projects (i.e., projects demonstrating significant differences in key outcomes) to begin implementing the sustainability plan in year two.

Application Project Narrative Content (pages 17-24)

- 1) Problem Statement
- 2) Organizational Capability
- 3) Project Plan – Goals, Objectives and Outcomes; Intervention; Work Plan
- 4) Evaluation Plan
- 5) Dissemination Plan
- 6) Sustainability Plan

Application Appendices (pages 32-34)

- Supplemental Information/Supporting Documentation for Work Plan
- Project Population(s) of Focus
- Organizational Chart
- Memorandums of Agreement and/or Letters of Commitment from Partners, Subrecipient Organizations, and Agencies
- Curriculum Vitae/Résumé for Key Project Personnel
- Logic Model
- Just in Time Institutional Review Board Agreement

Application Review Criteria (pages 40-46)

- a. Problem Statement (10 points)
- b. Organizational Capability (20 points)
- c. Project Plan (30 points)
- d. Evaluation Plan (25 points)
- e. Dissemination Plan (5 points)
- f. Sustainability Plan (10 points)

Refer to the NOFO for the full list of review criteria.

NOFO Appendices

- A. References
- B. Glossary
- C. Disparity Impact Statement
- D. Considerations in Plans for Oversight of Federal Funds

Evaluation Planning Resources

- Strategic Framework
<https://minorityhealth.hhs.gov/omh/content.aspx?lvl=1&lvlid=5&id=8842>
- Evaluation Planning Guidance
https://minorityhealth.hhs.gov/Assets/pdf/Checked/1/Evaluation_Planning_Guidelines.pdf
http://www.eblcprograms.org/docs/pdfs/CDC_EvaluationWorkbook_2011.pdf
- Evaluation Protocol
https://minorityhealth.hhs.gov/Assets/pdf/Checked/1/Evaluation_Protocol.pdf
- Community Tool Box's Evaluating Community Programs and Initiatives
<http://ctb.ku.edu/en/evaluating-community-programs-and-initiatives>
- CDC's Evaluation Guidance
<https://www.cdc.gov/eval/index.htm>
- Evaluation Design
<https://courses.lumenlearning.com/atd-herkimer-researchmethodsforsocialscience/>
http://www.baylorhealth.edu/Documents/Research/BIIR/Biostatistics/01_Study%20Design-Levels%20of%20Measurement-Sampling%20Methods.pdf
- Sample Size and Power Calculation
<https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=19&cad=rja&uact=8&ved=0ahUKEwirguqg3l3SAhWoxlQKHbmQCuk4ChAWCEgwCA&url=http%3A%2F%2Fweb.stanford.edu%2F~kcobb%2Fhrp259%2Flecture11.ppt&usq=AFQjCNEoDHbm-nP8OeGiWjk7wLbaaju9Pg&sig2=75YaDzOIDZvWZNiNJoUstg&bvm=bv.146786187,d.cGw>
<https://www.bu.edu/researchsupport/compliance/animal-care/working-with-animals/research/sample-size-calculations-iacuc/>
- Data Sources for Community Data
<https://www.cdc.gov/stltpublichealth/cha/data.html>

National Lupus Outreach and Clinical Trial Education Program Opportunity No: MP-CPI-21-005

Competitive Application Deadline

Due Date: Tuesday, June 29, 2021

Cutoff Time: 6:00 p.m. ET



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Submission Dates and Times

Application is due by 6:00 p.m. Eastern Time, Tuesday June 29, 2021.

- 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.

Eligible Applicants (NOFO, Section E.1, page 13)

Any public or private nonprofit entity located in a State (which includes one of the 50 United States, District of Columbia, Commonwealth of Puerto Rico, U.S. Virgin Islands, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federated States of Micronesia, and the Republic of the Marshall Islands) is eligible to apply for an award under this announcement. Faith-based organizations and American Indian/Alaska Native/Native American (AI/AN/NA) organizations are eligible to apply.

Eligible Applicants Examples (NOFO, Section E.1, page 13)

- 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 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 nonprofit institutions of higher education
- U.S. territories

Cost Sharing or Matching (Section E.2, pages 13)

- You are not required to provide cost sharing or matching in your proposed budget.
- If you voluntarily include cost sharing in your application, you must include in your budget narrative a non-federal sources justification. During the merit review of an application, cost sharing will only be considered in the overall review of the adequacy of the total proposed budget (Federal and non-Federal share) to support the project proposed.
- Applications including voluntary cost sharing or matching that result in an award will include the cost sharing or matching commitment on the notice of award at the level proposed in the application. Any change in that commitment will require prior approval of the Grants Management Officer.

Notice of Funding Opportunity (NOFO) Announcement

- The Notice of Funding Opportunity (NOFO) provides information and guidance related to applications.
- Read the entire funding announcement.
- Follow the NOFO carefully!
- **The information provided in the NOFO takes precedence over any conflicting information in other documents.**

Address to Request Application Package

- Obtain an application package electronically by accessing Grants.gov at <http://www.grants.gov/>. Find it by searching the Assistance Listing (formerly CFDA) Number found on page 2 of the NOFO.
- The Assistance Listing (CFDA) Number is 93.137.
- **Be sure to subscribe to the announcement in Grants.gov so you receive notification of any updates to the NOFO or supporting documents.**

Application Submission

- OASH requires that all applications be submitted electronically via Grants.gov unless an exemption has been granted by the grants management officer (Section F.5, page 27).
 - **If you submit an application via any other electronic communication, it will not be accepted for review.**
- Grants.gov is a 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 the OASH Grants and Acquisitions Management Division according to the deadlines specified in the “DATES” section of the NOFO (Section A.1, page 2).
- Contact Grants.gov with any questions or concerns regarding the electronic application process 1-800-518-4726.

Application Submission

Applications must be submitted as three (3) files:

File 1: The ENTIRE project narrative (Section F.3.a, page 17)

File 2: The ENTIRE budget narrative, including supporting documentation described in the Budget Narrative content section (Section F.3.b, page 24)

File 3: All documents in the appendices uploaded in the Attachments section of your Grants.gov application (Section F.3.c, page 32)

Note: required standard forms do not apply toward your page count limitations in the submission requirements as stated in Disqualification Criteria (Section E.4, pages X).

Application Submission

Any files uploaded or attached to the Grants.gov application must be of the following file formats –

- **Microsoft Word, PowerPoint, Adobe PDF, or image formats (JPG, GIF, TIFF, or BMP only).**
- **Microsoft Excel files will NOT be accepted.**

HHS/OASH strongly recommends that electronic applications be uploaded as Adobe PDF.

- **If you convert to PDF prior to submission, you may prevent any unintentional formatting that might occur with submission of an editable document.**
- **Check your page count of the PDF and/or print your file to ensure that the document does not exceed the page limit.**

Application Submission

- Be complete and do not leave blanks on forms unless the information is clearly not applicable.
- The individual submitting the application forms must have the legal authority to act on behalf of the organization.

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 Elements

Forms

- ☐ Application for Federal Assistance (SF-424)
- ☐ Budget Information for Non-construction Programs (SF-424A)
- ☐ Assurances for Non-construction Programs (SF-424B)
- ☐ Disclosure of Lobbying Activities (SF-LLL)
- ☐ Project Abstract Summary

Files

- ☐ Project Narrative – Submit all Project Narrative content as a single acceptable file.
- ☐ Budget Narrative – Submit all Budget Narrative content as a single acceptable file.
- ☐ Appendices – Submit all appendix content as a single acceptable file, in the Attachments section of your Grants.gov application.

Application Format

- ☐ Be sure to follow Project Narrative format instructions in the NOFO. Your application will be disqualified if it does not conform to the format requirements.
- ☐ You must double-space the Project Narrative pages.
- ☐ You must use 12-point font.
- ☐ You should use an easily readable typeface, such as Times New Roman or Arial.
- ☐ You may single-space tables or use alternate fonts but you must ensure the tables are easy to read.
- ☐ For Appendices and Budget Narrative, you should use the same formatting specified for the Project Narrative.
- ☐ Appendix documents such as résumés may use alternate formats common to such documents.

System for Award Management (SAM)

- If you are registering a new entity in SAM.gov, you need to create a login.gov account, if you don't already have one.
 - **Please note that the complete process for registering a new entity involves submission of a notarized letter by mail.**
- If you are renewing your registration, your old SAM.gov username and password will not work anymore. You will need to create a login.gov account if you do not already have one.
- Minimum timeframe to complete an initial SAM registration online is 30 min.
- Timeframe for applicant's registration to become active is up to 10 days and may take longer depending on volume. Average timeframe for updates in SAM.gov to appear in Grants.gov is up to 72hrs.
- SAM registration **must** be renewed each year.

SAM (continued)

- We strongly recommend applicants check for an active registration in SAM well before application deadline.
- If you are successful and receive an award, you must maintain an active SAM registration with current information **at all times** during the active award.
- If you have not complied with the SAM registration requirements, HHS/OASH
 - **May determine you are not qualified to receive an award; and**
 - **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, the recipient, make a sub-award.**

Funding Restrictions

- If you are successful and receive an award, by accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.
- Costs must be allowable, allocable, reasonable, and necessary direct expenses or indirect costs in accordance with regulations and current policy.
 - **Indirect costs may be included per 45 CFR 75.414. Applicants should indicate which method or rate is used for this application. (Section F.3.b.1.o, page 29)**
 - **Pre-award costs are not allowed. (Section F.7.a, page 37)**
 - **Current Salary Limitation: \$199,300 effective January 2021 (Section F.7.b, page 37)**

Budget Narrative and Forms

The Project Budget Information:

SF 424A Budget Forms

Budget Narrative

Detailed Budget Justification

- ☐ Must be consistent with the requirements of the NOFO
- ☐ Budgeted costs must reflect proposed activities
- ☐ Budget line item descriptions and justification requirements are explained in the NOFO
- ☐ Suggested table formats in the NOFO
- ☐ Plan for Oversight of Federal Award Funds (Section F.3.b.2, page 31)

Forms, narrative and detailed justification do not count toward page limit.

Application Disqualification Criteria

If your application does not meet the following requirements it will be disqualified and receive no further consideration:

- Submitted electronically via www.grants.gov by due date and time (unless an exemption was granted 2 business days prior to the deadline).
- If you successfully submit multiple applications for the same project, we will only review the last application received by the deadline.
- HHS/OASH/GAM deems your application eligible.
- Project Narrative must be 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.
- Project Narrative must not exceed 50 pages.
- The Total Application, including Project Narrative must not exceed 75 pages.

Application Disqualification Criteria (continued)

If your application does not meet the following requirements it will be disqualified and receive no further consideration:

- **Your Federal funds request including indirect costs does not exceed the maximum indicated in Award Ceiling.**
 - \$500,000
- **If you have included voluntary cost sharing or matching, you must include in your budget narrative a non-federal sources justification.**

Application Disqualification Criteria (continued)

- Applications that lack the required supporting documentation or submit additional appendix files will not be disqualified from competitive review;
 - **However, this may impact your application's scoring under the evaluation criteria.**
- **Be sure to follow submission instructions carefully.**

Application Review Criteria (Section G.1)

- a. Problem Statement (10 points)
- b. Organizational Capability (20 points)
- c. Project Plan (30 points)
- d. Evaluation Plan (25 points)
- e. Dissemination Plan (5 points)
- f. Sustainability Plan (10 points)

Application Merit Review

- Eligible applications will be reviewed and scored by a panel of independent reviewers with technical expertise in applicable fields according to the criteria listed in the NOFO.
- Objective Review Committee process is formal and confidential. Federal staff are available for questions and to ensure the process is consistent and fair, but do not participate in discussion and scoring.
- Applications are then also reviewed:
 - **By GAM staff for administrative & business compliance.**
 - **By OMH Program Office staff for programmatic compliance.**

Funding Decisions (Section G.4, page 48)

- The Director of the Office of Minority Health will make final award selections to be recommended to the Grants Management Officer for risk analysis.
- Upon completion of risk analysis and concurrence of the Grants Management Officer, HHS/OASH will then issue Notices of Award.
 - **No award decision is final until a Notice of Award is issued.**
 - **All award decisions, including level of funding, if an award is made, are final and you may not appeal.**

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 – 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 NOFO:
 - **Applicant's financial stability;**
 - **Quality of management systems and ability to meet the management standards prescribed in 45 CFR part 75;**
 - **History of performance – Applicant's record in managing Federal awards including timeliness of compliance with applicable reporting requirement, and 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.**

Plan for Oversight of Federal Award Funds (Section F.3.b.2, page 31)

- If your internal controls are available online, you may provide the link as part of your plan in the budget narrative.
- We have also included Appendix D, which contains questions applicants may find useful in considering their Plan for Oversight of Federal Funds.

Non-funded Applications as a Result of Risk Review

- If we determine your organization does not meet either or both of the minimum qualification standards as described in 45 CFR §75.205(a)(2) and we do not make an award to you as a result, we must report that determination to FAPIIS, if certain conditions apply.
- The standards include at a minimum, if you are a prior Federal award recipient the information in FAPIIS must “demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics.” 45 CFR § 75.205(a)(2)
- Information reported in FAPIIS is available for other organizations to review when considering you for an award.

Notice of Award (NOA)

The Notice of Award:

- Notifies the successful applicant of the selection; award amount; project and budget periods.
- Includes any conditions on the award (i.e., requirements that must be met as a condition of receiving the grant funds).
- Includes standard terms, reporting requirements and contact information for OASH/GAM and the Program Office.

Funding Process – Points of Contact

- GAM is the official contact for awardees throughout the award life cycle.
- All official communication related to the award is between GAM and the successful applicant.
- Unsuccessful applicants will be notified by OMH Program Office via letter.

Summary and Tips

Project Narrative Description:

- ☐ Be clear, complete and concise in the project description; follow and address exactly what is requested in the NOFO.
- ☐ Don't make the reviewer search for the required information. Generally, the easier the application is to review, the better the score.
 - ☐ **Reviewers are not allowed to do external research, follow embedded links, etc.**
- ☐ Clearly identify the sections of the application and indicate which component is being addressed.
- ☐ The project narrative must include all required information within the page limit. Do not use appendices to expand the page limit.

Summary and Tips

Project Narrative Description:

- ☐ Make the goals and objectives “SMART;” Specific; Measurable; Achievable; Realistic; and Time-framed.
- ☐ Activities presented in the work plan should relate directly to the proposed goals and objectives.
- ☐ The program work plan, evaluation plan and budget should provide a complete picture of how the applicant will address the needs as well as address the purpose and expectations in the NOFO.

Summary and Tips

Staffing:

- The staffing should be appropriate and reasonable for the goals, objectives and activities of the proposed project.
- Be complete in describing what staff will do, the expertise required and the percent time they will be assigned to the project.

Summary and Tips

Budget:

- The budget should include adequate funds to carry out the proposed work plan, evaluation plan and administrative responsibilities of the project.
- The budget should be reasonable and relate directly to the goals and objectives.
- Do not request more funds than are available, as listed in the NOFO. This amount is *inclusive* of indirect costs.
- The operating budget should be complete and include Federal and non-Federal funds, projected program income from fees and third party payers and other contributing funds.

Summary and Tips

Overall:

- Include full names (First Middle Last) for Authorized Official, Principal Investigator/Project Director and all Essential Personnel
- Electronic submission **IS** required.
- Do not wait until the last minute to begin SAM registration or update registration.
- Do not wait until the last minute to begin the electronic submission—problems could arise.

NOFO Inquiries

Program Questions

Program Office Attn: Office of Minority Health

Ramon Bonzon

Email: ramon.bonzon@hhs.gov

Telephone: 240-453-2824

Administrative or Financial Questions

Grants Management Specialist

Duane Barlow

Email: duane.barlow@hhs.gov

Telephone: 240-453-8822

Electronic Submission Requirements

Grants.gov Applicant Support

www.grants.gov

Email: support@grants.gov

Telephone: 800-518-4726

Please do not contact OASH Program or Grants office staff for Grants.gov issues.

Question and Answer Session

FAQs will be posted to [Grants.gov](https://www.Grants.gov)





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These slides will be posted on [grants.gov](https://www.grants.gov) following the presentation.

**The webinar recording will be posted to OMH's YouTube channel --
<https://www.youtube.com/user/OfficeMinorityHealth>**
