



Office of the
Assistant Secretary
for Health

Office on Women's Health

Notice of Funding Opportunity:

**Improving Maternal Health through Addressing
Endometriosis, Fibroids, and/or Polycystic Ovary Syndrome**

Opportunity Number: WH-AST-22-001

Application Due Date:

July 7, 2022 at 6:00 PM Eastern

OVERVIEW

FEDERAL AGENCY NAME

Office of the Assistant Secretary for Health, Office on Women's Health

FUNDING OPPORTUNITY TITLE

Improving Maternal Health through Addressing Endometriosis, Fibroids, and/or Polycystic Ovary Syndrome

ACTION

Notice

ANNOUNCEMENT TYPE

Initial Competitive Grant

FUNDING OPPORTUNITY NUMBER

WH-AST-22-001

ASSISTANCE LISTING NUMBER AND PROGRAM:

93.088 Advancing System Improvements for Key Issues in Women's Health

DATES

Application Deadline: July 7, 2022, by 6:00 PM Eastern.

Technical Assistance: Webinar, May 16, 2022 at 2:00 PM Eastern.

EXECUTIVE SUMMARY

The Office on Women's Health (OWH) announces the availability of funds for Fiscal Year (FY) 2022 Grants under the authority of Section 1703(a) of the Public Health Service (PHS) Act (42 U.S.C. § 300u-2(a)), and section 229 of the PHS Act (42 U.S.C. § 237a).

This notice solicits applications to fund demonstration projects to implement and evaluate evidence-based interventions to comprehensively identify and treat endometriosis, fibroids, and/or polycystic ovary syndrome (PCOS) with an emphasis on addressing and reducing disparities in underserved communities. Pain, heavy menstrual bleeding, irregular menstrual cycles, and other symptoms associated with gynecologic disorders are often overlooked and not addressed, causing women to feel unheard. Endometriosis, fibroids, and PCOS increase the risk of pregnancy complications and adverse maternal health outcomes including gestational diabetes, pre-eclampsia, placenta previa, and preterm birth. Additionally, women with endometriosis, fibroids, and PCOS are more likely to have a cesarean delivery. Therefore, addressing common conditions like endometriosis, fibroids, and PCOS during the preconception (i.e., during the reproductive

years) and interconception (i.e., between pregnancies) time periods is essential to optimizing maternal health outcomes.

The goals of this initiative are to:

- Develop a demonstration project that implements and evaluates one or more evidence-based interventions to comprehensively diagnose and treat endometriosis, fibroids, and/or PCOS, conditions which contribute to risk factors and inequities in maternal health outcomes in underserved communities. Applicants may focus on one, two, or all three conditions, but must address at least one of the three;
- Identify and track evidence-based outcomes to demonstrate improvements in early diagnosis and effective treatment of one or more of these conditions; and
- Transition a successful project to sustainability.

By funding projects for these three conditions, OWH expects this initiative to identify specific interventions that will lead to better maternal health outcomes through faster diagnosis and more effective treatment of endometriosis, fibroids, and/or PCOS in underserved communities. Interventions should focus on women of reproductive age, which may include those who have had a pregnancy with complications that may be associated with one or more of these conditions. The project(s) will be expected to track and evaluate outcomes to assess success.

Applicants may be a public or private (profit or non-profit) entity. Examples are found in Section E.1.

Under this announcement, OWH anticipates making up to 8 grant awards for a maximum of \$2,200,000 in the first year. OWH anticipates project periods of up to three years awarded in annual budget periods. Recipients will be required to submit a non-competing continuation application for each budget period for the second and third years. OWH anticipates offering a competing continuation for a fourth year for the purpose of providing funding to support selected recipients as they transition projects to sustainability. Funding for the budget periods after the first will be contingent upon availability of funding, satisfactory performance (including recipient progress towards meeting stated project milestones and goals, timely submission of required reports, and compliance with all grant terms and conditions), and the best interests of the government.

HHS/OASH encourages applicants to review all program requirements, eligibility information, application format and submission information, evaluation criteria, and other information in this funding announcement to ensure that its application complies with all requirements and instructions.

TABLE OF CONTENTS

A.	<i>DATES</i>	5
1.	Application Deadline _____	5
2.	Technical Assistance _____	6
B.	<i>PROGRAM DESCRIPTION</i>	6
1.	Background _____	6
2.	Expectations _____	8
C.	<i>AUTHORITY</i>	10
D.	<i>FEDERAL AWARD INFORMATION</i>	10
E.	<i>ELIGIBILITY INFORMATION</i>	11
1.	Eligible Applicants _____	11
2.	Cost Sharing or Matching _____	12
3.	Other – Application Responsiveness Criteria _____	12
4.	Application Disqualification Criteria _____	12
F.	<i>APPLICATION AND SUBMISSION INFORMATION</i>	14
1.	Address to Request Application Package _____	14
2.	Content and Form of Application Submission _____	14
3.	Application Content _____	15
4.	Unique Entity Identifier (UEI) and System for Award Management (SAM)___	27
5.	Submission Dates and Times _____	29
6.	Intergovernmental Review _____	29
7.	Funding Restrictions _____	29
8.	Other Submission Requirements _____	31
G.	<i>APPLICATION REVIEW INFORMATION</i>	33
1.	Criteria _____	33
2.	Review and Selection Process _____	36
•	<i>equitable geographic distribution of award recipients</i>	36
3.	Review of Risk Posed by Applicant _____	36
4.	Final Award Decisions, Anticipated Announcement, and Federal Award Dates	37
H.	<i>FEDERAL AWARD ADMINISTRATION INFORMATION</i>	38

1.	Federal Award Notices	38
2.	Administrative and National Policy Requirements	38
3.	Program Specific Terms and Conditions	39
4.	Closeout of Award	40
5.	Lobbying Prohibitions	40
6.	Non-Discrimination Requirements	41
7.	Smoke- and Tobacco-free Workplace	42
8.	Acknowledgement of Funding	42
9.	HHS Rights to Materials and Data	43
10.	Trafficking in Persons	43
11.	Efficient Spending	43
12.	Whistleblower Protection	43
13.	Prohibition on certain telecommunications and video surveillance services or equipment.	43
14.	Human Subjects Protection	44
15.	Research Integrity	45
16.	Reporting	45
<i>I.</i>	<i>CONTACTS</i>	<i>47</i>
1.	Administrative and Budgetary Requirements:	47
2.	Program Requirements	48
3.	Electronic Submission Requirements	48
<i>J.</i>	<i>OTHER INFORMATION</i>	<i>48</i>
1.	Awards under this Announcement	48
2.	Application Elements	49
<i>K.</i>	<i>SUPPLEMENTARY MATERIALS</i>	<i>50</i>
1.	Considerations in Recipient Plans for Oversight of Federal Funds	50
2.	Sample Work Plan Template	51
3.	Disparity Impact Statements	52
4.	References	53

FUNDING OPPORTUNITY DETAILS

A. DATES

1. Application Deadline

Your application is due July 7, 2022 by 6 p.m. Eastern Time. To receive consideration, you must submit your application electronically via Grants.gov no later than this due date and time. If you do not submit your application by the specified deadline, we will return it to you unread.

You must submit electronically via Grants.gov unless you obtain a written exemption from this requirement 2 business days in advance of the deadline from the Director, Grants and Acquisitions Management (GAM) Division, Office of the Assistant Secretary for Health (OASH), Department of Health and Human Services (HHS). To obtain an exemption, you must request one via email from GAM, and provide details as to why you are technologically unable to submit electronically through Grants.gov. Your request should be submitted at least 4 business days prior to the application deadline to ensure your request can be considered prior to 2 business days in advance of the deadline.

If you request an exemption, include the following in your e-mail request: the HHS/OASH announcement number; your organization's unique entity identifier (UEI) number; your organization's name, address and telephone number; the name and telephone number of your Authorizing Official; the Grants.gov Tracking Number (e.g., GRANT#####) assigned to your submission; and a copy of the "Rejected with Errors" notification from Grants.gov. Send the request with supporting documentation to OASH_Grants@hhs.gov.

Failure to have an active System for Account Management (SAM) registration prior to the application due date will not be grounds for receiving an exemption to the electronic submission requirement. Failure to follow Grants.gov instructions to ensure software compatibility will not be grounds for receiving an exemption to the electronic submission requirement.

GAM will only accept applications via alternate methods (hardcopy paper via U.S. mail or other provider or PDF via email) from applicants obtaining prior written approval. If you receive an exemption, you must still submit your application by the deadline. Only applications submitted through the Grants.gov portal or alternate format (hardcopy paper via U.S. mail or other service or PDF via email) with an approved written exemption will be accepted. *See* Section F.8 ("Other Submission Requirements") for information on application submission mechanisms.

To ensure adequate time to submit your application successfully, OASH recommends that you register as early as possible in Grants.gov because the registration process can take up to one month. You must register an authorizing official for your organization. OASH does not determine your organization's authorizing official; your organization makes that designation. For information on registering for Grants.gov, refer to <https://grants.gov> or contact the Grants.gov

Contact Center 24 hours a day, 7 days a week (excluding Federal holidays) at 1-800-518-4726 or support@grants.gov.

Your organization is strongly encouraged to register multiple authorized organization representatives in Grants.gov to ensure someone is available to submit your application.

2. Technical Assistance

We will provide a technical assistance webinar for potential applicants on May 16, 2022 at 2:00 PM Eastern. Details will be posted at <https://womenshealth.gov>.

We recommend you review the entire announcement promptly so you can have any questions answered well in advance of the application due date. We also recommend you subscribe to this announcement in Grants.gov so you receive any amendments, question and answer documents, or other updates.

B. PROGRAM DESCRIPTION

The Office of the Assistant Secretary for Health (OASH), HHS Office on Women's Health (OWH) announces the availability of funds for Fiscal Year (FY) 2022 under the authority of section 1703(a) of the PHS Act (42 U.S.C. § 300u-2(a)), and section 229 of the PHS Act (42 U.S.C. § 237a). The primary focus of the Office of the Assistant Secretary for Health is leading America to healthier lives, especially for those who are most vulnerable, including those who have suffered historic disparities. In support of this vision, OWH provides national leadership and coordination to improve the health of women and girls through policy, education, and innovative programs. OWH advances and coordinates a comprehensive women's health agenda across the Department of Health and Human Services and works to develop and expand innovative approaches to advance the field of women's and girls' health.

1. Background

This initiative is designed to support and complement national objectives and strategic frameworks advancing maternal health and health equity for women in America, including the recent White House Call to Action to Reduce Maternal Mortality and Morbidity; the United States Strategy for Addressing the Maternal Health Crisis; Executive Order on White House Initiative on Advancing Educational Equity, Excellence, and Economic Opportunity for Black Americans; the White House Proclamation on Black Maternal Health Week; the Biden Administration's priority on maternal health in rural America; and Healthy People 2030. These strategies detail the principles, priorities, and actions guiding the national health response and provide a blueprint for coordinated implementation across the federal government and other sectors. This initiative

supports the application of these strategies, and recipients should align their organization's efforts with these strategies to the extent possible within the parameters of program guidance.

Endometriosis, fibroids, and PCOS are common conditions that can impact maternal health outcomes in the preconception and interconception time periods. Preconception health refers to the health during the reproductive years, and interconception health refers to health in between pregnancies (Centers for Disease Control and Prevention, 2020). Identifying conditions from symptoms such as painful or irregular periods and listening to women can improve health outcomes through earlier diagnosis and better treatment. Endometriosis, fibroids, and PCOS increase the risk of pregnancy complications and loss, miscarriage in early pregnancy, and adverse maternal health outcomes, including gestational diabetes, pre-eclampsia, placenta previa, and preterm birth. (Lalani, et al., 2018) (Radhika, Naik, Shreelatha, & Vana, 2015) (Chen, 2021) (Lee, 2010). Additionally, women with endometriosis, fibroids, and PCOS are more likely to have a cesarean delivery.

Furthermore, better diagnosis and treatment of these conditions will address health equity. More than 175 million women globally present with endometriosis (Guidone, 2020) (American College of Obstetricians and Gynecologists (ACOG), 2016) and between 35-77% of reproductive-age women have fibroids (Guo, 2012). Black or African American women experience higher rates of fibroids, and Black women with endometriosis have lower diagnosis rates (Bougie, Yap, Sikora, Flaxman, & Singh, 2019). In addition, PCOS affects an estimated 6-12% of reproductive-age women (American College of Obstetricians and Gynecologists (ACOG), 2016). Hispanic women with PCOS have the most severe metabolic symptoms compared to Non-Hispanic Black women and Non-Hispanic white women (Engmann, et al., 2017).

Despite the prevalence of these conditions, diagnosis is often delayed for years due to a lack of patient and provider understanding of symptoms, including irregular or painful periods (Johns Hopkins Medicine, n.d.). For example, on average, women with fibroids delay seeking treatment for more than three years, and 40% see two or more providers before receiving a diagnosis (Borah, 2013). Symptoms of endometriosis are regularly dismissed as routine due to low disease literacy (Guidone, 2020). Irregular periods underpin PCOS diagnosis; however, as many as 70% of patients with PCOS remain undiagnosed (Teede, et al., 2018). This underdiagnosis is in part due to challenges in defining individual components in diagnostic criteria, including during pubertal transition when an irregular period may reflect reproductive immaturity or may reflect PCOS (Teede, et al., 2018).

Moreover, pain and other symptoms associated with gynecologic disorders are often overlooked and unaddressed, causing women to feel unheard. Providing the tools for healthcare providers and women to better engage in conversation empowers women to speak up, raise concerns, and potentially receive lifesaving diagnoses and treatment.

Severe delays in diagnosis and treatment negatively impact patients' physical, psychological, emotional, and social well-being and highlight the need for improved awareness and education (Guidone, 2020). To improve maternal health outcomes, healthcare providers

everywhere, from hospitals to high schools, need information and education to support their understanding of these three conditions to increase early detection and care (Eltoukhi HM, 2014) (Gibson-Helm, Tassone, Teede, Dokras, & Garad, 2018).

Development and dissemination of educational resources to healthcare providers will be critical to promote health and exchange of information. For example, in Australia, one university has designed an evidence-based guideline for provider assessment and management of PCOS and is implementing the approach with an accredited course (Teede, et al., 2018). Therefore, it is reasonable to anticipate that providing consistent support to clinicians may prove effective in using the recommended diagnostic criteria, recommending lifestyle management, and ensuring early detection and treatment of symptoms and complications (Gibson-Helm, Tassone, Teede, Dokras, & Garad, 2018).

This initiative intends to go beyond traditional education and seek innovative approaches. For example, the U.S. Department of Veterans Affairs utilized an app to educate providers (U.S. Department of Veterans Affairs, n.d.). Apps also have the potential to track project outcomes, such as uptake of project implementation and identification of disparities.

2. Expectations for Funded Projects

Award recipients under this announcement should meet each of the below expectations in the execution of their funded projects.

- a. Implement and evaluate one or more evidence-based interventions.

Recipients should develop a demonstration project that implements and evaluates one or more evidence-based interventions to comprehensively diagnose and treat endometriosis, fibroids, and/or PCOS, conditions which contribute to risk factors and inequities in maternal health outcomes in underserved communities. Applicants must focus on at least one condition and up to three.

We expect recipients to design evidence-based projects that will support women and providers in underserved communities to better understand and identify symptoms indicative of endometriosis, fibroids, and/or PCOS. We encourage recipients to partner, as appropriate, with organizations and institutions, such as hospitals, clinics, and community and faith-based organizations, that serve diverse races and ethnicities.

Approaches should be developed to address health equity in underserved and disadvantaged populations, including racial/ethnic minorities, limited-English speaking populations, and persons with disabilities.

b. Identify and track evidence-based outcomes to demonstrate improvements.

Recipients should identify and track evidence-based outcomes to demonstrate improvements in early diagnosis and effective treatment of endometriosis, fibroids, and/or PCOS. We expect recipients to quantitatively evaluate their projects in improving early diagnosis, treatment, and outcomes for the condition(s) they have selected to study. Recipients should articulate how their intervention has impacted diagnosis and treatment rates and methods for assessing whether goals have been achieved.

At a minimum, we expect projects to quantitatively monitor outcomes that are indicators of long-term impacts on maternal health outcomes. Additionally, we encourage project evaluations to include qualitative features such as collecting stories of women who positively benefitted from the project, including women who initially felt unheard after reporting symptoms. Stories should focus on how the funded intervention changed their course of treatment, improved their clinical outcomes, and addressed any symptoms that were overlooked and undiagnosed. We expect recipients to address all applicable privacy considerations and be fully compliant with applicable federal/state privacy laws, including HIPAA, to protect confidentiality in the collection and sharing of those stories.

Additionally, recipients should describe the dissemination plan to share both quantitative and qualitative outcomes of the intervention.

c. Transition a successful project to sustainability

We expect recipients to plan for and work toward sustainability of successful evidence-based interventions beyond the end of the funded project. Recipients should begin to develop a plan for sustainability by the end of the second year. We expect the plan to identify key individuals and/or organization(s) whose support will be required to sustain activities; financial and staff resources needed; and existing collaborative partnerships with organizations that might support continuation of the project after the final budget period expires. After three years, successful projects will have the option to compete for one more year of funding to transition to sustainability.

d. Disparity Impact Statement

Recipients are expected to develop a disparity impact statement (DIS) during the project period using local data to identify populations at highest risk for health disparities relative to this initiative.¹ A DIS refers to the demographic, cultural, and linguistic data that identify the population(s) in which health disparities exist and the quality improvement plan designed to

¹ Applicants may choose to use the Centers for Disease Control (CDC)/Agency for Toxic Substances and Disease Registry (ATSDR) Social Vulnerability Index (SVI) [<https://www.atsdr.cdc.gov/placeandhealth/svi/index.html>], or other local data tools, in developing disparity impact statements.

address the noted disparities. The DIS will provide the measurement framework for ongoing monitoring and determining the impact of the project activities on outcomes and overarching goal of advancing health equity. Project activities must comply with the non-discrimination requirements described in Section H.6.

Below are available HHS resources:

- CMS.gov: Quality Improvement & Interventions: Disparity Impact Statement (<https://www.cms.gov/About-CMS/Agency-Information/OMH/resource-center/hcps-and-researchers/quality-improvements-and-interventions>)
- SAMHSA.gov: Disparity Impact Statement (<https://www.samhsa.gov/grants/grants-management/disparity-impact-statement>)
- OMH Disparity Impact Strategy (<https://www.minorityhealth.hhs.gov/omh/content.aspx?ID=22540>)

Additional information and links to resources are available in Section K.3.

C. AUTHORITY

Section 1703(a) of the PHS Act (42 U.S.C. § 300u-2(a)), and section 229 of the PHS Act (42 U.S.C. § 237a)

D. FEDERAL AWARD INFORMATION

The Office on Women’s Health intends to make funds available for competing grant awards. The final funding amount will not be determined until enactment of the FY 2022 federal budget.

We will fund awards in annual increments (budget periods) and generally for a period of performance up to three (3) years with an optional competitive fourth year, although we may approve shorter periods of performance. Recipients will be required to submit a non-competing continuation application for each budget period for the second and third years. We anticipate offering a competing continuation for a fourth year for the purpose of providing funding to support selected recipients as they transition projects to sustainability. Budget periods may also vary from the estimate indicated below due to timing of award issuance or other administrative factors. Funding for all approved budget periods beyond the first is generally level with the initial award amount and is contingent upon the availability of funds, satisfactory progress of the project, adequate stewardship of Federal funds, and the best interests of the government.

Award Information

Estimated Federal Funds Available: \$ 2,200,000

Anticipated Number of Awards: 8

Award Ceiling (Federal Funds including indirect costs): \$ 300,000 per budget period

Award Floor (Federal Funds including indirect costs): None (i.e., \$0)

Anticipated Start Date: September 15, 2022

Estimated Period of Performance: Not to exceed 3 year(s) with an optional competitive 4th year for transition to sustainability

Anticipated Initial Budget Period Length: 12 months

Type of Award: Grant

Type of Application Accepted:

Electronic via Grants.gov ONLY unless an exemption is granted

E. ELIGIBILITY INFORMATION

1. Eligible Applicants

Any public or private (profit or 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. Community-based organizations, faith-based organizations and American Indian/Alaska Native/Native American (AI/AN/NA) organizations are eligible to apply. Examples of eligible Organizations include:

- State Governments
- U.S. territories
- 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 institutions of higher education
- For profit organizations, including small businesses.

2. Cost Sharing or Matching

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 as described in Section F.3.b.1(t). Voluntary cost sharing is not expected for research applications. 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 cost sharing or matching, whether required or voluntary, 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. See Section F.3.b.1(s). Any change in the responsibility to provide cost sharing or matching at that level will require prior approval of the grants management officer.

3. Other – Application Responsiveness Criteria

We will review your application to determine whether it meets the responsiveness criteria below. If your application does not meet the responsiveness criteria, we will disqualify it from the competition; we will not review it beyond the initial screening. The responsiveness criteria are as follows:

- You must identify in the first paragraph of your project narrative at least one of the three conditions (endometriosis, fibroids, or PCOS) that you focus on in your project. You may focus on one, two, or all three, but you must state at least one of the three to be responsive.

4. Application Disqualification Criteria

If you successfully submit an application, we will screen it to ensure it meets the below requirements. If we determine your application fails to meet the criteria described below, we will disqualify it, that is, we will **not** review it and will give it **no** further consideration.

- (a) You must submit your application electronically via <https://grants.gov/> (unless an exemption was granted 2 business days prior to the deadline) by the date and time indicated in the DATES section (A.1) of this announcement.
- (b) If you successfully submit multiple applications from the same organization for the same project, we will only review the last application received by the deadline.
- (c) HHS/OASH/GAM deems your application eligible according to section E.1 Eligible Applicants.
- (d) You must complete the required forms in the application package: SF-424, SF-424A, SF-424B, SF-LLL, and Project Abstract Summary.
- (e) Your application must be submitted in the English language and must be in the terms of U.S. dollars (45 C.F.R. § 75.111(a)).
- (f) Your Project Narrative section of the application must be double-spaced, on the equivalent of 8 ½ ” x 11” page size, with 1” margins on all sides (top, bottom, left and right) and font size not less than 12 points.
- (g) Your Project Narrative must not exceed **25** pages. NOTE: The following items do not count toward the Project Narrative page limit: all required forms, including SF-424, SF-424A, SF-424B, SF-LLL, Project Abstract Summary, and Budget Narrative (including budget tables).
- (h) Your total application, including the Project Narrative plus Appendices, must not exceed **50** pages. NOTE: items listed in “(g)” immediately above do not count toward total page limit.
- (i) Your Federal funds request including indirect costs must not exceed the maximum indicated in Award Ceiling.
- (j) Your Federal funds request including indirect costs must not be below the minimum indicated in Award Floor.
- (k) Your application must meet the Application Responsiveness Criteria outlined above.
- (l) If your application includes cost sharing (voluntary or required), you must include in your budget narrative a non-federal sources justification.

F. APPLICATION AND SUBMISSION INFORMATION

1. Address to Request Application Package

You may obtain an application package electronically by accessing Grants.gov at <https://www.grants.gov/>. You can find it by searching on the CFDA number shown on page 1 of this funding opportunity announcement. If you have problems accessing the application or difficulty downloading, contact:

OASH Grants and Acquisitions Management Division

Phone: 240-453-8822

Email: OASH_Grants@hhs.gov

2. Content and Form of Application Submission

a. Application Format

Your application must be prepared using the forms and information provided in the online application package. This includes but is not limited to: SF-424 Application for Federal Assistance; SF-424A Budget Information for Non-Construction Programs; SF-424B Assurances for Non-Construction Programs.; SF-LLL Disclosure of Lobbying Activities; and Project Abstract Summary.

We encourage individuals to use their full name (first, middle, last) on the Standard Forms and other documents such as resumes and curriculum vitae to distinguish them for verification in the System for Award Management exclusion records. Delays may result in award processing if full names are not provided. NOTE: only one Project Director/Principal Investigator will be named on any resulting award. You should clearly identify the individual in that role in your application.

The Project Narrative, and total application including appendices, must adhere to the page limit indicated in Application Disqualification Criteria listed in Section E.4. The page limit does not include the Budget Narrative (including budget tables), required forms, assurances, and certifications as described in the Application Disqualification Criteria.

Please do not number pages or include a table of contents. Our grants management system will generate page numbers once your application is complete. If your application exceeds the specified page limits for the Project Narrative or Project Narrative plus Appendices when printed on 8.5" X 11" paper, we will not review it. We recommend you print out your application before submitting electronically to ensure that it is within the page limits and is easy to read.

You must double-space the Project Narrative pages.

You should use an easily readable typeface, such as Times New Roman or Arial. You *must* use 12-point font. You may single-space tables or use alternate fonts but you must ensure the tables are easy to read.

b. Appendices Format

Your Appendices should include any specific documents outlined in Section F.3.c, under the heading “Appendices” in the Application Content section of this funding opportunity announcement. Your documents should be easy to read. You should use the same formatting specified for the Project Narrative. However, documents such as résumés/CVs, organizational charts, tables, or letters of commitment may use formatting common to those documents, but the pages must be easy to read. All of your appendices must be uploaded as a single, consolidated file in the Attachments section of your Grants.gov application.

c. Project Abstract Summary Format

You must complete the Project Abstract Summary form provided in the application package. The abstract will be used to provide reviewers with an overview of the application and will form the basis for the application summary in grants management and program summary documents. If your project is funded, HHS may publish information from your form; therefore, do not include sensitive or proprietary information.

Research awards may enter zero for “Estimated number of people to be served as a result of the award of this grant.

d. Budget Narrative Format

The Budget Narrative should use the formatting required of the Project Narrative for the explanatory text. Budget tables may be single-spaced but should be laid out in an easily-readable format and within the printable margins of the page.

3. Application Content

Successful applications will contain the following information:

a. Project Narrative Content

The Project Narrative is the most important part of the application, since it will be used as the primary basis to determine whether your project meets the minimum requirements for an award under this announcement. The Project Narrative should provide a clear and concise description of your project. HHS/OASH recommends that your project narrative include the following

components: 1) Statement of Need, 2) Goals, Objectives, and Outcomes, 3) Proposed Demonstration Project, 4) Evaluation, 5) Dissemination, and 6) Organizational Capability.

NOTE: You must identify in the first paragraph of your project narrative at least one of the three conditions (endometriosis, fibroids, or PCOS) that you focus on in your project. You may focus on one, two, or all three, but **you must state at least one of the three to be responsive.** You will be disqualified if you do not identify **in the first paragraph of your project narrative** the condition(s) that your project focuses on (Section E.3).

1) Statement of Need

You should describe in this section, in both quantitative and qualitative terms, the nature and scope of the problem, the proposed intervention, and the condition(s) of focus. Describe the population(s) of focus, including demographic characteristics, and the geographic location. You should detail how the project will potentially affect the populations served, specific subgroups within those populations, and other interested stakeholders as identified. We recommend that you focus your statement of need on the specific aspects of the history and policy considerations bearing on the project area and existing literature with a focus on high-quality evidence, including randomized controlled trials (RCTs), cohort studies, case control studies, and if necessary, case series from the primary literature. Avoid providing a broad or sweeping historical overview that is not directly related to the proposed interventions and activities.

You should describe how your proposed intervention will serve racial/ethnic minorities and disadvantaged populations, including limited-English speaking populations and persons with disabilities. Note, project activities may not involve the selection or exclusion of participants based on race/ethnicity. Additionally, this section should outline who you consider vested stakeholders in the project (e.g., community-based organizations and/or hospitals), how they were or will be identified, and how they will be meaningfully engaged into the project. If applicable, you should provide memoranda of agreement and/or letters of commitment as described below in Section F.3.c.2.

2) Goals, Objectives, and Outcomes

This section should start with the specific question or hypothesis you will address, the rationale for this hypothesis, and how your project's proposed goals and major objectives will address this question. You should provide a realistic and clear timetable for the project activities, and rationale that these timelines are achievable. Describe your objectives in the SMART format (Specific, Measurable, Achievable, Relevant and Time-Oriented). For example: "By [Month Day, Year], create a plan for developing and facilitating pilot programs."

You should clearly state the expected outcome(s) that will result from your project after you: (1) Develop a demonstration project that implements and evaluates one or more evidence-

based interventions to comprehensively diagnose and treat endometriosis, fibroids, and/or PCOS, conditions which contribute to risk factors and inequities in maternal health outcomes in underserved communities. Applicants must focus on at least one condition and up to three; (2) Identify and track evidence-based outcomes to demonstrate improvements in early diagnosis and effective treatment of one or more of these conditions; and (3) Transition a successful project to sustainability.

HHS/OASH will not fund any project that does not include measurable outcomes. In addition, you should describe how you envision the project will benefit the field at large.

A measurable outcome is an observable end-result that describes how a particular intervention benefits the project participants. It demonstrates the “impact” of the intervention. For example, a change in a client’s financial, health, and/or functional status; mental well-being; knowledge; skill; attitude; awareness; or behavior. It can also describe a change in the degree to which participants exercise choice over the types of services they receive, or whether they are satisfied with the way a service is delivered. Additional examples include: a change in the responsiveness or cost-effectiveness of a service delivery system; a new model of support or care that can be replicated; new knowledge; a measurable increase in community awareness; or a measurable increase in persons receiving services. A measurable outcome is not a measurable output, such as: the number of clients served; the number of training sessions held; or the number of service units provided without demonstration that this improved a measurable clinical outcome.

3) Proposed Demonstration Project

You should provide a clear and concise description of the intervention(s) you are proposing to use to address the need you identified in your statement of need. You should explain the rationale for using a particular intervention(s) and to present a clear connection between identified system gaps and needs and your proposed activities.

Your proposal should detail the nature of the activities to be undertaken, how they address identified issues, and how they will assist in achieving the overall project goals and objectives. You should clarify why these specific activities were selected (e.g., has this approach been successful in other settings or does the research suggest this direction). You should describe how your intervention is evidence-based. For an intervention to be evidence-based, it must be informed by research and utilize effective methodology.

Your proposal should demonstrate how technology will be incorporated to advance programs and services, provide training and/or technical assistance, and/or disseminate information and products. You should provide specifics about the intervention strategies, expected outcomes, and barriers for all anticipated years of the award.

In reference to the Work Plan that you will submit as a table or chart in the Appendices of your application (see Section F.3.c.1), describe your implementation of the above approach over the three-year project. Your proposed approach should include, at a minimum, a description of how you will:

- Develop a demonstration project that implements and evaluates one or more evidence-based interventions to comprehensively diagnose and treat endometriosis, fibroids, and/or PCOS, conditions which contribute to risk factors and inequities in maternal health outcomes in underserved communities. Applicants must focus on at least one condition and up to three.
- Identify and track evidence-based outcomes to demonstrate improvements in early diagnosis and effective treatment of one or more of these conditions.
- Transition a successful project to sustainability.

4) Evaluation

You should describe the methods you will use to evaluate whether or not the proposed intervention achieves its measurable outcome(s) and assess and evaluate the impact of activities you propose. You should describe how you will measure and report on the outcomes of the project, including how the expectation for independence of the evaluator will be met. You should describe the quantitative tools and techniques, and any additional qualitative tools and techniques that you will employ to measure the outcome(s) and how you will identify and document the lessons learned. Your evaluation plan should describe your approach for a robust statistical analysis.

5) Dissemination

You should describe the method you will use to disseminate the project's results and findings in a timely manner and in easily understandable formats to the population served, the general public, and other parties who might be interested in using the results of the project. This may include but is not limited to peer reviewed journals. HHS/OASH may publish (including on a website), all appropriate findings and products (Section H.9). You should propose other, innovative approaches to informing parties who might be interested in using the results of your project to inform practice, service delivery, program development, and/or policy-making, especially to those parties who would be interested in replicating the project.

6) Organizational Capability

You should describe your organization's capability to successfully implement the proposed project. You should describe how your agency (or the particular division of a larger agency which will have responsibility for this project) is organized, the nature and scope of its work, and the capabilities it possesses. Your description should cover your capabilities not included elsewhere in the project narrative, including demonstrated capacity and capability to work with the population of focus, any current or previous relevant experience, and/or the record of the project team in preparing cogent and useful reports, publications, and other products. You should demonstrate relevant, appropriate experience and educational background for proposed positions on the project, as supported by the Curricula vitae or bio sketches for key personnel. If appropriate,

include an organizational chart in Supplementary Information showing the relationship of the project to the current organization (See Section F.3.c.3).

You should clearly delineate the roles and responsibilities of project staff and subrecipients and how they will contribute to achieving the project's objectives and outcomes. You should specify who would have day-to-day responsibility for key tasks such as: leadership of project; monitoring the project's on-going progress; preparation of reports; and communications with other partners and HHS/OASH. You should also describe the approach that will be used to monitor and track progress on the project's tasks and objectives. You should clearly identify the individual who will serve as the Principal Investigator/Project Director and that individual's qualifications, competing time commitments, and related ongoing projects. HHS/OASH expects that, throughout the award period, the Principal Investigator/Project Director will have involvement in, and substantial knowledge about, all aspects of the project.

If applicable, you should describe any collaborative partnership(s) which will support project activities. You should describe the role and makeup of partners intended to be involved in completing specific tasks. Describe the anticipated level of effort and responsibilities of each partner in completing programmatic activities.

Also include information about any contractual and/or supportive staff/organization(s) that will have a secondary role(s) in implementing the project and achieving project goals.

b. Budget Narrative Content

You must complete the required budget forms and submit a budget narrative with detailed justification as part of your application. You must enter the project budget on the Budget Information Non-construction Programs standard form (SF-424A) according to the directions provided with this standard form. The budget narrative consists of a detailed line-item budget that includes calculations for all costs and activities by "object class categories" identified on the SF-424A and justification of the costs. You must indicate the method you are selecting for your indirect cost rate. See Indirect Costs below for further information.

Project budget calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient to verify the calculations. If matching or cost sharing is required, you must include a detailed listing of any funding sources identified in box 18 of the SF-424 (Application for Federal Assistance).

Please be sure to carefully review section F.7 Funding Restrictions for specific information regarding allowable, unallowable, and restricted costs.

You must provide an object class category budget using Section B, box 6 of the SF-424A for the first year of the proposed project. Provide a budget justification, which includes explanatory text and line-item detail, for the first year of the proposed project. The budget narrative should

describe how the categorical costs are derived. Discuss the necessity, reasonableness, and allocation of the proposed costs.

For subsequent budget years, provide a summary narrative and line item budget. For categories or items that differ significantly from the first budget year, provide a detailed justification explaining these changes. Note, **do not include costs beyond the first budget period** in the object class budget in box 6 of the SF-424A or box 18 of the SF-424; the amounts entered in these sections should only reflect the first budget period.

Your budget narrative should justify the overall cost of the project as well as the proposed cost per activity, service delivered, and/or product. For example, the budget narrative should define the amount of work you have planned and expect to perform, what it will cost, and an explanation of how the result is cost effective. For example, if you are proposing to provide services to clients, you should describe how many clients you are expecting to serve, the unit cost of serving each client, and how this is cost effective.

Use the following guidelines for preparing the detailed object class budget required by box 6 of the SF-424A. The object class budget organizes your proposed costs into a set of defined categories outlined below. Both federal and non-federal resources (when required) must be detailed and justified in the budget narrative. "Federal resources" refers only to the HHS/OASH funds for which you are applying. "Non-federal resources" are all other non-HHS/OASH federal and non-federal resources. We recommend you present budget amounts and computations in a columnar format: first column, object class categories; second column, federal funds requested; third column, non-federal resources; and last column, total budget.

Sample Budget Table

Object Class	Federal Funds Requested	Non-federal Resources	Total Budget
Personnel	\$100,000	\$25,000	\$125,000

Note, subrecipient/contract and consultant detailed costs should all be included in those specific line items, not in the overall project object class line items, i.e., subrecipient travel should be included in the Contractual line item not in Travel. **Subrecipient/contract and consultant activities must be described in sufficient detail to describe accurately the project effort that each will conduct.**

1) Object Class Descriptions and Required Justifications

(a) Personnel Description

Costs of staff salaries and wages, excluding benefits.

(b) Personnel Justification

Clearly identify the project director or principal investigator, if known at the time of application. Provide a separate table for personnel costs detailing for each proposed staff person: the title; full name (if known at time of application), time commitment to the project as a percentage or full-time equivalent; annual salary and/or annual wage rate; federally funded award salary; non-federal award salary, if applicable; and total salary. No salary rate may exceed the statutory limitation in effect at the time you submit your application (see Section F.7.b Funding Restrictions, *Salary Rate Limitation* for details). Do not include the costs of consultants, personnel costs of delegate agencies, or of specific project(s) and/or businesses to be financed by the applicant. Contractors and consultants should not be placed under this category.

Sample Personnel Table

Position Title and Full Name	Percent Time	Annual Salary	Federally-funded Salary	Non-federal Salary	Total Project Salary
Project Director, John K. Doe	50%	\$100,000	\$50,000	\$0	\$50,000
Data Assistant, Susan R. Smith	10%	\$30,000		\$3,000	\$3,000

(c) Fringe Benefits Description

Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

(d) Fringe Benefits Justification:

Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, Federal Insurance Contributions Act (FICA) taxes, retirement insurance, and taxes.

(e) Travel Description

Costs of travel by staff of the applicant organization only.

(f) Travel Justification

For each trip proposed for applicant organization staff only, show the date of the proposed travel, total number of traveler(s); travel destination; duration of trip; per diem; mileage allowances, if privately owned vehicles will be used; and other transportation costs and subsistence allowances. **Do not** include travel costs for subrecipients or contractors.

(g) Equipment Description

Equipment means tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the lesser of the capitalization level established by the non-Federal entity for financial statement purposes, or \$5,000. (Note: Acquisition cost means the cost of the asset including the cost to ready the asset for its intended use. Acquisition cost for equipment, for example, means the net invoice price of the equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Acquisition costs for software includes those development costs capitalized in accordance with generally accepted accounting principles (GAAP). Ancillary charges, such as taxes, duty, protective in transit insurance, freight, and installation may be included in or excluded from the acquisition cost in accordance with the non-Federal entity's regular accounting practices.) See 45 C.F.R. § 75.2 for additional information.

(h) Equipment Justification

For each type of equipment requested you must provide a description of the equipment; the cost per unit; the number of units; the total cost; and a plan for use of the equipment in the project; as well as a plan for the use, and/or disposal of, the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy, or section of its policy, that includes the equipment definition; include this with your Budget Narrative file. Reference the policy in this justification and include the policy copy in your Budget Narrative file (not your appendices).

(i) Supplies Description

Costs of all tangible personal property other than those included under the Equipment category. This includes office and other consumable supplies with a per-unit cost of less than \$5,000.

(j) Supplies Justification

Specify general categories of supplies and their costs. Show computations and provide other information that supports the amount requested.

(k) Contractual Description

Costs of all contracts or subawards for services and goods except for those that belong under other categories such as equipment, supplies, construction, etc. Include third-party evaluation contracts, if applicable, and contracts or subawards with subrecipient organizations (with budget detail), including delegate agencies and specific project(s) and/or businesses to be financed by the applicant. This line item is not for individual consultants.

(l) Contractual Justification

Demonstrate that all procurement transactions will be conducted in a manner to provide, to the maximum extent practical, open, and free competition. Recipients and subrecipients are required to use 45 C.F.R. § 75.329 procedures and must justify any anticipated procurement action that is expected to be awarded without competition and exceeds the simplified acquisition threshold fixed by 41 U.S.C. § 134 and currently set at \$250,000. Recipients may be required to make pre-award review and procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc., available to HHS/OASH.

Note: Whenever you intend to delegate part of the project to another entity (including non-employee individuals), you must provide a detailed budget and budget narrative for each subrecipient/contractor, by title/name, along with the same supporting information referred to in these instructions. If you plan to select the subrecipients/contractors post-award and a detailed budget is not available at the time of application, you must provide information on the nature of the work to be delegated, the estimated costs, and the process for selecting the delegate agency.

(m) Other Description

Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to: consultants; insurance; professional services (including audit charges); space and equipment rent; printing and publication; training, such as tuition and stipends; participant support costs including incentives, staff development costs; and any other costs not addressed elsewhere in the budget.

(n) Other Justification

Provide computations, a narrative description, and a justification for each cost under this category.

(o) Indirect Costs Description

Total amount of indirect costs. This category has one of two methods that you may select. You may only select one.

- Your organization currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant federal agency. You should enclose a copy of the current approved rate agreement in your Budget Narrative file. If you request a rate that is less than allowed, your authorized representative must submit a signed acknowledgement that the organization is accepting a lower rate than allowed.
- Per 45 C.F.R. § 75.414 (f) Indirect (F&A) costs, “any non-Federal entity [i.e., applicant] that has never received a negotiated indirect cost rate, ... may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. As described in § 75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or

inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time.”

This method only applies if you have never received an approved negotiated indirect cost rate from HHS or another cognizant federal agency. If you are waiting for approval of an indirect cost rate, you may request the 10% de minimis rate. If you choose this method, costs included in the indirect cost pool must not be charged as direct costs to the award.

(p) Indirect Costs Justification

Provide the calculation for your indirect costs total, i.e., show each line item included in the base, the total of these lines, and the application of the indirect rate. If you have multiple approved rates, indicate which rate as described in your approved agreement is being applied and why that rate is being used. For example, if you have both on-campus and off-campus rates, identify which is being used and why.

(q) Program Income Description

Program income means gross income earned by your organization that is directly generated by this project if funded except as provided in 45 C.F.R. § 75.307(f). Program income includes but is not limited to income from fees for services performed or the use or rental of real or personal property acquired under the award. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income does not include rebates, credits, discounts, and interest earned on any of them. See also 45 C.F.R. § 75.307 and 35 U.S.C. §§ 200-212 (applies to inventions made under Federal awards).

(r) Program Income Justification

Describe and estimate the sources and amounts of program income that this project may generate if funded. Unless being used for cost sharing, if applicable, these funds should not be added to your budget. This amount should be reflected in box 7 of the SF-424A.

(s) Non-Federal Resources Description

Amounts of non-federal resources that will be used to support the project as identified in box 18 of the SF-424. For all federal awards, any shared costs or matching funds and all contributions, including cash and third-party in-kind contributions, must be accepted as part of the recipient’s cost sharing or matching when such contributions meet all of the criteria listed in 45 C.F.R. § 75.306.

For awards that require matching by statute, you will be held accountable for projected commitments of non-federal resources in your application budgets and budget justifications by budget period or by period of performance for fully-funded awards, even if the justification by budget period, or by period of performance for fully-funded awards, exceeds the amount required. Your failure to provide the required matching amount may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports.

For awards that do not require matching or cost sharing by statute or regulation, where “cost sharing” refers to costs of a project in addition to Federal funds requested that you voluntarily propose in your budget, if your application is successful, we will include this non-federal cost sharing in the approved project budget and you will be held accountable for the non-federal cost-sharing funds as shown in the Notice of Award (NOA). Your failure to provide voluntary cost sharing of non-federal resources that have been accepted by HHS/OASH as part of the approved project costs and that are shown as part of the approved project budget in the NOA may result in the disallowance of federal funds. If you are funded, you will be required to report these funds on your Federal Financial Reports. Note, you will not receive any preference, priority, or special consideration in the funding process for voluntarily including non-Federal cost sharing in your proposed budget.

(t) Non-federal Resources Justification

You must provide detailed budget information for every funding source identified in box 18. "Estimated Funding (\$)" on the SF-424. Provide this documentation as part of your Budget Narrative file, not your Appendices.

You must fully identify and document in your application the specific costs or contributions you propose in order to meet a matching requirement. You must provide documentation in your application on the sources of funding or contribution(s). In-kind contributions must be accompanied by a justification of how the stated valuation was determined. Matching or cost sharing must be documented by budget period (or by period of performance for fully-funded awards). **If your application does not include the required supporting documentation for required or voluntary cost-sharing or matching, it will be disqualified from competitive review.**

2) Plan for Recipient Oversight of Federal Award Funds

You must include a plan for oversight of federal award funds which describes:

- how your organization will provide oversight of federal funds and how award activities and partner(s) will adhere to applicable federal award and programmatic regulations. Include identification of risks specific to your project as proposed and how your oversight plan addresses these risks.

- the organizational systems that demonstrate effective control over and accountability for federal funds and program income, compare outlays with budget amounts, and provide accounting records supported by source documentation.
- for any program incentives proposed, the specific internal controls that will be used to ensure only qualified participants will receive them and how they will be tracked.
- organizational controls that will ensure timely and accurate submission of Federal Financial Reports to the OASH Grants and Acquisitions Management Division via the Payment Management System as well as timely and appropriate withdrawal of cash from the Payment Management System.

If your internal controls are available online, it is recommended that you provide the link as part of your plan in the budget narrative. We have also included supplementary information in Section K.1, which contains questions applicants may find useful in considering their Recipient Plans for Oversight of Federal Funds.

c. Appendices

All items described in this section will count toward the total page limit of your application. You must submit them as a **single electronic file** uploaded to the Attachments section of your Grants.gov application.

1) Work Plan

Your Work Plan should reflect, and be consistent with, the Project Narrative and Budget Narrative, and must cover all years of period of performance. However, each year's activities should be fully attainable in one budget year. You may propose multi-year activities, as well as activities that build upon each other, but each phase of the project must be discreet and attainable within a single budget year. Your Work Plan should include a statement of the project's overall goal, anticipated outcome(s), key objectives, and the major tasks, action steps, or products that will be pursued or developed to achieve the goal and outcome(s). For each major task of each year, action step, or product, your work plan should identify the timeframes involved (including start- and end-dates), and the lead person responsible for completing the task. A suggested Work Plan Template is included in Section K.2.

2) Memoranda of Agreement and/or Letters of Commitment

If applicable and available at the time of submission, signed Memoranda of Agreement (MOAs) or signed Letters of Commitment (LOCs) should be submitted for each partner (or one signed MOA with all partners). MOAs must include specific roles, responsibilities, resources, and contributions of partner(s) to the project. If you are unable to submit signed MOAs, you should submit an unsigned MOA(s).

Signed LOCs must detail the specific role and resources that will be provided, or activities that will be undertaken, in support of your project. The partner's expertise, experience, and access to the targeted population(s) should also be described in the LOC.

If applicable, fully executed MOAs may be required as a condition of any award made under this announcement.

MOAs and LOCs are not the same as letters of support. Letters of support are letters that are general in nature that speak to the writer's belief in the capability of an applicant to accomplish a goal/task. Letters of support also may indicate an intent or interest to work together in the future, but they lack specificity. You should NOT provide letters of support. Letters of support will not be considered during the review.

3) Organizational Chart

Include an organizational chart that reflects the management structure for the project and demonstrates where the project resides within the greater organization.

4) Curriculum Vitae/Résumé/Biosketches for Key Project Personnel

You must submit with your application curriculum vitae and/or résumés and/or biographical sketches of the Project Director/Principal Investigator and all other Key Personnel. Key Personnel includes those individuals who will oversee the technical, professional, managerial, and support functions and/or assume responsibility for assuring the validity and quality of your organization's program. This includes at a minimum Project Director/Principal Investigator. You should use full names (first, middle, last) on these documents to distinguish them for verification in the System for Award Management exclusion records. Omission of a middle name or initial may delay the award of an approved application. You should use the formatting common to those documents. (See <https://grants.nih.gov/grants/forms/biosketch.htm> for templates and sample biographical sketches.)

5) References Cited

You should include your references cited in your project narrative. You may use any standard format that you choose as long as it will clearly lead to your source of the information or data.

4. Unique Entity Identifier (UEI) and System for Award Management (SAM)

For applications submitted prior to April 4, 2022, you are required to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal awards through Grants.gov. It is a unique, nine-digit identification number, which provides unique identifiers of single business entities. The DUNS number is free and easy to obtain.

On April 4, 2022, the federal government will complete its transition from using the nine digit DUNS number as the official unique entity identifier to the twelve digit UEI(SAM) number.

The UEI(SAM) will be required for submission of applications from that point forward. You may find additional information about the transition for both existing and new SAM registrants at https://www.fsd.gov/gsafsd_sp?id=gsafsd_kb_articles&sys_id=e31c534f1b40c1103565ed3ce54bcbce.

You will find instructions on the Grants.Gov web site as part of the organization registration process at <https://www.grants.gov/web/grants/applicants/organization-registration.html>.

Your organization must register online in the System for Award Management (SAM). Grants.gov will reject submissions from applicants with nonexistent or expired SAM Registrations.

If you are registering a new entity or renewing your registration, you must submit a notarized letter formally appointing an Entity Administrator to SAM.GOV For detailed instructions on the content of the letter and process for domestic entities see: https://www.fsd.gov/gsafsd_sp?sys_kb_id=8cfe46491b1cb8909ac5ddb6bc4bcbbb&id=kb_article_view&sysparm_rank=1&sysparm_tsqueryId=c6131c131bdcf0d0a7d7da49bc4bcb1a.

A quick start guide for registrants is available at https://www.fsd.gov/sys_attachment.do?sys_id=80f49f211bdcfc909ac5ddb6bc4bcb76. You should allow a minimum of five days to complete an initial SAM registration. Allow up to 10 business days after you submit your registration for it to be active in SAM. This timeframe may be longer if SAM flags the information you provide for manual validation. You will receive an email alerting you when your registration is active.

If your organization is already registered in SAM, you must renew your SAM registration each year. Organizations registered to apply for Federal awards through <https://www.grants.gov> will need to renew their registration in SAM.

You should make sure your SAM registration information is accurate, especially your organization's legal name and physical address including your ZIP+4. Should you successfully compete and receive an award, this information must be included on a Notice of Award. For instructions on updating this information see https://www.fsd.gov/sys_attachment.do?sys_id=d08b64ab1b4434109ac5ddb6bc4bcbbc.

It may take 24 hours or more for SAM updates to take effect in Grants.gov, so if you plan to apply for this funding opportunity or think you might apply, you should ensure your organization's registration is active in SAM well before the application deadline and will be active through the competitive review period.

If you are successful and receive an award, you must maintain an active SAM registration with current information at all times during which your organization has an active award or an application or plan under consideration by an HHS agency.

HHS/OASH cannot make an award until you have complied with these requirements. In accordance with 2 C.F.R. § 25.205, at the time an award is ready to be made, if you have not complied with these requirements, HHS/OASH:

- May determine that 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/UEI number at the time you, the recipient, make a sub-award.

5. Submission Dates and Times

You must submit your application for this funding opportunity by **the date and time indicated in Section A.1 of this announcement**. Your submission time will be determined by the date and time stamp provided by Grants.gov when you **complete** your 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. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or with <https://grants.gov>. Grants.gov can take up to 48 hours to notify you of a successful or rejected submission. You are better off having a less-than-perfect application successfully submitted and under consideration than no application.

If your submission fails due to a system problem with Grants.gov, we may consider your application if you provide verification from Grants.gov indicating system problems existed at the time of your submission **and that time was before the submission deadline**. A “system problem” does not include known issues for which Grants.gov has posted instructions regarding how to successfully submit an application such as compatible Adobe versions or file naming conventions. **As the applicant, it is your responsibility to review all instructions available on Grants.gov regarding successfully submitting an application.**

6. Intergovernmental Review

This program is not subject to the Intergovernmental Review requirements of Executive Order 12372, “Intergovernmental Review of Federal Programs,” as implemented by 45 C.F.R. part 100.

7. Funding Restrictions

Direct and Indirect Costs proposed and, if successful, charged to the HHS/OASH award must meet the cost requirements of 45 C.F.R. part 75 “Uniform Administrative Requirements,

Cost Principles, and Audit Requirements for HHS Awards,” Subpart E—Cost Principles. These requirements apply to you, the applicant, and any subrecipients. You should thoroughly review these regulations before developing your proposed budget.

Indirect costs may be included per 45 C.F.R. § 75.414. See the Budget Narrative section of this announcement for more information. To obtain a negotiated indirect cost rate with the Federal Government you may contact the U.S. Department of Health and Human Services Cost Allocation Services (CAS) regional office that is applicable to your State. CAS regional contact information is available at <https://rates.psc.gov/fms/dca/map1.html>.

a. Pre-Award Costs

Pre-award costs (per 45 C.F.R. § 75.458) are those incurred prior to the effective date of the Federal award directly pursuant to the negotiation and in anticipation of the Federal award where such costs are necessary for efficient and timely performance of the scope of work. Such costs are allowable only to the extent that they would have been allowable if incurred after the date of the Federal award and only with the written approval of the HHS awarding agency.

Pre-award costs are NOT allowed.

b. Salary Rate Limitation

Each year’s appropriations act limits the salary rate that we may award and you may charge to HHS/OASH grants and cooperative agreements. You should not budget award funds to pay the salary of an individual at a rate in excess of Federal Executive Pay Scale Executive Level II. As of January 2022, the Executive Level II salary is \$203,700. This amount reflects an individual’s base salary exclusive of fringe benefits and any income that an individual working on the award project may be permitted to earn outside of the duties to the applicant organization. This salary rate limitation also applies to subawards/subcontracts under an HHS/OASH award.

An example of the application of this limitation for an individual devoting 50% of their time to this award is broken down below:

Individual's <i>actual</i> base full-time salary: \$350,000 50% of time devoted to project, i.e., 0.5 FTE	
Direct salary (\$350,000 x 0.5)	\$175,000
Fringe (25% of salary)	\$43,750
Total	\$218,750
Amount that may be claimed on the application budget due to the legislative salary rate limitation: Individual's base full-time salary <i>adjusted</i> to Executive Level II: \$203,700 with 50% of time devoted to the project	
Direct salary (\$203,700 x 0.5)	\$101,850
Fringe (25% of salary)	\$25,462.50
Total amount allowed	\$127,312,50

Appropriate salary rate limits will apply as required by law.

8. Other Submission Requirements

a. Electronic Submission

HHS/OASH requires that all applications be submitted electronically via the Grants.gov portal unless an exemption has been granted. If you submit an application via any other means of electronic communication, including facsimile or electronic mail, it *will not* be accepted for review unless you receive an exemption as described in the DATES section of this announcement.

You may access the Grants.gov website portal at <https://grants.gov>.

Applications, excluding required standard forms, must be submitted as three (3) files (see acceptable file types below). One file must contain the entire Project Narrative, another the entire Budget Narrative including supporting documentation described in the Budget Narrative content section; and the third file must contain all documents in the Appendices. Any additional files submitted as part of the Grants.gov application will not be accepted for processing and will be excluded from the application during the review process.

Any files uploaded or attached to the Grants.gov application must be Adobe PDF, Microsoft Word, or image formats (JPG, GIF, TIFF, or BMP only) and must contain a valid file format extension in the filename. **We do not accept Microsoft Excel files.**

We strongly recommend 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. Please note, although Grants.gov allows you to attach any file format as part of your application, we restrict this practice and only accept the file formats identified above. Any file submitted as part of the Grants.gov application that is not in a file format listed above will not be accepted for processing and will be excluded from the application during the review process.

Any file submitted as part of the Grants.gov application that contains password protection will not be accepted for processing and will be excluded from the application during the review process. We will not contact you for passwords or resubmission of unprotected files. Unprotected information in the application will be forwarded for consideration but password protected portions will not. You should avoid submitting personally identifiable information such as personal contact information on résumés.

In addition, the use of compressed file formats such as ZIP, RAR, or Adobe Portfolio will not be accepted. We will not contact you for resubmission of uncompressed versions of files. Compressed information in the application will not be forwarded for consideration.

You must submit your application in a format that can easily be copied and read by reviewers. We do not recommend that you submit scanned copies through Grants.gov unless you confirm the clarity of the documents. Pages cannot be reduced resulting in multiple pages on a single sheet to avoid exceeding the page limitation. If you submit documents that do not conform to these instructions, we will exclude them from your application during the review process.

b. Important Grants.gov Information

You may access the electronic application for this program on <https://grants.gov>. You must search the downloadable application page by the Opportunity Number or Assistance Listing (formerly CFDA) number, both of which can be found on page 1 of this funding opportunity announcement.

To ensure successful submission of your application, you should 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. **You are responsible for reviewing all Grants.gov submission requirements on the Grants.gov site.**

You should contact Grants.gov with any questions or concerns regarding the electronic application process conducted through Grants.gov. See Section I.3 for contact information.

See Section F.4 for requirements related to DUNS/UEI numbers and SAM registration.

c. Program-Specific Requirements

There are no program specific requirements.

G. APPLICATION REVIEW INFORMATION

1. Criteria

Federal staff and an independent review panel will assess all eligible applications according to the following criteria. Disqualified applications will not be reviewed against these criteria.

a. Statement of Need (**5 points**)

The degree to which the applicant:

- Identified and clearly defined the need and contributing factors to the need that will be addressed by the project activities using high-quality evidence including randomized controlled trials, cohort studies, case control studies, and if necessary, case series from the primary literature, and policy considerations bearing on the project area.
- Provided relevant quantitative data to describe the evidence-based intervention(s).
- Comprehensively described the population(s) of focus, including demographic characteristics, race/ethnicity, and the geographic area of focus, using recent, local, and disaggregated data wherever possible. Note, project activities may not involve the selection or exclusion of participants based on race/ethnicity.
- Described appropriately the connection between the population of focus and the identified condition(s).
- Detailed how the project will potentially affect the populations served, specific subgroups within those populations, and other interested stakeholders as identified.

b. Goals, Objectives, and Outcomes (**15 points**)

The degree to which the applicant:

- Demonstrated a strong and clear alignment of goals and objectives with the initiative's purpose, expectations, and the statement of need.
- Described the question or hypothesis to be tested, and the expected improvements following intervention(s) described in this project.

- Described goals addressing endometriosis, fibroids, and/or PCOS by improving diagnosis and treatment.
- Described major objectives that outline specific, measurable steps along with a timeline to achieve stated goals. Objectives are Specific, Measurable, Achievable, Relevant, and Time-Oriented (SMART).
- Provided a realistic and clear timetable for the project, and rationale that these timelines are achievable.

c. Proposed Demonstration Project (**25 points**)

The degree to which the applicant:

- Provided a clear and concise work plan, describing the intervention(s) proposed to improve diagnosis, treatment, and outcomes of endometriosis, fibroids, and/or PCOS.
- Described an intervention that is evidence-based. For an intervention to be evidence-based, it must be informed by research and utilize effective methodology.
- Explained the rationale for using a particular intervention and presented a clear connection between identified issues and your proposed activities.
- Detailed the plan for addressing the identified issues, the nature of the activities to be undertaken, how the activities address the identified issues, and how they will assist in achieving the overall project goals and objectives.
- Clarified why these specific activities were selected (i.e., Has this approach been successful in other settings? Does the research suggest this direction?).
- Provided detailed descriptions of specific products or outcomes proposed for development or modification.
- Proposed solutions that are reasonable for any foreseeable significant barriers to the project's execution.
- Demonstrated how technology will be incorporated to advance programs and services, provide training and/or technical assistance, and/or disseminate information and products.
- Provided specifics about the intervention strategies, expected outcomes, and barriers for all anticipated years of the award.

d. Evaluation (**20 points**)

The degree to which the applicant:

- Described the methods this project will use to evaluate whether the proposed intervention achieves its measurable, quantitative outcome(s) and to assess and evaluate the impact of proposed activities.
- Described how outcomes of the project will be measured and reported, including a description of the quantitative tools and techniques, and any additional qualitative tools and techniques this project will employ to measure the outcome(s) and how “lessons learned” will be identified and documented. Your evaluation plan should describe your approach for a robust statistical analysis.

e. Dissemination (**10 points**)

The degree to which the applicant:

- Described the method(s) this project will use to disseminate results and findings in a timely manner and in easily understandable formats to the population served, the general public, and other parties who might be interested in using the results of the project to inform practice, service delivery, program development, and/or policy-making, especially to those parties who would be interested in replicating the project.

f. Organizational Capability (**20 points**)

The degree to which the applicant:

- Demonstrated the organization’s capability and readiness to implement the proposed project to achieve the proposed outcomes.
- Demonstrated a capacity and capability to work with the population of focus.
- Demonstrated relevant, appropriate experience and educational background for proposed positions on the project as supported by the Curricula vitae or bio sketches for key personnel.
- Described the relationships among project personnel in the applicant organization with accountability for project activities in the Organizational chart.
- If applicable, described the role and makeup of potential subrecipients or partners intended to be involved in completing specific tasks and identified the

level of effort each subrecipient is anticipated to provide in completing programmatic activities.

g. **Budget (5 points)**

- The extent to which the proposed budget is adequate for the proposed project, including the degree to which the budget and budget narrative show how the total amount requested was determined; is detailed, reasonable, adequate, cost efficient, and aligned with the proposed technical approach.

2. Review and Selection Process

Each OASH Program's office is responsible for facilitating the process of evaluating applications and setting funding levels according to the criteria set forth above.

An independent review panel will evaluate applications that meet the responsiveness criteria, if applicable, and are not disqualified. These reviewers are experts in their fields, and are drawn from academic institutions, non-profit organizations, state and local government, and Federal government agencies. Based on the Application Review Criteria as outlined under Section E.1, the reviewers will comment on and rate the applications, focusing their comments and scoring decisions on the identified criteria. In addition to the independent review panel, Federal staff will review each application for programmatic, budgetary, and grants management compliance.

The Deputy Assistant Secretary for Women's Health will provide recommendations for funding to the Grants Management Officer to conduct risk analysis. No award decision is final until a Notice of Award is issued by the Grants Management Officer.

In providing these recommendations the Deputy Assistant Secretary for Women's Health will take into consideration the following additional factor(s):

- equitable geographic distribution of award recipients.

3. Review of Risk Posed by Applicant

GAM will evaluate, in accordance with 45 C.F.R. § 75.205, each application recommended for funding by the program official indicated in Review and Selection Process for risks before issuing an award. This evaluation may incorporate results of the evaluation of eligibility or the quality of an application. If we determine that a Federal award will be made, special conditions that correspond to the degree of risk assessed will be applied to the Federal award. Such conditions may include additional programmatic or financial reporting or releasing funds on a

reimbursable rather than cash advance basis. We will use a risk-based approach and may consider any items such as the following:

- a. Your financial stability;
- b. Quality of management systems and ability to meet the management standards prescribed in 45 C.F.R. part 75;
- c. History of performance. Your record in managing Federal awards, if you are a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
- d. Reports and findings from audits performed; and
- e. Your ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

Prior to making a Federal award with a total Federal share greater than the simplified acquisition threshold (currently \$250,000), we are required to review and consider any information about you that is in the designated integrity and performance system accessible through the System for Award Management (SAM) (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). You may, at your option, review information in SAM and comment on any information about yourself that a Federal awarding agency previously entered and is currently available through SAM. We will consider any comments by you, in addition to the other information in the designated system, in making a judgment about your integrity, business ethics, and record of performance under Federal awards when completing the review of risk.

If we do not make an award to you because we determine your organization does not meet either or both of the minimum qualification standards as described in 45 C.F.R. § 75.205(a)(2), we must report that determination to FAPIIS, if certain conditions apply. At a minimum, the information in the system if you are a prior Federal award recipient must “demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics.” 45 C.F.R. § 75.205(a)(2); see also 45 C.F.R. § 75.212 for additional information.

4. Final Award Decisions, Anticipated Announcement, and Federal Award Dates

Upon completion of risk analysis and concurrence of the Grants Management Officer, OASH will issue Notices of Award. No award decision is final until a Notice of Award is issued.

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

OASH seeks to award funds as much in advance of the anticipated project start date shown in Section B “Federal Award Information,” as practicable, with a goal of 10-15 days. Note this is an estimated start date and award announcements may be made at a later date and with a later period of performance start date.

H. FEDERAL AWARD ADMINISTRATION INFORMATION

1. Federal Award Notices

We do not release information about individual applications during the review process. If you would like to track your application, please see instructions at <https://www.grants.gov/web/grants/applicants/track-my-application.html>. The official document notifying you that an application has been approved for funding is the Notice of Award (NOA), approved by a Grants Management Officer of the HHS/OASH GAM. If you are successful, you will receive this document via a system notification from our grants management system (Grant Solutions) and/or via e-mail. This document notifies the successful recipient of the amount awarded, the purposes of the award, the anticipated length of the period of performance, terms and conditions of the award, and the amount of funding to be contributed by the recipient to project costs, if applicable.

If you receive an NOA, we strongly encourage you to read the entire document to ensure your organization’s information is correct and that you understand all terms and conditions. You should pay specific attention to the terms and conditions, as some may require a time-limited response. The NOA will also identify the Grants Management Specialist and Program Project Officer assigned to the award for assistance and monitoring.

If you are unsuccessful or deemed ineligible according to the disqualification criteria, you will be notified by OASH by email and/or letter. If your application was reviewed by the independent review panel, you may receive summary comments pertaining to the application resulting from the review process. On occasion, you may receive a letter indicating that an application was approved but unfunded. These applications may be kept active for one year and may be considered for award without re-competing should funds become available during the hold period.

2. Administrative and National Policy Requirements

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 C.F.R. 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.

In addition, your organization must comply with all terms and conditions outlined in the Notice of Award, the U.S. Department of Health and Human Services (HHS) Grants Policy Statement (GPS), requirements imposed by program statutes and regulations and HHS grant administration regulations, as applicable, as well as any requirements or limitations in any applicable appropriations acts. The current HHS GPS is available at <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>. Please note HHS plans to revise the HHS GPS to reflect changes to the regulations; 45 C.F.R. parts 74 and 92 have been superseded by 45 C.F.R. part 75.

You may only use award funds to support activities outlined in the approved project plan. If your application is funded, your organization will be responsible for the overall management of activities within the scope of the approved project plan. Please consult the HHS GPS Section II and 45 C.F.R. § 75.308 for aspects of your funded project that will require prior approval from the Grants Management Officer for any changes. Modifications to your approved project that will require prior approval include, but are not limited to: a change in the scope or the objective(s) of the project or program (even if there is no associated budget revision, such as reduction in services, closing of service or program site(s)); significant budget revisions, including changes in the approved cost-sharing or matching; a change in a key person specified in your application; reduction in time devoted to the project by the approved project director or principal investigator, either as percentage of full-time equivalent of 25% or more or absence for 3 months or more; or the subawarding, transferring or contracting out of any work that was not described in the approved proposal.

Note that the termination provisions located at 45 CFR § 75.372, Termination, apply to all awards. No additional termination provisions apply unless otherwise noted.

3. Program Specific Terms and Conditions

a. Documentation of Partnerships

If applicable, submission of signed MOAs or LOCs documenting the formation of partnerships may be required as a condition of any award made under this announcement.

b. Disparity Impact Statement

Successful applicants may be expected to develop a disparity impact statement using local data to identify populations at highest risk for health disparities and low health literacy. Additional information and links to resources are available in Section K.3.

4. Closeout of Award

Upon expiration of your period of performance, if we do not receive acceptable final performance, financial, and/or cash reports in a timely fashion within the closeout period, and we determine that closeout cannot be completed with your cooperation or that of the Principal Investigator/ Project Director, we must complete a unilateral closeout with the information available to us. (See H.16 Reporting below for closeout reporting requirements.) If you do not submit all reports within one year of the period of performance end date, we must report your material failure to comply with the terms and conditions of the award with the OMB-designated integrity and performance system (currently FAPIIS). As a result, we may also determine that enforcement actions are necessary, including on another existing or future award, such as withholding support or a high-risk designation.

5. Lobbying Prohibitions

You shall not use any funds from an award made under this announcement for other than normal and recognized executive legislative relationships. You shall not use funds for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

You shall not use any funds from an award made under this announcement to pay the salary or expenses of any employee or subrecipient, or agent acting for you, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

The above prohibitions include any activity to advocate or promote any proposed, pending, or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

6. Non-Discrimination Requirements

Should you successfully compete for an award, recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex (including gender identity, sexual orientation, and pregnancy). This includes ensuring programs are accessible to persons with limited English proficiency and persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficient individuals. See <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>.
- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.
- HHS funded health and education programs must be administered in an environment free of sexual harassment, see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>.
- For guidance on administering your program in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

Contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> or call 1-800-368-1019 or TDD 1-800-537-7697.

The *National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care* (National CLAS Standards), 78 Fed. Reg. 58539, 58543 (HHS Office of Minority Health, 2013, <https://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23164.pdf>), provides a practical framework for applicants to provide quality health care and services to culturally and linguistically diverse communities, including persons with limited English proficiency. For

further guidance on providing culturally and linguistically appropriate services, you should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>.

7. Smoke- and Tobacco-free Workplace

The HHS/OASH strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. This is consistent with the HHS/OASH mission to protect and advance the physical and mental health of the American people.

8. Acknowledgement of Funding

Each year's annual appropriation requires that when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all organizations receiving Federal funds, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state— (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

You must also acknowledge Federal support in any publication you develop using funds awarded under this program, with language such as:

This [project/publication/program/website, etc.] was supported by [Award Number] issued by the Office of the Assistant Secretary for Health of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$XX with 100 percent funded by [PROGRAM OFFICE]/OASH/HHS.

Recipients must also include a disclaimer stating the following

The contents are solely the responsibility of the author(s) and do not necessarily represent the official views of, nor an endorsement by, [PROGRAM OFFICE]/OASH/HHS, or the U.S. Government. For more information, please visit [PROGRAM OFFICE website, if available].

9. HHS Rights to Materials and Data

All publications you develop or purchase with funds awarded under this announcement must be consistent with the requirements of the program. You own the copyright for materials that you develop under this award, and pursuant to 45 C.F.R. § 75.322(b), HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for Federal purposes, and to authorize others to do so. In addition, pursuant to 45 C.F.R. § 75.322(d), the Federal government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

10. Trafficking in Persons

Awards issued under this funding opportunity announcement are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. § 7104) (See <https://www.govinfo.gov/content/pkg/USCODE-2010-title22/html/USCODE-2010-title22-chap78-sec7104.htm>).

11. Efficient Spending

This award may also be subject to the HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing and Publications available at <https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/>.

12. Whistleblower Protection

If you receive an award, you will be subject to a term and condition that applies the terms of 48 C.F.R. § 3.908 to the award, and requires that you inform your employees in writing of employee whistleblower rights and protections under 41 U.S.C. § 4712 in the predominant native language of the workforce.

13. Prohibition on certain telecommunications and video surveillance services or equipment.

As described in 2 C.F.R. 200.216, recipients and subrecipients are prohibited from obligating or spending grant funds (to include direct and indirect expenditures as well as cost share and program) to:

- a. Procure or obtain;
- b. Extend or renew a contract to procure or obtain; or

c. Enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).

1) For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

2) Telecommunications or video surveillance services provided by such entities or using such equipment.

3) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

14. Human Subjects Protection

Federal regulations (45 C.F.R part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, you must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in 45 C.F.R. part 46. You may find it online at <https://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.

Applicants that plan to engage in research involving human subjects are encouraged to provide information regarding participation in research in their recruitment efforts and provide a link to <https://www.hhs.gov/about-research-participation>.

OASH may require, as part of any award, the submission of all IRB approvals within 5 days of the IRB granting the approval and before any work requiring IRB approval begins.

15. Research Integrity

An applicant for or recipient of PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with 42 C.F.R. part 93, including have written policies and procedures for addressing allegations of research misconduct that meet the requirements of part 93, file an Assurance of Compliance with the Office of Research Integrity (ORI), and take all reasonable and practical steps to foster research integrity consistent with 42 C.F.R. § 93.300. The assurance must state that the recipient (1) has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) complies with its own policies and procedures and the requirements of part 93. More information is available at <https://ori.hhs.gov/assurance-program>.

16. Reporting

a. Performance Reports

You must submit performance reports on a **semiannual** basis. Your performance reports must address content required by 45 C.F.R. § 75.342(b)(2). The awarding program office may provide additional guidance on the content of the progress report. You must submit your performance reports by the due date indicated in the terms and conditions of your award via upload to our grants management system (GrantSolutions.gov).

You will also be required to submit a final performance report covering the entire period of performance 120 days after the end of the period of performance. You must submit the final report by upload to our grants management system (GrantSolutions.gov).

b. Performance Measures

At the end of each reporting period, you should be able to:

- Describe accomplishments and progress toward program purpose/strategies/interventions and quantify measurable outcomes as defined in the Work Plan.
- Summarize the status of the project's staffing situation.
- Describe the role and activities of each partnering organization, if applicable.
- Describe accomplishments, current or anticipated problems, changes and progress on the evaluation plan.

c. Financial Reports

You will be required to submit quarterly Federal Financial Reports (FFR) (SF-425). Your specific reporting schedule will be issued as a condition of award. You will also be required to submit a final FFR covering the entire period of performance 120 days after the end of the period of performance. You must submit FFRs via HHS Payment Management System (PMS) (<https://pms.psc.gov>). Quarterly cash reporting via PMS on the FFR is also required.

Once submitted and accepted, your financial reports will be available in GrantSolutions, which is our grant management system.

d. Audits

If your organization expends \$750,000 or greater in Federal funds, it must undergo an independent audit in accordance with 45 C.F.R. 75, subpart F.

e. Non-competing Continuation Applications and Awards

Each year of the approved period of performance, you will be required to submit a noncompeting application which includes a progress report for the current budget year, and work plan, budget and budget justification for the upcoming year. Specific guidance will be provided via Grant Solutions well in advance of the application due date. OASH will award continuation funding based on availability of funds, satisfactory progress of the project, grants management compliance, including timely reporting, and continued best interests of the government. . Progress is assessed relative to meeting the goals, objectives, and outcomes in the approved, funded project as described in the work plan. Additionally, failure to provide final progress or financial reports on other awards from HHS may affect continuation funding.

f. FFATA and FSRS Reporting

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (<https://www.FSRS.gov>) for all sub-awards and sub-contracts issued for \$25,000 or more as well as addressing executive compensation for both recipient and sub-award organizations.

g. Reporting of Matters Relating to Recipient Integrity and Performance

If the total value of your currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of this Federal award, then you must maintain the currency of information reported to the System for Award Management (SAM) that is made available in the

designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) about civil, criminal, or administrative proceedings described in paragraph A.2 of Appendix XII to 45 C.F.R. part 75—Award Term and Condition for Recipient Integrity and Performance Matters. This is a statutory requirement (41 U.S.C. § 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. For more information about this reporting requirement related to recipient integrity and performance matters, see Appendix XII to 45 C.F.R. part 75.

h. Other Required Notifications

Before you enter into a covered transaction at the primary tier, in accordance with 2 C.F.R. § 180.335, you as the participant must notify OASH, if you know that you or any of the principals for that covered transaction:

- Are presently excluded or disqualified;
- Have been convicted within the preceding three years of any of the offenses listed in 2 C.F.R. § 180.800(a) or had a civil judgment rendered against you for one of those offenses within that time period;
- Are presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses listed in 2 C.F.R. § 180.800(a); or
- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

At any time after you enter into a covered transaction, in accordance with 2 C.F.R. § 180.350, you must give immediate written notice to OASH if you learn either that—

- You failed to disclose information earlier, as required by 2 C.F.R. § 180.335; or
- Due to changed circumstances, you or any of the principals for the transaction now meet any of the criteria in 2 C.F.R. § 180.335.

I. CONTACTS

1. Administrative and Budgetary Requirements:

For information related to administrative and budgetary requirements, contact the HHS/OASH grants management specialist listed below.

Duane Barlow
Grants and Acquisitions Management
1101 Wootton Parkway, Plaza Level
Rockville, MD 20852
Phone: 240-453-8822
Email: duane.barlow@hhs.gov

2. Program Requirements

For information on program requirements, please contact the program office representative listed below.

Linda Stella
Office on Women's Health,
200 Independence Ave. SW
Washington, DC 20201
Phone: 202-690-7650
Email: linda.stella@hhs.gov

3. Electronic Submission Requirements

For information or assistance on submitting your application electronically via Grants.gov, please contact Grants.gov directly. Assistance is available 24 hours a day, 7 days per week.

GRANTS.GOV Applicant Support
Website: <https://www.grants.gov>
Phone: 1-800-518-4726
Email: support@grants.gov

J. OTHER INFORMATION

1. Awards under this Announcement

We are not obligated to make any Federal award as a result of this announcement. If awards are made, they may be issued for periods shorter than indicated. 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.

2. Application Elements

The below is a summary listing of all the application elements required for this funding opportunity.

- 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
- Project Narrative – Submit all Project Narrative content as a single acceptable file, specified above.
- Budget Narrative – Submit all Budget Narrative content as a single acceptable file, specified above.
- Appendices – Submit all appendix content as a single acceptable file, specified above **in the Attachments section of your Grants.gov application.**
 - Work Plan
 - MOAs and Letters of Commitment
 - Organizational Chart
 - Curriculum Vitae/Resume/Biographical Sketches
 - References Cited

Dorothy Fink, MD
Deputy Assistant Secretary for Women's Health
Director, Office on Women's Health

4/28/2022

Date

K. SUPPLEMENTARY MATERIALS

1. Considerations in Recipient Plans for Oversight of Federal Funds

(See also Section F.3.b.2)

To the maximum extent possible, a recipient organization should segregate responsibilities for receipt and custody of cash and other assets; maintaining accounting records on the assets; and authorizing transactions. In the case of payroll activities, the organization, where possible, should segregate the timekeeping, payroll preparation, payroll approval, and payment functions.

Questions for consideration in developing your plan may include:

- Do the written internal controls provide for the segregation of responsibilities to provide an adequate system of checks and balances?
- Are specific officials designated to approve payrolls and other major transactions
- Does the time and accounting system track effort by cost objective?
- Are time distribution records maintained for all employees when his/her effort cannot be specifically identified to a particular program cost objective?
- Do the procedures for cash receipts and disbursements include:
 - Receipts are promptly logged in, restrictively endorsed, and deposited in an insured bank account?
 - Bank statements are promptly reconciled to the accounting records, and are reconciled by someone other than the individuals handling cash, disbursements and maintaining accounting records?
 - All disbursements (except petty cash or EFT disbursements) are made by pre-numbered checks?
 - Supporting documents (e.g., purchase orders, Invoices, etc.) accompany checks submitted for signature and are marked "paid" or otherwise prominently noted after payments are made?

2. EXAMPLE WORK PLAN TEMPLATE

Sept. 15, 2022 – Sept. 14, 2023

Recipient Name _____ Funds Requested _____

<i>Goal 1:</i>		
<i>SMART Objective 1:</i>		
Measurable Outcomes for Objective 1: a. b. c.		
<i>Activities</i> in support of Objective 1: a. b. c.	Person/agency responsible for <i>Accomplishing Activities.</i> a. b. c.	<i>Activity Timeline.</i> a. b. c.

3. Disparity Impact Statements

Disparity impact statements are a part of a comprehensive data-driven approach for identifying and addressing health disparities to promote health equity for racial and ethnic minority populations. A DIS refers to the demographic, cultural, and linguistic data that identify the population(s) in which health disparities exist and the quality improvement plan designed to address the noted disparities.

The DIS will provide the measurement framework for ongoing monitoring and determining the impact of the project activities on outcomes and overarching goal of advancing health equity.

Agencies within the U.S. Department of Health and Human Services offer resources to support developing a Disparity Impact Statement, including the following:

- Building an Organizational Response to Health Disparities: Disparities Impact Statement (<https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf>)
- HDPulse — An Ecosystem of Minority Health and Health Disparities Resources (<https://www.nimhd.nih.gov/resources/hd-pulse.html>)

4. References

- American College of Obstetricians and Gynecologists (ACOG). (2016, July). *Polycystic Ovary Syndrome*. Retrieved from Clinical Updates in Women's Health Care: <https://www.acog.org/clinical/journals-and-publications/clinical-updates/2016/07/polycystic-ovary-syndrome>
- Armed Forces Health Surveillance Center (AFHSC). (2011, December). Uterine fibroids, active component females, U.S. Armed Forces, 2001-2010. *MSMR*, 18(12), 10-13.
- Borah, B. J. (2013, July 24). The Impact of Uterine Leiomyomas: A National Survey of Affected Women. *American Journal of Obstetrics and Gynecology*. doi:doi: 10.1016/j.ajog.2013.07.017
- Bougie, O., Yap, M. I., Sikora, L., Flaxman, T., & Singh, S. (2019, August). Influence of race/ethnicity on prevalence and presentation of endometriosis: a systematic review and meta-analysis. *BJOG*, 126(9), 1104-1115. doi:10.1111/1471-0528.15692
- Businesswire. (2021, October 19). Experts Issue a Call-to-Action to Recognize Periods as a Vital Sign of Health to Reduce Disparities in Uterine Fibroid Care for Black Women. *Businesswire*. Retrieved from <https://www.businesswire.com/news/home/20211019005698/en/Experts-Issue-a-Call-to-Action-to-Recognize-Periods-as-a-Vital-Sign-of-Health-to-Reduce-Disparities-in-Uterine-Fibroid-Care-for-Black-Women>
- Centers for Disease Control and Prevention. (2020, February 26). *Overview: Preconception Health*. Retrieved from Before Pregnancy: <https://www.cdc.gov/preconception/overview.html>
- Centers for Disease Control and Prevention. (2020, November 25). *Pregnancy Mortality Surveillance System*. Retrieved from [cdc.gov: https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm#trends](https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm#trends)
- Charron-Prochowik, D., Ferons-Hannan, M., Sereika, S., & Becker, D. (2008, July 1). Randomized Efficacy Trial of Early Preconception Counseling for Diabetic Teens (READY-Girls). *Diabetes Care*, 31(7), 1327-1330. doi:10.2337/dc07-1266
- Chen, Y. M. (2021). Uterine fibroids increase the risk of hypertensive disorders of pregnancy: a prospective cohort study. *Journal of Hypertension*, 1002-1008. doi:doi: 10.1097/HJH.0000000000002729.
- Eltoukhi HM, M. M. (2014). The health disparities of uterine fibroid tumors for African American women: a public health issue. *Am J Obstet Gynecol*, 210(3):194-9. doi: 10.1016/j.ajog.2013.08.008.

- Engmann, L., Jin, S., Sun, F., Legro, R. S., Polotsky, A. J., Hansen, K. R., . . . Santoro, N. (2017, May). Racial and ethnic differences in the polycystic ovary syndrome metabolic phenotype. *Am J Obstet Gynecol*, *216*(5), 493.e1-493.e13. doi:10.1016/j.ajog.2017.01.003
- Gibson-Helm, M., Tassone, E. C., Teede, H. J., Dokras, A., & Garad, R. (2018, January). The Needs of Women and Healthcare Providers regarding Polycystic Ovary Syndrome Information, Resources, and Education: A Systematic Search and Narrative Review. *Semin Reprod Med*, *36*(1), 35-41. doi:10.1055/s-0038-1668086
- Guidone, H. C. (2020). The Womb Wanders Not: Enhancing Endometriosis Education in a Culture of Menstrual Misinformation. In C. Bobel, I. T. Winkler, B. Fahs, K. A. Hasson, E. A. Kissling, & T. A. Roberts, *The Palgrave Handbook of Critical Menstruation Studies* (pp. 269-286). Singapore: Palgrave Macmillan.
- Guo, X. C. (2012). The Impact and Management of Fibroids for Fertility: an evidence-based approach. *Obstetrics and Gynecology Clinics of North America*, *39*(4), 521-533. doi:https://doi.org/10.1016/j.ogc.2012.09.005
- Johns Hopkins Medicine. (n.d.). *Polycystic Ovary Syndrome (PCOS)*. Retrieved November 5, 2021, from Health: Conditions and Diseases: <https://www.hopkinsmedicine.org/health/conditions-and-diseases/polycystic-ovary-syndrome-pcos>
- Kiconco, S., Teede, H. J., Earnest, A., Loxton, D., & Joham, A. E. (2021). Menstrual cycle regularity as a predictor for heart disease and diabetes: Findings from a large population-based longitudinal cohort study. *Clinical Endocrinology*, 1-12. doi:10.1111/cen.14640
- Lalani, S., Choudhry, A. J., Firth, B., Bacal, V., Walker, M., Wen, S. W., . . . Chen, I. (2018, October 1). Endometriosis and adverse maternal, fetal and neonatal outcomes, a systematic review and meta-analysis. *Hum Reprod*, *33*(10), 1854-1865. doi:10.1093/humrep/dey269
- Lee, H. J. (2010). Contemporary Management of Fibroids in Pregnancy. *Obstetrics & Gynecology*, Retrieved from US National Library of Medicine, National Institutes of Health: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2876319/>.
- Radhika, B. H., Naik, K., Shreelatha, S., & Vana, H. (2015). Case series: Pregnancy Outcome in Patients with Uterine Fibroids. *J Clin of Diagn Res*, *9*(10), QR01-QR04. doi:10.7860/JCDR/2015/14375.6621
- Teede, H., Misso, M., Costello, M., Dokras, A., Laven, J., Moran, L., . . . Norman, R. (2018). *International evidence-based guideline for the assessment and management of polycystic ovary syndrome 2018*. Melbourne: Monash University. Retrieved from https://www.monash.edu/_data/assets/pdf_file/0004/1412644/PCOS_Evidence-Based-Guidelines_20181009.pdf
- U.S. Department of Veterans Affairs. (n.d.). *Preconception Care*. Retrieved from VAMobile.

World Helath Organization. (2019, Spetember 19). *Maternal mortality*. Retrieved from Newsroom Factsheets: <https://www.who.int/news-room/fact-sheets/detail/maternal-mortality>