Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

U.S. Food and Drug Administration (FDA (http://www.fda.gov/))

NOTE: The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH. Where this Funding Opportunity Announcement (FOA) provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this FOA.

The FDA does not follow the NIH Page Limitation Guidelines or the NIH Review Criteria. Applicants are encouraged to consult with FDA Agency Contacts for additional information regarding page limits and the FDA Objective Review Process.

Components of Participating Organizations

Center for Biologics Evaluation and Research (CBER (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/default.htm))
Center for Drug Evaluation and Research (CDER (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm))
Center for Devices and Radiological Health (CDRH (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/default.htm))
Center for Tobacco Products (CTP (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/default.htm))
Center for Veterinary Medicine (CVM (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/default.htm))
Center for Food Safety and Applied Nutrition (CFSAN (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/default.htm))
National Center for Toxicological Research (NCTR (http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/default.htm))
Office of the Commissioner (OC (http://www.fda.gov/AboutFDA/CentersOffices/OC/default.htm))
Office of Regulatory Affairs (ORA (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/default.htm))

Funding Opportunity Title

FDA Support for Conferences and Scientific Meetings (R13 Clinical Trial Not Allowed)

Activity Code

R13 (//grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=r13&Search.x=0&Search.y=0&Search_Type=Activity) Support for Conferences and Scientific Meetings

Announcement Type

Reissue of PAR-19-306 (https://grants.nih.gov/grants/guide/pa-files/PAR-19-306.html)

Related Notices

None

Funding Opportunity Announcement (FOA) Number

PAR-23-072

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.103

Funding Opportunity Purpose

The purpose of the FDA (R13) Scientific Conference Grant Program is to facilitate the provision of federal financial assistance in support of high-quality conferences and scientific meetings designed to research and investigate a topic clearly aligned with the FDA mission. The FDA recognizes the value of supporting high quality conferences and scientific meetings relevant to its mission and to the public health. A conference or scientific meeting is defined as a symposium, seminar, workshop, or any formal meeting, whether conducted face-to-face or virtually to exchange information and explore a defined subject, issue, or area of concern impacting the public's health within the scope of the FDA's mission. Permission to submit a conference grant application does not assure funding or funding at the level requested. FDA will not issue a conference grant award unless it can be issued before the conference start date.

Key Dates

Posted Date

December 1, 2022

Open Date (Earliest Submission Date)

February 1, 2023, 2024, 2025 for April 2023, 2024, 2025 application due dates.

August 1, 2023, 2024, 2025 for October 2023, 2024, 2025 application due dates.

Letter of Intent Due Date(s)

8 weeks prior to the selected application due date.

Prior approval (advance permission to apply) in the form of a Letter of Intent is required before submission of an application for conference support. Advance permission to submit an application must be requested early in the process and must be submitted no later than 8 weeks before the selected application due date. Letter(s) of Intent received after 8 weeks prior to the application submission date will not be accepted.

Application Due Date(s)

April 12, 2023 and October 12, 2023 by 11:59 PM Eastern Time.

April 12, 2024 and October 11, 2024 by 11:59 PM Eastern Time.

April 11, 2025 and October 10, 2025 by 11:59 PM Eastern Time.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Applicants should be aware that on-time submission means that an application is submitted error free (of both Grants.gov and eRA Commons errors) by 11:59 PM Eastern Time on the application due date.

Late applications will not be accepted for this FOA.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

April deadline - June review

October deadline - December review

Generally objective review will occur two-three months after application receipt date. However, objective review date(s) depends on the availability of qualified reviewers and may not occur as listed above. Applicants are strongly encouraged to pursue funding for their conferences and scientific meetings well in advance of the anticipated meeting date.

Advisory Council Review

Not Applicable

Earliest Start Date

April deadline - July

October deadline - January

Note: Earliest start date depends on objective review date(s) and may not occur as listed above. Applicants are strongly encouraged to pursue funding for their scientific conference well in advance of (at least 6 months) the anticipated meeting date.

Expiration Date

October 11, 2025

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts* (//grants.nih.gov/grants/guide/)). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons (http://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov (https://www.grants.gov/web/grants/applicants/download-application-package.html#search=true&oppNum=PAR-23-072) Workspace to prepare and submit your application and eRA Commons (/grants/guide/ApplyButtonSplash.cfm?dest=http://public.era.nih.gov/commons/) to track your application.

Table of Contents

Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

The FDA recognizes the value of supporting high quality conferences and scientific meetings relevant to its mission and to the public health. A conference or scientific meeting is defined as a symposium, seminar, workshop, or any other organized and formal meeting, whether conducted face-to-face or virtually, to exchange technical information and views or explore or clarify a defined subject, problem, or area of knowledge impacting the public's health within the scope of the FDA's mission, whether or not a published report results from such meeting. Support of such meetings is contingent upon the fiscal and programmatic interests and priorities of the FDA's respective Offices and Centers.

Therefore, a conference grant application is required to contain an advance permission-to-submit letter from one of the participating FDA Centers listed under Components of Participating Organizations. Applicants are urged to initiate contact well in advance of the chosen application due date and no later than 8 weeks before that date. Please note that agreement to accept an application does not guarantee funding. In general, FDA will not issue a conference grant award unless the Federal award date can precede the conference start date.

Advanced Permission to Submit an Application:

A Letter of Intent requesting advanced permission to submit a conference application is required and must be received via e-mail no later than eight (8) weeks prior to the selected application due date.

To request advanced permission to submit an application letter from one of the participating FDA Centers/Offices, applicants must submit the following information on applicant organizational letterhead:

- FOA Number and Title;
- Selected application due date;
- FDA Center/Office that the application is seeking advanced permission to apply to;
- Meeting/conference title;
- Location and date of proposed meeting/conference;
- Names, Address, Telephone number and email address of Institution(s) participating in the application;
- Name, Address, Telephone number and email address of the Principal Investigator/Project Director;
- Names of other key personnel (if any) and points of contact;
- Number of anticipated attendees;
- Purpose, benefit, objectives and/or justification of the meeting/conference and how it aligns with the mission and program priorities of the targeted FDA Center/Office;
- Estimated budget that will be requested for the meeting/conference and purpose; and
- List other sources of funding (secured and planned), if applicable.

All advanced permission to submit an application requests must be submitted via email to the Grants Management Contact listed in Section VII. Agency Contacts of this FOA. Applicants are urged to initiate contact well in advance of the chosen application due date and no later than 8 weeks before that date. Advanced permission to submit an application requests received after 8 weeks prior to the selected application due date will not be accepted. Please note that agreement to accept an application does not guarantee funding or funding at the level requested.

The FDA recognizes that the value of conferences is enhanced when persons from diverse backgrounds and perspectives are included in all aspects of conference/meeting planning and when attendees are assured of a safe, respectful, and inclusive environment free from discrimination, harassment, and other barriers that might prevent or inhibit one's participation. FDA encourages conference grant applicants to enhance diversity by increasing the participation of individuals from diverse backgrounds, including those from underrepresented groups, in the planning and implementation, and ultimately, participation in the proposed conference. Underrepresented groups include individuals from nationally (US) underrepresented racial and ethnic groups, individuals with disabilities, individuals from disadvantaged backgrounds, and women. Applications for FDA support of conferences and scientific meetings must include a plan to enhance diversity in all aspects of conference planning and implementation. Diversity plans will be assessed during the scientific and technical merit review of the application.

FDA is also committed to changing the culture of science to end sexual harassment (https://www.nih.gov/about-nih/who-we-are/nih-director/statements/changing-culture-science-end-sexual-harassment) and other forms of harassment, including harassment on the basis of race, color, national origin, sex/gender, disability, and age in FDA-funded activities. Harassment, in any form, is detrimental and presents obstacles that hinder an individual's ability to fully participate in science. Only in safe, respectful, and inclusive environments can individuals achieve their fullest potential and support the mission of the FDA. It is expected that organizers of FDA-supported conferences and scientific meetings take steps to maintain a safe and respectful environment for all attendees by providing an environment free from all forms of discrimination and harassment, sexual or otherwise. Consistent with Federal civil rights laws, it is expected that organizers of FDA-supported conferences employ strategies that seek to prevent or mitigate the effects of discrimination and harassment, sexual and otherwise. Below are examples of strategies, which are not inclusive of all strategies, that could be employed to support a safe environment (conference organizers should consider additional strategies as appropriate):

- Establishing a conference code of conduct with clearly stated expectations of behavior, systems of reporting, and procedures for addressing inappropriate behavior. The code of conduct and reporting mechanisms should be clear and accessible to all meeting attendees.
- Providing resources to support individuals who report incidents of harassment, including:
  - personnel trained in advocacy and counseling
  - referrals to legal or health care resources
  - procedures for ensuring the safety of all conference attendees, up to and including removing a perpetrator from the conference
- Conducting conference climate surveys specifically related to sexual harassment and professional misconduct

Additionally, all FDA sponsored and/or supported conferences must be held at accessible sites, as outlined by section 504 of the Rehabilitation Act of 1973 and, as applicable, the Americans with Disabilities Act of 1990. Conference registration materials should provide a questionnaire that will allow participants with disabilities to voluntarily identify any special needs, so that conference organizers can make plans to accommodate these needs.

See Section VIII. Other Information for award authorities and regulations.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Renewal

The OER Glossary (//grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this FOA.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials

Need help determining whether you are doing a clinical trial? (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

The number of awards is contingent upon FDA appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect):

Application budgets submitted to the following FDA Centers/Offices for review and funding consideration may not exceed the following in total cost per year:

OC: up to $50,000

CTP: up to $50,000

CVM: up to $25,000

ORA: up to $50,000

NCTR: up to $30,000

CBER: up to $250,000

CDRH: Unlimited

CFSAN: Unlimited

CDER: Unlimited

All funding consideration is based on the availability of funds

Award Project Period

Awards in support of a single conference will be made for a project period commensurate with the time involved in planning and conducting the conference, including post-conference activities. Typically, this will be one (1) year.

Applicants may propose a multi-year project period, up to five (5) years, for permanently sponsored conferences held annually or biennially on a recurring topic or theme. The availability of funding for subsequent years of multi-year project periods depends on annual appropriations, grantee performance, and Program priorities.

The scope of the proposed project should determine the project period. The maximum project period is five (5) years.

HHS grants policies as described in the *HHS Grants Policy Statement* (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made from this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for FDA support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.
Foreign components, as *defined in the HHS Grants Policy Statement* (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- System for Award Management (SAM)– (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
  - NATO Commercial and Government Entity (NCAGE) Code (//grants.nih.gov/grants/guide/url_redirect.htm?id=11176) – Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
  - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their full SAM and Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.

- Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for FDA support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

2. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement. (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The FDA will not accept duplicate or highly overlapping applications under review at the same time. This means that the FDA will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Research (R) Instructions in the SF424 (R&R) Application Guide (//grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits (//grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed with the following additional requirements:

For this specific FOA, the Research Strategy section is limited to 6 pages.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed with the following additional requirements:

Descriptive Title of Applicant's Project: Enter the title of the scientific conference.

Cover Letter: Advance permission to submit an application is required for all FDA conference grant applications, including new and renewal applications. The letter from an FDA Center/Office documenting advance permission to submit an application (i.e., the permission-to-submit letter) must be submitted with the application and attached as a PDF document. Applications that do not include a permission-to-submit letter will not be accepted for review. Note that advanced permission to submit an application does not guarantee funding.

Only one advanced permission-to-submit letter is required per application.

Applicable only to Renewal Applications:

- For field **4. a. Federal Identifier** - The Federal Identifier is required. Include only the IC and serial number of the previously assigned award number (e.g., use FD007777 from 5R13FD007777-05).
- For field **8. TYPE OF APPLICATION** - applicant must mark "RENEWAL'.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Other Attachments: Diversity Plan

Applicants must include a Diversity Plan attachment in the Other Attachment section. The PDF-formatted document must be named “DiversityPlan.pdf” (no spaces) and must not exceed 1 page in length. The Diversity Plan must:

Specifically describe plans to enhance diversity by increasing the participation of individuals from diverse backgrounds, including those from underrepresented groups (e.g., underrepresented racial and ethnic groups, individuals with disabilities, individuals from disadvantaged backgrounds, and women) in the selection of and/or the makeup of:

- Organizing committee
- Speakers
- Invited participants (e.g., session chairs, panel discussants, etc.)
- Audience

Applicants should consider the geographical conference area from where anticipated participants will come (i.e., national, statewide), the expected size and composition of the audience, as well as the method of selection in describing efforts under the Diversity Plan and how these efforts will be assessed afterwards. Where applicable, applicants should describe the success of previous strategies to enhance diversity in the planning and implementation of conferences. Applicants should describe strategies on including topics and/or activities that support clear aspects of diversity, equity, inclusion, and accessibility (DEIA) and increasing the target audience to include members of "underserved communities", and/or promote DEIA concepts and efforts. Describe any outputs from this conference/meeting that support DEIA objectives. Describe any organizational partnerships with institutions and organizations serving historically underserved communities such as: Historically Black Colleges and Universities (HBCUs); Hispanic-Serving Institutions; Tribal Colleges and Universities; Asian American and Pacific Islander-Serving Institutions; Women’s Colleges and Universities; Organizations serving veterans, individuals with disabilities, LGBTQIA+ individuals, economically disadvantaged; etc.

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R Budget

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

- • Applications requesting multiple years of support must complete and submit a separate detailed budget breakdown and narrative justification for each year of financial support requested.
- • Applications must state if registration fees will be charged; however, such fees should not appear on the proposed budget.
- • Enter the direct costs requested. Facilities and Administrative (F&A) costs are not allowed.

- Provide a narrative justification for each proposed personnel position, including the role of the individual in the conference and the proposed level of effort.
- Include information regarding efforts to obtain funding for this conference from other sources.

Please review allowable and unallowable costs outlined in 6. Funding Restrictions (https://grants.nih.gov/grants/guide/pa-files/PAR-19-306.html#_6._Funding_Restrictions) in developing the budget request.

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Research Strategy: Note that this section will be called “Conference Plan” in the system-generated Table of Contents.

The “Conference Plan” section of the application (uploaded as the Research Strategy attachment), is where applicants should attach their narrative responses to the selection criteria and requirements published in this FOA.

The following information must be included and addressed in the Conference Plan (Research Strategy):

- Title of the meeting/conference;
- Dates of conference(s);
- Location of the conference (venue, city, state);
- Estimate anticipated geographic conference area where participants will come from (i.e., national, statewide), expected number of registrants and type of audience expected with their credentials, as well the method of selection; if possible, provide a percentage breakdown of Federal vs. Non-Federal attendees;
- Conference format and projected agenda(s), including list of principal areas or topics to be addressed, and list of speakers;
- Physical facilities and logistical arrangements required for the conduct of the meeting;
- Justification of the conference(s), including the objectives, the problems it intends to clarify, and any developments it may stimulate; the public health need, timeliness, and usefulness of the conference/meeting to the scientific community;
- Description of the composition and role of the organizing committee, and provide the names and credentials of key participants in the conference /meeting, including the basis for their selection and documentation of their agreement to participate (Letters of agreement to participate from key conference participants, e.g. - speakers, presenters, and session moderators should be attached to line item #14 'Letters of Support') and;
- Information about all related conferences held on this subject during the last 3 years, if available, and how the proposed conference/meeting is similar to, and/or different from these, and why it is still necessary and useful. If this is one of a series of periodic conferences/meetings held by a permanent sponsoring organization, briefly describe and evaluate the last conference/meeting in the series;
- Plans for publicizing the conference/meeting to all interested participants and, if applicable for publishing the proceedings (note that publishing proceedings is not required).If the conference will be a virtual conference, the applicant must address relevant details, such as the medium to be used, how invitations will be issued, and whether participation will be controlled in any manner.

Applications requesting multiple years of support must provide the following additional information for each future year requested, in as much detail as possible:

- budget,
- meeting topics,
- tentative dates, locations, and participants,
- contingency plans for future meetings dependent upon, for example, the outcome of the first year’s conference/meeting or developments in the field.

Applicable only to Renewal Applications:

For Renewal applications, the Conference Plan (Research Strategy) should include a brief Progress Report that summarizes Progress to Date and accomplishments achieved during the current funding period. The Progress Report should include a summary of the aims of the previous project period and the importance of the findings, progress made towards achievements, explanation on any significant changes to the specific aims and any new directions.

Letters of Support: Provide letters of agreement to participate from key conference participants, e.g. speakers, presenters, and session moderators, and attach to line item #14 'Letters of Support'.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide, with the following modification:

- Generally, Resource Sharing Plans are expected, but they are not applicable for this FOA.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered “Yes” to the question “Are Human Subjects Involved?” on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset (https://grants.nih.gov/grants/glossary.htm#DelayedOnsetHumanSubjectStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

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

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to Grants.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (//grants.nih.gov/grants/guide/url_redirect.htm?id=11123), FDA’s electronic system for grants administration. eRA Commons and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. **Late applications will not be accepted for this FOA.**

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (//grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

6. Funding Restrictions

All FDA awards are subject to the terms and conditions, cost principles, and other considerations described in the *HHS Grants Policy Statement* (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) and 45 CFR 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.

Pre-award costs are allowable only as described in the *HHS Grants Policy Statement* (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

Conference awards must be issued before the actual start date of the conference.

Additional funding restrictions may be part of the Notice of Award.

Allowable Costs:

- Conference Services: Grant funds may be used for necessary recording of proceedings, simultaneous translation, and subsequent transcriptions.
- Consultant Services: Grant funds may be used to pay consultant fees, including travel and supporting costs (per diem; subsistence is not allowable).
- Equipment Rental: Grant funds may be used for the rental of necessary equipment.
- Publication Costs: When grant funds are awarded to pay for either the entire or partial cost of publication of proceedings or a book or pamphlet, allowable costs include special plates, charts, diagrams, printing, distribution, mailing, postage, and general handling, unless otherwise specified at the time the grant is awarded.
- Salaries: In accordance with the policy of the grantee organization, grant funds may be used for all or part of the salaries of professional personnel, clerical assistants, editorial assistants, and other non-professional staff in proportion to the time or effort directly related to the conference.
- Speakers Fees: Speakers' fees for services rendered are allowable.
- Supplies: Grant funds may be used for the purchase of supplies for the conference if the supplies are received and used during the budget period.
- Travel: Funds may be used for the travel of staff, speakers, participants, and attendees, if identified in the application and approved at the time of award. Travel expenses for employees of the grantee organization are governed by the grantee's travel policies, consistently applied regardless of the source of funds.
- Any U.S. foreign travel restrictions that are in effect at the time of the award will be followed, such as:
  - A. Limitations or restrictions on countries to which travel will be supported or
  - B. Budgetary or other limitations on availability of funds for foreign travel.

  Transportation costs for attendees and participants at the conference may not exceed coach class fares. In all cases, U.S. flag carriers must be used where possible.

Unallowable Costs:

- Registration Fees: Not allowable.
- Indirect Costs/Facilities and Administrative (F&A) Costs: Not allowable.
- Alterations and Renovations (A&R): Not allowable.
- Membership Dues: Not allowable.
- Entertainment and Personal Expenses: Costs of amusement, diversion, social activities, ceremonials, and related incidental costs related thereto, such as meals, lodging, rentals, transportation gratuities, bar charges, tips, personal telephone calls, and laundry charges of participants or guests, are not allowable.
- Food: All meals/food, beverages or light refreshments, regardless if certain meals are an integral and necessary part of a conference (i.e., a working meal where business is transacted), are not allowable and grant funds may not be used for such costs.
- Equipment Purchase: Grant funds may not be used for the purchase of equipment.
- Federal Employees: Grant funds may not be used to pay for travel costs, or any payment to a Federal employee, except when the employee is on leave without pay status from his or her employing office.
- Visas and Passports: Costs associated with obtaining visas and passports are not allowable.
- Honoraria: Honoraria or other payments given for the purpose of conferring distinction or to symbolize respect, esteem, or admiration are not allowable.
- Local Participants' Expenses: With the exception of local mileage as indicated under "allowable costs under Travel" grant funds may not be used to pay per diem or expenses for local participants in the conference.

- Transportation costs exceeding U.S. carrier coach class fare: Not allowable

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide (https://grants.nih.gov/grants/how-to-apply-application-guide.html). For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to FDA. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (//grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the assigned Grants Management Specialist and responsiveness by components of participating organizations, FDA. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Post Submission Materials

Post-submission materials are those submitted after submission of the grant application but prior to objective review. They are not intended to correct oversights or errors discovered after submission of the application. FDA accepts limited information between the time of initial submission of the application and the time of objective review. Applicants must contact the assigned Grants Management Specialist to receive approval, prior to submitting any post submission materials. Acceptance and/or rejection of any post submission materials is at the sole discretion of the FDA. Any inquiries regarding post submission materials should be directed to the assigned Grants Management Specialist.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific/technical merit.

Significance (20 Points)

Does this conference address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these endeavors on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s) (20 Points)

Is (are) the PD/PI(s) well suited for organizing and fulfilling the goals of this conference/scientific meeting? Are the qualifications and past performance of the PD/PI(s) appropriate, and are they well suited for their described roles in the conference/scientific meeting? Are the key personnel and selected speakers appropriate and well suited for their described roles in the conference/scientific meeting?

Innovation (20 Points)

Does the conference/scientific meeting draw together appropriate experts who may otherwise not have an opportunity to meet?

Approach (20 Points)

Are the format and agenda for the conference/meeting appropriate for achieving the specified goals? Is the conference/meeting timely for the subject matter? For applications designating multiple PDs/PIs, is the Leadership Plan approach, including the designated roles and responsibilities, governance and organizational structure consistent with and justified by the topics of the conference/meeting and the expertise of each of the PD/PIs?

Environment (20 Points)

Is the conference site appropriate? Does the applicant organization have the ability to contribute to the probability of success? Do the proposed meetings, exhibits, interactions, etc., take advantage of unique features of the environment or employ useful collaborative arrangements? Is institutional support evident?

Additional Review Considerations

As applicable for the project proposed, reviewers will evaluate the following additional items but will not give separate scores for these items and should not consider them in providing an overall score.

Diversity Plan

How well does the diversity plan demonstrate efforts to enhance diversity by increasing the participation of individuals from diverse backgrounds, including those from underrepresented groups, in the planning and implementation, and participation in the proposed conference? Underrepresented groups include individuals from nationally underrepresented racial and ethnic groups, individuals with disabilities, individuals from disadvantaged backgrounds, and women.

Protections for Human Subjects

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Vertebrate Animals

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Biohazards

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Resubmissions

Not Applicable.

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

Revisions

Not Applicable.

Applications from Foreign Organizations

Not Applicable.

Select Agent Research

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Resource Sharing Plans

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Authentication of Key Biological and/or Chemical Resources:

Generally not applicable. Reviewers should bring any concerns to the attention of assigned Grants Management Specialist.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Objective Review Committee using the stated review criteria.

As part of the objective review, all applications:

- Will receive a written critique.

Appeals of objective review will not be accepted for applications submitted in response to this FOA.

Applications will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by objective review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

3. Anticipated Announcement and Award Dates

Successful applicants will be notified of additional information that may be required or other actions leading to an award. The decision not to award a grant, or to award a grant at a particular funding level, is discretionary and is not subject to appeal to any FDA or HHS official or board.

Section VI. Award Administration Information

1. Award Notices

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section IV.5. Funding Restrictions and in the Notice of Award. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), this FOA, and Notice of Award.

Institutional Review Board or Independent Ethics Committee Approval: For projects that involve Human Subjects and/or Clinical Trials Research, Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in FDA-funded studies, the recipient must provide FDA copies of documents related to all major changes in the status of ongoing protocols.

2. Administrative and National Policy Requirements

All FDA grant and cooperative agreement awards include the *HHS Grants Policy Statement* (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) as part of the NoA.

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions 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.

Should the applicant organization 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 identify, 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. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html (https://www.hhs.gov/civil-

rights/for-providers/provider-obligations/index.html) and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html)

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to FDA grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this FOA.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to 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 (https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html) and https://www.lep.gov (https://www.lep.gov/).
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including reasonable accommodations and making services accessible to them, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (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 (https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html). For information about FDA's commitment to supporting a safe and respectful work environment, and what FDA's expectations are for institutions and the individuals supported on FDA-funded awards, please see https://www.fda.gov/science-research/about-science-research-fda/fda-sexual-harassment-policy-concerning-extramural-research (https://www.fda.gov/science-research/about-science-research-fda/fda-sexual-harassment-policy-concerning-extramural-research).

For guidance on administering programs in compliance with applicable federal conscience protection and associated anti-discrimination laws see https://www.hhs.gov/conscience/conscience-protections/index.html (https://www.hhs.gov/conscience/conscience-protections/index.html) and https://www.hhs.gov/conscience/religious-freedom/index.html (https://www.hhs.gov/conscience/religious-freedom/index.html).

Please 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 (https://www.hhs.gov/ocr/about-us/contact-us/index.html) or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), FDA awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a Federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all FDA grants and cooperative agreements.

FDA considers the sharing of research resources developed through FDA-sponsored research an important means to enhance the value and further the advancement of research. When research resources have been developed with FDA funds and the associated research findings published, those findings must be made readily available to the scientific community.

Upon acceptance for publication, scientific researchers must submit the author's final manuscript of the peer-reviewed scientific publication resulting from research supported in whole or in part with FDA funds to the NIH National Library of Medicine's (NLM) PubMed Central (PMC). FDA defines the author's final manuscript as the final version accepted for journal publication, which includes all modifications from the publishing peer review process. The PMC archive is the designated repository for these manuscripts for use by the public, health care providers, educators, scientists, and FDA. Please see the FDA Public Access Policy.

Termination provisions in 2 CFR 200.340 (a) (1-4) are applicable to awards issued under this Notice of Funding Opportunity.

Additional terms and conditions regarding FDA regulatory and programmatic requirements may be part of the Notice of Award.

Standard Terms and Conditions of Award

Reporting Requirements:

All FDA grants require both Financial and Performance reporting.

Financial Reporting:

A. Financial Expenditure Reports

A required Federal Financial Report (FFR) must be submitted annually. All annual FFRs must be submitted electronically using the Payment Management System (PMS) . This includes all initial FFRs being prepared for submission and any revised FFRs being submitted or re-submitted to FDA. Paper expenditure/FFR reports will not accepted.

Annual FFRs must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ended. The reporting period for an annual FFR will be that of the budget period for the particular grant; however, the actual submission date is based on the calendar quarter. If a grant is under expanded authorities, the grantee must indicate the carryover amount in Section 12. Remarks of the annual FFR.

Performance Progress Reporting:

When multiple years (more than one budget period) are involved, awardees will be required to submit the Research Performance Progress Report (RPPR) annually as required in the Notice of Award. Annual RPPRs must be submitted using the RPPR module in eRA Commons. The annual RPPR must include a detailed budget. Annual RPPRs are due no later than 60 days prior to the start of the next budget period.

Failure to submit timely reports may affect future funding. Additional Financial and Performance Progress reports may be required for this award. Any additional reporting requirements will be listed under Section IV – Special Terms and Condition of the Notice of Award.

Salary Caps:

None of the funds in this award shall be used to pay the salary of an individual at a rate in excess

of the current Executive Level II of the Federal Executive Pay Scale.

Certificates of Confidentiality – 42 U.S.C. 241(d)

Awardees are responsible for complying with all requirements to protect the confidentiality of identifiable, sensitive information that is collected or used in biomedical, behavioral, clinical, or other research (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs) funded wholly or in part by the Federal Government. See 42 U.S.C. 241(d). All research funded by FDA, in whole or in part, that is within the scope of these requirements is deemed to be issued a “Certificate of Confidentiality” through these Terms and Conditions. Certificates issued in this manner will not be issued as a separate document.

Awardees are expected to ensure that any investigator or institution not funded by FDA who receives a copy of identifiable, sensitive information protected by these requirements, understand they are also subject to the requirements of 42 U.S.C. 241(d). Awardees are also responsible for ensuring that any subrecipient that receives funds to carry out part of the FDA award involving a copy of identifiable, sensitive information protected by these requirements understand they are also subject to subsection 42 U.S.C. 241(d).

Acknowledgment of Federal Support:

When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents --such as tool-kits, resource guides, websites, and presentations (hereafter “statements”)--describing the projects or programs funded in whole or in part with FDA federal funds, the recipient must clearly state:

1. the percentage and dollar amount of the total costs of the program or project funded with federal money; and,

2. the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by FDA financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following statements.

If the FDA Grant or Cooperative Agreement is NOT funded with other non-governmental sources:

This [project/publication/program/website, etc.] [is/was] supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award [FAIN] totaling $XX with 100 percent funded by FDA]/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

If the FDA Grant or Cooperative Agreement IS partially funded with other nongovernmental sources:

This [project/publication/program/website, etc.] [is/was] supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award [FAIN] totaling $XX with XX percentage funded by FDA/HHS and $XX amount and XX percentage funded by non-government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA/HHS, or the U.S. Government.

The federal award total must reflect total costs (direct and indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement. Any amendments by the recipient to the acknowledgement statement must be coordinated with FDA. If the recipient plans to issue a press release concerning the outcome of activities supported by FDA financial assistance, it should notify FDA in advance to allow for coordination.

Additional prior approval requirements pertaining to Acknowledgement of Federal Support, publications, press statements, etc. may be required, and if applicable, will be listed under Section IV – Special Terms and Condition of the Notice of Award.

Prior Approval:

All prior approval requests must be submitted using the Prior Approval module in eRA Commons. Any requests involving budgetary issues must include a new proposed budget and a narrative justification of the requested changes. If there are any questions regarding the need or requirement for prior approval for any activity or cost, the grantee is to contact the assigned Grants Management Specialist prior to expenditure of funds.

For grant awards not covered under Expanded Authorities, Carryover and No Cost Extension (NCE) requests will require prior approval. All Carryover and NCE requests should be submitted using the Prior Approval module in eRA Commons. ****Please review the section on Expanded Authorities to determine if this award is covered/not covered under Expanded Authorities and whether prior approval is needed for carryover and no cost extension requests.****

The following activities require prior approval from FDA on all awards:

1. Change in Grantee Organization

2. Significant Rebudgeting

3. Change in Scope or Objectives

4. Deviation from Terms and Conditions of Award

5. Change in Key Personnel which includes replacement of the PD/PI or other key personnel as specified on the NoA.

6. Disengagement from the project for more than three months, or a 25 percent reduction in time devoted to the project, by the approved PD/PI. No individual may be committed to more than 100% professional time and effort. In the event that an individual's commitment exceeds 100%, the grantee must make adjustments to reduce effort. For FDA-sponsored projects, significant reductions in effort (i.e., in excess of 25% of the originally proposed level of effort) for the PD/PI and key personnel named on named on this Notice of Award must receive written prior approval from FDA.

Additional prior approval requirements may be required for this award, and if applicable, will be listed under Section IV – Special Terms and Condition of the Notice of Award.

Audits and Monitoring:

Audit Requirements:

1. Recipients of Federal funds are subject to annual audit requirements as specified in 45 CFR 75.501 (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=8040c4036b962cc9d75c3638dedce240&ty=HTML&h=L&r=PART&n=pt45.1.75#se45.1.75_1501 (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=8040c4036b962cc9d75c3638dedce240&ty=HTML&h=L&r=PART&n=pt45.1.75%23se45.1.75_1501)). Grantees should refer to this regulation for the current annual Federal fund expenditure threshold level which requires audit.

2. Foreign recipients are subject to the same audit requirements as for-profit organizations (specified in 45 CFR 75.501(h) through 75.501(k).

3. For-profit and foreign entities can email their audit reports to AuditResolution@hhs.gov or mail them to the following address:

U.S. Department of Health and Human Services

Audit Resolution Division, Room 549D

Attention: Robin Aldridge, Director

200 Independence Avenue, SW

Washington, DC 20201

Monitoring:

Recipients are responsible for managing the day-to-day operations of grant-supported activities using their established controls and policies, as long as they are consistent with Federal, DHHS and FDA requirements. However, to fulfill their role in regard to the stewardship of Federal funds, FDA monitors our grants to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of reports and correspondence from the recipient, audit reports, site visits, and other information available to FDA.

1. Desk review: FDA grants monitoring specialists will periodically reach out to recipients to request information for the completion of desk reviews. Requested information may include:

- Policies and procedures
- List of grant expenditures
- Accounting records
- Supporting documents (e.g., invoices, receipts, paystubs, timesheets, contracts, etc.)
- Financial statements
- Audit reports
- Other related documentation

2. Site visits: FDA will conduct site visits when necessary and will notify the recipient with reasonable advance notice of any such visit(s).

3. Foreign entities: All Foreign entities are subject to the same monitoring requirements as domestic entities. Foreign entities covered under immunity Executive Orders will provide supporting documents for monitoring requirements unless such an action is a violation of the Executive Orders. Recipients may discuss with the FDA to come up with an alternate approach to satisfy the award monitoring requirements.

All recipients will make reasonable efforts to resolve issues found, including audit findings. Successful resolutions to issues are important as they are part of the grant performance review. All recipients are responsible for submitting all requested information in an expeditious manner. Failure to submit timely reports and/or respond to inquiries from FDA may affect future funding or enforcement actions, including withholding, or conversion to a reimbursement payment method.

Financial Conflict of Interest (FCOI):

This award is subject to the Financial Conflict of Interest (FCOI) regulation at 42 CFR Part 50 Subpart F.

Closeout Requirements (when applicable):

A Final Research Performance Progress Report (FRPPR), Final Invention Statement HHS-568 (if applicable), Tangible Personal Property Report SF-428 (if applicable), and Statement of Disposition of Equipment (if applicable) must be submitted within 120 days after the expiration date of the project period. All closeout documents must be submitted electronically in eRA Commons.

The Final Federal Financial Report (FFR SF-425), must be submitted in PMS and indicate the exact balance of unobligated funds and may not reflect unliquidated obligations. There must be no discrepancies between the Final FFR expenditure data and FFR cash transaction data in the Payment Management System (PMS). The expended funds reported on the Final FFR must exactly match the disbursements and the charge advances in PMS. It is the recipient's responsibility to reconcile reports submitted to PMS and to the FDA.

Program Income:

The grantee is required to report any Program Income generated during the Project Period of this grant. Except for royalty income generated from patents and inventions, the amount and disposition of Program Income must be identified on lines 10 (l), (m), (n), and (o) of the grantee's Federal Financial Report (FFR) SF-425.

Examples of Program Income include (but are not limited to): fees for services performed during the grant or sub-grant period, proceeds from sale of tangible personal or real property, usage or rental fees, patent or copyright royalties, and proceeds from the sale of products and technology developed under the grant.

Any Program Income generated during the Project Period of this grant by the grantee or sub-grantee will be treated as identified below.

Treatment of Program Income:

Prohibition on certain telecommunications and video surveillance services or equipment:

(a) As described in CFR 200.216, recipients and subrecipients are prohibited to obligate or spend grant funds (to include direct and indirect expenditures as well as cost share and program) to:

(1) Procure or obtain,

(2) Extend or renew a contract to procure or obtain; or

(3) Enter into contract (or extend or renew 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).

i. 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).

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

iii. 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.

Other:

This award is subject to the requirements of 2 CFR Part 25 for institutions to maintain an active registration in the System of Award Management (SAM). Should a consortium/subaward be issued under this award, a requirement for active registration in SAM must be included.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75.

You must administer your project 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 taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by 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/providerobligations/index.html (https://www.hhs.gov/civil-rights/for-providers/providerobligations/index.html) and https://www.hhs.gov/civil-rights/forindividuals/nondiscrimination/index.html (https://www.hhs.gov/civil-rights/forindividuals/nondiscrimination/index.html).

- You must take reasonable steps to ensure that your project provides meaningful access 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/civilrights/for-individuals/special-topics/limited-english-proficiency/fact-sheetguidance/index.html (https://www.hhs.gov/civilrights/for-individuals/special-topics/limited-english-proficiency/fact-sheetguidance/index.html) and https://www.lep.gov (https://www.lep.gov).
- For information on your specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and taking appropriate steps to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html (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/sexdiscrimination/index.html (https://www.hhs.gov/civil-rights/for-individuals/sexdiscrimination/index.html).
- For guidance on administering your project in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscienceprotections/index.html (https://www.hhs.gov/conscience/conscienceprotections/index.html) and https://www.hhs.gov/conscience/religiousfreedom/index.html (https://www.hhs.gov/conscience/religiousfreedom/index.html).

3. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) (//grants.nih.gov/grants/rppr/index.htm) annually and financial statements as required in the Notice of Award.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the terms and conditions of award and the *HHS Grants Policy Statement* (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf). FDA FOAs outline intended goals and objectives. Post award, FDA will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable FDA grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (//grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over the threshold.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (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. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200 – Award Term and Condition for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: http://grants.nih.gov/support/ (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov (mailto:support@grants.gov)

Objective Review Contact(s)

Janelle Fundersburg
Office of Acquisitions & Grants Services (OAGS)

Food and Drug Administration
Email: Janelle.Fundersburg@fda.hhs.gov (mailto:Janelle.Fundersburg@fda.hhs.gov)

Financial/Grants Management Contact(s)

Janelle Fundersburg
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Email: Janelle.Fundersburg@fda.hhs.gov (mailto:Janelle.Fundersburg@fda.hhs.gov)

Section VIII. Other Information

All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), Notice of Award, and 45 CFR 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.

Authority and Regulations

Awards are made under the authorization of Section 301 of the Public Health Service Act as amended (42 USC 241) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75 and 2 CFR Part 200.

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?12-02-22)
NIH Funding Opportunities and Notices (/grants/guide/index.html)

Note: For help accessing PDF, RTF, MS Word, Excel, PowerPoint, Audio or Video files, see Help Downloading Files (/grants/edocs.htm).