Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	U.S. Food and Drug Administration (FDA) NOTE: The policies, guidelines, terms, and conditions stated in this Notice of Funding Opportunity (NOFO) may differ from those used by the NIH. Where this NOFO provides specific written guidance that may differ from the general guidance provided in the grant application form, please follow the instructions given in this NOFO. 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 Peer Review Process.
Components of Participating Organizations	Center for Veterinary Medicine (CVM)
Funding Opportunity Title	**Animal and Veterinary Innovation Centers (U18)**
Activity Code	U18 Research Demonstration – Cooperative Agreements
Announcement Type	New
Related Notices	None
Funding Opportunity Number (FON)	**PAR-24-251**
Companion Notice of 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 this Funding Opportunity Announcement (FOA) is to solicit applications for inclusion as Animal and Veterinary Innovation Centers, which are intended to form long-term partnerships to address priority areas for FDA's Center for Veterinary Medicine (CVM). This includes CVM developing cooperative agreement(s) with academic research institutions (public and private) to: 1. Drive research that supports the development of interventions to prevent, control, or eliminate emerging zoonotic disease threats or One Health issues. 2. Drive research that supports the development of intentional genomic alternations in animals and the advancement of regulatory science in this field, with a focus on intentional genomic alternations that support agricultural resilience, food security, animal health, or public health. 3. Drive research that supports the development of products for minor species, minor uses in major species (dogs, cats, horses, cattle, pigs, chickens, and turkeys) and other unmet veterinary medical needs in major species that create a significant animal or public health burden.

Key Dates

Posted Date	May 4, 2026
Open Date (Earliest Submission Date)	May 4, 2026
Letter of Intent Due Date(s)	Not applicable for June 05, 2026 application due date. April 14, 2027, for May 14, 2027 application due date. April 12, 2028, for May 12, 2028 application due date.
Technical Session (Optional)	**May 11, 2026 1:00 PM–2:30 PM EDT** Meeting Link Meeting ID: 275 581 706 897 72 Passcode: 4e3xC98U **March 31, 2027 1:00 PM–2:00 PMEDT** Meeting Link Meeting ID: 226 859 396 324 76 Passcode: NA2bV9Z4 **March 29, 2028 1:00 PM–2:00 PMEDT** Meeting Link Meeting ID: 269 790 109 691 70 Passcode: ey9H9Lv6

Application Due Date(s)	June 12, 2026 May 14, 2027 May 12, 2028 All applications are due by 11:59 PM local time of applicant organization. All types of non-AIDS applications allowed for this notice of funding opportunity are due on the listed date(s) 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. **Late applications will not be accepted for this FOA.**
AIDS Application Due Date(s)	Not Applicable
Scientific Merit Review	August 2024, June of each subsequent year
Advisory Council Review	Not Applicable
Earliest Start Date	September 2026
Expiration Date	September 30, 2028
Due Dates for E.O. 12372	Not Applicable

Required Application Instructions

It is critical that applicants follow the Research (R) Instructions in How to Apply - Application Guide, except where instructed to do otherwise (in this NOFO or in a Notice from the *Guide for Grants and Contracts*). Conformance to all requirements (both in the How to Apply - Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the How to Apply - Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the How to Apply - Application Guide , follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) regulates animal food and animal drugs. To help meet the growing needs to develop and regulate new animal drug products, CVM released an Animal and Veterinary Innovation Agenda (AVIA), which communicated CVM's plans to address critical unmet needs impacting animal and human health.

In support of the AVIA, CVM is announcing the establishment of Animal and Veterinary Innovation Centers (AVICs) comprised of academic research institutions (public and private). These Centers are intended to have a long-standing relationship with CVM and must have strong institutional support to advance CVM priorities in a specific topic area listed below.

To become an AVIC, applications are sought for cooperative agreements to address research needs identified by CVM. These applications must have detailed, multi-year research plans to address one or more of the priority areas listed below. This includes clear proposals for how these critical animal, human, or environmental health concerns will be addressed. The focus should be on research and related efforts that seek to answer regulatory science questions about new products or technologies or that potentially support the development and approval of FDA-regulated animal and veterinary products. The Agency's goal is that these Innovation Centers will contribute research and work that will result in more FDA-regulated products coming to market - particularly products that are innovative or address high-impact needs such as food security, agricultural resilience, unmet animal health needs, or public health. Because areas of interest may shift over time, applicants are highly encouraged to visit the AVIC website for the most up to date information. The AVIC will update its list of research priorities and post it onto the program website annually.

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

Section II. Award Information

Funding Instrument	Cooperative Agreement: A financial assistance mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, FDA scientific or program staff will assist, guide, coordinate, or participate in project activities. See Section VI.2 for additional information about the substantial involvement for this NOFO.
Application Types Allowed	New The OER Glossary and the How to Apply - Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.
Clinical Trial?	Not Allowed: Only accepting applications that do not propose clinical trials

	Need help determining whether you are doing a clinical trial?
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(s) will provide one (1) year of support and include future recommended support for up to four (4) additional year(s) contingent upon annual appropriations, availability of funding and satisfactory recipient performance. FDA intends to fund an estimate of up to 5 awards each funding cycle. Funding levels and the number of awards will depend on annual appropriations.
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 costs): YR 01: $1,000,000 YR 02: $1,250,000 YR 03: $1,500,000 YR 04: $1,750,000 YR 05: $2,000,000
Award Project Period	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 will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

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

Foreign Organizations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **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, **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the How to Apply - 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, please reference the HHS Grants Policy Statement for additional information.

- System for Award Management (SAM)– 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 – 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 - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registration; 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 – 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 their organization to develop an application for 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 How to Apply - Application Guide.

2. Cost Sharing
This NOFO does not require cost sharing as defined in the HHS Grants Policy Statement.

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.

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 NOFO. 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 How to Apply - Application Guide, except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the How to Apply - Application Guide is required and strictly enforced. Applications

that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Jenise McNair
Email: jenise.mcnair@fda.hhs.gov

Page Limitations

All page limitations described in the How to Apply – Application Guide and the Table of Page Limits must be followed.

For this specific NOFO, the Research Strategy section is limited to 30 pages.

Instructions for Application Submission

The following section supplements the instructions found in the How to Apply – Application Guide and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the How to Apply - Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the How to Apply - Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the How to Apply - Application Guide must be followed.

SF424(R&R) Senior/Key Person Profile

All instructions in the How to Apply - Application Guide must be followed.

R&R or Modular Budget

All instructions in the How to Apply - 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.

If an applicant is requesting indirect costs as part of their budget, a copy of the most recent Federal indirect cost rate or F&A agreement must be provided as part of the application submission. This agreement should be attached to the RESEARCH & RELATED Other Project Information Component as line #12 'Other Attachments'.

R&R Subaward Budget

All instructions in the How to Apply - Application Guide must be followed.

PHS 398 Cover Page Supplement
All instructions in the How to Apply - Application Guide must be followed.

PHS 398 Research Plan
All instructions in the How to Apply - Application Guide must be followed, with the following additional instructions:
1. The research plan should address one of the scientific questions and/or priorities discussed under part 2 of this notice, considering the associated animal health, human health, environmental health, or regulatory impacts.
2. Collaboration with other entities is encouraged and plans for interactions with other potential Innovation Centers should be included, where applicable.
3. Prospective applicants should reach out to the science/research contact about budget and scope before submission. This can ensure alignment of potential applications with programmatic needs.

Resource Sharing Plan:

All instructions in the How to Apply - Application Guide must be followed, with the following additional instructions:

- All applicants planning research (funded or conducted in whole or in part by the FDA) that results in the generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the How to Apply - Application Guide .

PHS Human Subjects and Clinical Trials Information
Trials involving human subjects are not allowed for this funding opportunity.

PHS Assignment Request Form
All instructions in the How to Apply - 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. When a submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (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, FDA's electronic system for grants administration. FDA 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. Applications that miss the due date and time are subjected to the FDA Policy on Late Application Submission.

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 How to Apply – Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

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.

- Recipients must comply with all applicable federal anti-discrimination laws material to the government's payment decisions for purposes of 31 U.S.C. § 3729(b)(4).
- Discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate:
  - racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation.
  - denial by the recipient of the sex binary in humans or the notion that sex is a chosen or mutable characteristic.
  - harm reduction
  - illegal immigration; or
  - any other initiatives that compromise public safety or promote anti-American values.

All activities proposed in your application and budget narrative must align with applicable law, including but not limited to statutes, executive orders, federal regulations, and applicable judicial holdings. Accordingly, discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate: racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation; denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic; illegal immigration; or any other initiatives that compromise public safety. If an application does not align, the application will not receive funding to the extent permitted by law and applicable court orders.

Non-allowable costs:
1. Vehicle purchases.
2. New building construction.
Additional funding restrictions may be part of the Notice of Award.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the How to Apply - 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. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance. 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 NOFO 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 How to Apply - Application Guide.

See more tips for avoiding common errors.

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

Mandatory Disclosure
Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, 2 CFR 200.113 and HHS Grants Policy Statement.

Send written disclosures to the FDA Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the HHS Office of Inspector Grant Self Disclosure Program at grantdisclosures@oig.hhs.gov.

Post Submission Materials
Not applicable.

Section V. Application Review Information

1. Criteria
Only the review criteria described below will be considered in the review process.
Applications submitted to the FDA in support of the HHS mission are evaluated for scientific and technical merit through the FDA peer review system.

Overall Impact
Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria
Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance (25 points)
Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods,

technologies, treatments, services, or preventative interventions that drive this field? What tangible impact will be made to animal/human/environmental health or regulatory science? Will this project result in new therapies being made available or other significant advances? Does this application address not only a specific short-term project, but demonstrate sufficient long-term significance to be established as an Innovation Center?

Investigator(s) (15 points)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?

Innovation (20 points)

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed? Is the work reflective of new technologies or innovations and their impact on public health and regulatory science?

Approach (25 points)

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables for studies in vertebrate animals? Is there IACUC oversight of research involving vertebrate animals? Are there existing or planned collaborations that will help drive the project forward? Is the work to be accomplished of reasonable scope to be accomplished in the planned study period? Is there a clear multi-year strategy to address the topic areas described in this NOFO?

Environment (15 points)

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements? Is there ongoing research in this area at the institution that increases the likelihood of success? Does the institution have the proper support to justify long-term presence as an Innovation Center?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following three points: (1) a complete description of all proposed procedures including the species, strains, ages, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including

analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the Worksheet for Review of the Vertebrate Animals Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

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

Revisions

For Revisions, the committee will consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the committee, then the committee will consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Additional Review Considerations

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

Applications from Foreign Organizations

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

Authentication of Key Biological and/or Chemical Resources:

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

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 Scientific Review Group(s) convened by the FDA, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- Will receive a written critique.

Appeals of initial peer review will not be accepted for applications submitted in response to this NOFO.

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

- Scientific and technical merit of the proposed project as determined by scientific peer 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.

Information regarding the disposition of applications is available in the HHS Grants Policy Statement.

Section VI. Award Administration Information

1. Award Notices

A Notice of Award (NoA) is the official authorizing document notifying the applicant that an award has been made and that funds may be requested from the designated HHS payment system or office. The NoA is signed by the Grants Management Officer and emailed to the recipient's business official.

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.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Any pre-award costs incurred before receipt of the NoA are at the applicant's own risk These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this NOFO will be subject to terms and conditions found on the Award Conditions and Information for FDA Grants website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

The following Federal wide and HHS-specific policy requirements apply to awards funded through the FDA:

- The rules listed at 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
- All FDA grant and cooperative agreement awards include the HHS Grants Policy Statement as part of the terms and conditions in the Notice of Award (NoA). The NoA includes the requirements of this NOFO.

- If a recipient receives an award, the recipient must follow all applicable nondiscrimination laws. The recipient agrees to this when registering in SAM.gov. The recipient must also submit an Assurance of Compliance (HHS-690). To learn more, see the Laws and Regulations Enforced by the HHS Office for Civil Rights website.
    - HHS recognizes that FDA 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 NOFO.

All federal statutes and regulations relevant to federal financial assistance, including those highlighted in the HHS Grants Policy Statement.

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. FDA may terminate awards under certain circumstances. See the HHS Grants Policy Statement.

Cooperative Agreement Terms and Conditions of Award

The administrative and funding instrument used for this program will be the cooperative agreement, an assistance mechanism (rather than an acquisition mechanism), in which substantial FDA programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, FDA's purpose is to support and stimulate the recipient's activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project, although specific tasks and activities may be shared among the awardees and FDA as defined below. Substantive involvement may include, but is not limited to, the following:
(1) General guidance on activities
(2) Site visits from FDA staff
(3) Facilitating cooperation and joint advancement of priorities among multiple grant recipients.
The following conditions of the award will apply to all funded applicants and must be maintained throughout the cooperative agreement.

Principal Investigator Rights and Responsibilities
The PD(s)/PI(s) will have the primary responsibility for the scientific, technical, and programmatic aspects of the cooperative agreement and for day-to-day management of the project or program. The PD(s)/PI(s) will maintain general oversight for ensuring compliance with the financial and administrative aspects of the award, as well as ensuring that all staff have sufficient clearance and/or background checks to work on this project or program. This individual will work closely with designated officials within the recipient organization to create and maintain necessary documentation, including both technical and administrative reports; prepare justifications; appropriately acknowledge Federal support in publications, announcements, news programs, and other media; and ensure compliance with other Federal and organizational requirements.

Additional conditions:
1. Cooperate with other Innovation Centers and identify common procedures, as applicable.
2. Participate in site visits or attend meetings as requested by the FDA. A portion of the budget may be reserved for such travel.
3. The awardees will provide FDA any samples if requested by FDA.
4. The awardees will provide FDA any data obtained from work under the cooperative agreement as requested. Data will be posted to appropriate or available data repositories as requested by FDA.

5. FDA may also request data be made available through speaking engagements and publications, presentations at scientific symposia and seminars, while making sure that confidentiality and privacy of the data is protected.
6. Any publication or oral presentation of the results of funded work must undergo FDA review and approval process. This process can take 30-90 days.
7. The grantee must provide quarterly reports as requested, to include status and budget updates.

FDA Responsibilities:
An FDA Project Officer (PO) will have substantial programmatic involvement as described below. The PO is the official responsible for monitoring the programmatic, scientific, and/or technical aspects of assigned applications and grants. The PO's responsibilities include, but are not limited to, post-award monitoring of project/program performance, including review of progress reports and making site visits; and other activities complementary to those of the Grants Management Officer (GMO). The PO and the GMO work as a team in many of these activities.

FDA will provide technical monitoring and/or direction of the work, including monitoring of data analysis, interpretation of analytical findings and their significance.

FDA will assist and approve (as deemed appropriate) the substance of publications, co-authorship of publications and data release.

3. Data Management and Sharing

Consistent with the 2023 FDA Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the HHS Grants Policy Statement. Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the HHS Grants Policy Statement.

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 HHS Grants Policy Statement.

FDA NOFOs outline intended research 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 2 CFR Part 200.301.

5. Evaluation

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: https://www.era.nih.gov/need-help (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

Scientific/Research Contact(s)

Claudine Kabera
Center for Veterinary Medicine
Email: claudine.kabera@fda.hhs.gov

Peer Review Contact(s)

Jenise Mc Nair
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Email: jenise.mcnair@fda.hhs.gov

Financial/Grants Management Contact(s)

Jenise McNair
Office of Acquisitions & Grants Services (OAGS)
Food and Drug Administration
Email: jenise.mcnair@fda.hhs.gov

Section VIII. Other Information

Recently issued policy notices may affect your application submission. A full list of policy notices published by the *Guide for Grants and Contracts*. All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 of the Public Health Service Act as amended (42 USC 241), section 573(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 360ccc-2(b)) and under Federal Regulations 42 CFR Part 52, and 2 CFR Part 200.