



REQUEST FOR APPLICATIONS

Biotechnology Risk Assessment Research Grants Program

FUNDING YEAR: Fiscal Year 2022
APPLICATION DEADLINE: February 15, 2022
ANTICIPATED FUNDING: \$5,000,000
AVERAGE AWARD RANGE: \$50,000-\$500,000
FUNDING OPPORTUNITY NUMBER: USDA-NIFA-BRAP-008702
ASSISTANCE LISTING NUMBER: 10.219
LETTER OF INTENT DEADLINE: January 4, 2022
Note: Letter of Intent Encouraged but Not
Required

INITIAL ANNOUNCEMENT
National Institute of Food and Agriculture
United States Department of Agriculture

Assistance Listing: The Biotechnology Risk Assessment Research Grants Program (BRAG) is listed under number 10.219.

Table 1: Key Dates and Deadlines

Task Description	Deadline
Application:	5:00 P.M. Eastern, February 15, 2022
Letter of Intent (LOI):	5:00 P.M. Eastern, January 4, 2022 (LOI encouraged but not required)
Applicants Comments:	Within six months from the issuance of this notice (NIFA may not consider comments received after the sixth month)

Stakeholder Input. The National Institute of Food and Agriculture (NIFA) seeks comments on all request for applications (RFAs) so it can deliver programs efficiently, effectively, with integrity, and with a focus on customer service. NIFA considers comments, to the extent possible when developing RFAs and uses comments to help meet the requirements of [Section 103\(c\)\(2\) of the Agricultural Research, Extension, and Education Reform Act of 1998 \(7 U.S.C. 7613\(c\)\(2\)\)](#). These requirements require the Secretary to consider the results of the fiscal year review when formulating each request for proposals, and evaluating proposals, involving an agricultural research, extension, or education activity funded, on a competitive basis. Applicants may submit written comments to Policy@usda.gov (email is for comments only). Please use the following subject line: Response to the Biotechnology Risk Assessment Research Grants Program RFA.

Centers of Excellence. Applicants are encouraged to visit the NIFA’s [Center of Excellence \(COE\)](#) for information on COE designation process, including COE criteria, and a list of programs offering COE opportunities. A recording of COE outreach and COE implementation webinars are also available.

EXECUTIVE SUMMARY

This notice identifies the objectives for the Biotechnology Risk Assessment Research Grants Program (BRAG) projects, deadlines, funding information, eligibility criteria for projects and applicants, and application forms and associated instructions.

NIFA requests applications for the BRAG program for fiscal year (FY) 2022 to support environmental assessment research concerning the introduction of genetically engineered (GE) organisms into the environment.

This RFA is being released prior to the passage of a full appropriations act for FY 2022. Enactment of additional continuing resolutions or a full appropriations act may affect the availability or level of funding for this program. The anticipated amount available for grants in FY 2022 is approximately \$5,000,000.

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PART I. FUNDING OPPORTUNITY DESCRIPTION

A. Legislative Authority

Authority for the Biotechnology Risk Assessment Research (BRAG) Program is contained in ([7 U.S.C. 5921](#)) the BRAG program supports research designed to identify and develop appropriate management practices to minimize physical and biological risks associated with genetically engineered animals, plants, and microorganisms. NIFA and the Agricultural Research Service (ARS) of the U.S. Department of Agriculture jointly administer the BRAG program, while USDA-NIFA, USDA-ARS and USDA-Forest Service (FS) provide annual funding for the BRAG program.

B. Purpose and Priorities

The purpose of the BRAG program Assistance Listing 10.219, is to support the generation of new information that will assist [Federal regulatory agencies](#) [[USDA's – Animal and Plant Health Inspection Service - Biotechnology Regulatory Services](#) (APHIS-BRS), [Environmental Protection Agency](#) (EPA), and Department of Health and Human Services (DHHS) [Food and Drug Administration](#) (FDA)] in making science-based decisions about the environmental effects of introducing genetically engineered (GE) organisms by techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome. The organisms include plants, microorganisms (including fungi, bacteria, and viruses), arthropods, fish, birds, livestock, and other animals these include related wild and agricultural organisms.

The statutory program goals and objectives are to authorize and support environmental assessment research to help identify and analyze environmental effects of biotechnology; and to authorize research to help regulators develop long-term policies concerning the introduction of such technology.

The BRAG program supports applied and/or fundamental research relevant to environmental risk assessment, including biological risk, and the Federal regulatory process. When evaluating GE organisms, Federal regulators must answer the following four general questions:

1. Is there a hazard? (Potential hazard identification.)
2. How likely is the hazard to occur? (Quantifying the probability of occurrence; identifying likely exposure scenarios.)
3. What is the severity and extent of the hazard if it occurs? (Quantifying the effects); and
4. Is there an effect beyond what might occur with an unmodified organism or an organism that has similar traits, but was developed using other technologies?

The BRAG program will also support risk management research, which is defined as either:

1. Research aimed primarily at reducing negative effects of specific biotechnology derived agents; or
2. A policy and decision-making process that uses risk assessment data in deciding how to avoid or mitigate the negative consequences identified in a risk assessment.

Although project directors (PDs) are not required to perform actual risk assessments as part of the research they propose, they should design studies that will provide useful science-based information for Federal regulators assessing GE organisms or that have been derived via

synthetic biology defined as: the ability to generate novel traits or organisms using synthetic genes (synthesized de novo outside the organism of origin).

NIFA is soliciting applications for the BRAG program under the following program areas:

1. Standard Research Proposals
2. Conference Proposals

Handling of baseline data and data collection will be addressed in the Data Management Plan (DMP) in accordance with the [Part IV\(C\)](#) of this RFA.

The BRAG program is aligned with the following [USDA Strategic Goals](#):

Strategic Goal 1: Ensure USDA Programs Are Delivered Efficiently, Effectively, With Integrity and a Focus on Customer Service.

Strategic Goal 3: Promote American Agriculture Products and Exports

Strategic Goal 7: Provide all Americans Access to a Safe, Nutritious, and Secure Food Supply.

Additional requirements on expected performance goals, indicators and targets may be required as a condition of award.

Table 2: Program Key Information

Title	Description
Program Code:	HX
Program Code Name:	Biotechnology Risk Assessment
CFDA Number	10.219
Project Type:	Standard
Grant Type:	Standard
Application Deadline	February 15, 2022
Grant Duration:	Approximately 24-48 Months
Anticipated # of Award:	N/A
Minimum Award Amount:	Approximately \$50,000
Maximum Award Amount:	Approximately \$500,000
Total Award Amount:	Approximately \$5,000,000

Program Federal Agency Collaboration. NIFA will competitively award research grants to support biotechnology regulation, thereby helping to address concerns about the effects genetically engineered (GE) organisms introduced into the environment and helping regulators develop policies regarding such introduction. The BRAG program also encourages proposals seeking partnership with or involvement of international entities where appropriate and domestically beneficial. Research proposals must be of high quality and have merit based upon their relevance to the purpose of the BRAG program. The BRAG program is especially

interested in research that is not already in well-developed areas of study. Exploratory research that relates specifically to federal regulatory needs is preferred.

Applications to the BRAG program **MUST** address one of the following standard research program areas (see below) or seek funding for a conference/workshop. In addition, applicants **must** state in the first sentence of their Project Summary which **SINGLE** standard research program area aligns best with their proposed project.

Standard Research Proposals. Address issues related to newly developed GE organisms that are animals, plants, insects, and/or microorganisms. Research proposals can be applied and/or fundamental and must address one of the following five program areas:

1. *Management Practices to Minimize Environmental Risk of GE Organisms.* Research designed to develop appropriate management practices to minimize physical and biological risks to the environment associated with GE organisms. Potential areas of research include, but are not limited to:
 - a) Evaluation of management, monitoring, and mitigation methodologies (e.g., devitalization), for assuring confinement of GE organisms during field trials, particularly insects, microbes, perennial plant species, and weeds.
 - b) Evaluation of safeguards for controlling the spread of gene drives during research to understand the effect of the desired genetic change on organisms and populations.
 - c) Development of practical management methodologies for reducing the spread and persistence of GE organisms in natural and managed environments after intentional release or escape from containment.
 - d) Development or evaluation of effective strategies, including molecular and/or genetic, to limit gene transfer (gene flow) or outcrossing to sexually compatible organisms or transfer of genetic material between viruses, insects, or microorganisms.
 - e) Mitigation measures to limit gene flow when GE organisms are released or escape into the environment, physical containment fails, or biological containment is unavailable.
 - f) Ecological effects of technologies for reducing the undesired spread of GE organisms; and/or
 - g) Exploration of risk mitigation strategies to ameliorate undesirable environmental impacts associated with GE organisms.
2. *Methods to Monitor and Understand the Dispersal of GE Organisms.* Research designed to develop methods to monitor and understand the dispersal and/or population dynamics of GE organisms. Potential areas of research include, but are not limited to:
 - a) Ability to survive and/or fitness of GE organisms in the wild as compared to appropriate non-GE or previous GE counterparts, particularly across different environmental conditions (e.g., drought, presence of interspecific competitors).
 - b) Understanding and predicting the dynamics of gene drives in organisms when released into the environment; especially the identification of the key factors impacting persistence, spread, and frequencies in populations of the organism and its relatives.
 - c) Strategies for large-scale deployment or field studies of GE organisms, with special reference to those considerations that may not be revealed through contained or small-scale evaluation and tests.

- d) Assessing the effects of engineered traits in animal species that may easily disperse, such as birds, rodents, aquatic species, arthropods, and other invertebrates. This area may include:
 - i. Basic biological information about the non-modified species that is important for risk assessment and population models, particularly information about life history traits like mating structure, dispersal, and behavior.
 - ii. Studies on genotype and phenotype stability over multiple generations.
 - iii. Comparative mating competence or reproductive studies.
 - iv. Comparative behavior and biological studies, including studies addressing whether traits introduced by genetic engineering can alter the range or ecological interactions of organisms such as birds, rodents, aquatic species, arthropods, and other invertebrates
- e) To prevent persistence of plants used in field trials, information on dormancy in the seed (e.g., wheat, barley, rice and canola or other propagules affecting persistence of such propagules), particularly variety x environment interactive effects. This would include dormancy of crop, sexually compatible weedy species, and hybrids of the crop and weedy relatives and sexually compatible crops cultivated in sympatry; or
- f) Development and/or evaluation of tools for assessing weediness or invasiveness of GE plants relative to unmodified parent organisms.

3. *Gene Transfer between Genetically Engineered Animals, Plants, and Microorganisms and Related Wild and Agricultural Organisms.* Research designed to further existing knowledge about the characteristics, rates, and mechanisms of gene transfer that may occur between GE organisms, and related wild and agricultural organisms. Gene flow research should be directed to organisms with a high potential for transfer of genetic material (e.g., outcrossing to sexually compatible species or transfer of genetic material between microorganisms or viruses) and to genes that have a high potential for altering the fitness of the recipient organism in its environment. For plants, preference will be given to studies with species that have sexually compatible wild or weedy relatives in the United States. For microorganisms, preference will be given to species co-occurring in the same host organism or microenvironment. Potential areas of research include, but are not limited to:

- a) Impacts of gene flow from GE plants, particularly perennials (e.g., trees, grasses such as switchgrass), insects, animals, or microorganisms to related organisms, communities, or ecosystems.
- b) Fate and stability (persistence) of engineered genes that have been moved by outcrossing or other means into populations of non-GE organisms, and the degree to which they confer a selective advantage or disadvantage upon the recipients/carriers or are inherited in a non-Mendelian manner (e.g., gene drives), especially with regard to engineered genes that may confer increased fitness (e.g. enhanced growth or abiotic stress tolerance) in wild populations, and the environmental contexts in which those advantages or disadvantages manifest;
- c) Assessing the influence of genetic background on the phenotypic expression conferred by genetic modification, to inform understanding of the characteristics and potential outcomes of gene transfer in a new genetic background.
- d) Basic research on the genes related to weediness and their location in the genome of weedy relatives of crop plants; and/or

- e) Modeling engineered gene escape into the environment, including modeling to identify parameters that influence gene dispersal and its consequences.
4. *Environmental effects of GE relative to Non-GE Organisms in the Context of Production Systems.* Environmental assessment research on production systems that compare the relative impacts of animals, plants, and microorganisms modified through incorporation of traits introduced by genetic engineering to other types of production systems. Potential areas of research include, but are not limited to:
- a) Assessment of how traits introduced by genetic engineering may change aspects of the ecology or behavior of engineered organisms (e.g., mating systems, host range).
 - b) Assessment of the influence of GE organisms as compared to non-GE organisms on managed (agricultural, aquatic, or forest ecosystems such as on community structures of agro or forest ecosystems) or unmanaged ecosystems. Important focus areas are the impacts of GE organisms on:
 - i. The population dynamics and ecology of various types of beneficial organisms.
 - ii. The magnitude and types of changes in communities or indicator species that could trigger concerns regarding ecosystem impacts.
 - iii. The biology and ecology of indicator taxa with respect to geography, seasonal fluctuations, species, pests, etc.
 - c) Assessment of how the cultivation of GE organisms alters the agriculture impacts on the rural environment, such as altered land use practices, species displacement, soil erosion, water usage and water quality, or other geographically dispersed events. Comparative assessment of management techniques and resources for maintenance of non-GE animals versus GE animals (e.g., changes in land use or manure management practices required for GE animals engineered to utilize feed more efficiently).
 - d) Comparative assessment of environmental impacts of agricultural production systems using organic and/or conventional methods with those involving plant, animal, or microbial biotechnology. Appropriate parameters or metrics are to include, but are not limited to:
 - i. Soil health, fertilizer, pesticide, and soil amendment inputs.
 - ii. Changes in toxicant and pesticide residue levels.
 - iii. Prevalence, shifts, and distribution of and damage from weeds, including those with single or multiple herbicide resistance.
 - iv. Prevalence, distribution, and damage from pests and pathogens, including emergence of resistance; and/or
 - v. Land use related to yield and productivity.
 - e) Identification and experimental assessment, modeling, or meta-analysis of potential adverse environmental impacts of large-scale cultivation of GE plants, with emphasis on plants used for bioenergy, bio-based or construction products (e.g., sorghum, *Camelina*, sugarcane, eukaryotic algae, or perennial species such as trees and some grasses), and plant made pharmaceuticals and industrials to support the development of a risk assessment framework. For the purposes of this standard area, large-scale refers to cultivation on 100 or more acres. Projects must address multiple BRAG topic areas, preferentially chosen from the following:
 - i. Biological and ecological baseline studies, including fitness characteristics, associated with unmodified perennial species that are being genetically

engineered and that will aid in the development of comparative risk assessment methodologies and include measurements of variation among cultivars and environments.

- ii. Strategies for conducting large scale GE field studies with minimal environmental risk and incorporating adaptive management.
 - iii. Landscape level studies to assess environmental impacts of land use changes and/or ecosystem function and services.
 - iv. Assessment and documentation of significant community or ecosystem effects that are not revealed by studies on small plots: such as effects on plant, microbial or animal communities; species displacement; soil health; fertilizer, soil amendment, and pesticide inputs; hydrology; water quality; fire frequency or intensity; toxicant and pesticide residue levels; and/or new plant pests.
 - v. Assessment of the likelihood and impact of gene flow to sexually compatible plants and stable inheritance in related organisms under various management strategies; and/or
 - vi. Weediness or invasiveness of the GE organism relative to non-GE parent organism.
5. *Other Research Topics Designed to Further the Purposes of this Program.* Other areas of research designed to improve the knowledge of emerging technologies in genomics, genome editing, and/or biotechnology as it relates to the BRAG program. Potential areas of research include, but are not limited to:
- a) Research addressing phenotypic effects associated with on- or off-target errors in GE organisms developed using genome editing technology or other genetic engineering techniques and potential hazards or adverse effects associated with these phenotypic effects to the environment.
 - b) Research evaluating the potential hazards or adverse effects of GE livestock intended to be reared under commercial conditions on the environment, including the potential need for containment.
 - c) Research evaluating the potential hazards or adverse effects associated with GE animals intended for release into the environment (e.g., for pest population suppression).
 - d) Research evaluating the performance of various technologies to track the effectiveness of limited field release conditions designed to contain genetically engineered animals or microbes.
 - e) Modeling approaches to understand the impact of genetic engineering for population suppression or alteration (gene drives including for weed control, release of an insect carrying a dominant lethal, etc.) on target populations or non-target species that interact with the targeted species, especially when incorporating biologically realistic parameters (e.g., numbers of individuals released, dispersal, mating behavior, and other life history traits, etc.).
 - f) Research evaluating the impact of GE microorganisms used in animal agriculture on the environment (e.g., effect of GE microorganisms on biological diversity of soil microorganisms, fate of GE microorganisms in the environment);
 - g) Research focused on the environmental effects of introducing RNA interference transgenes or other gene silencing mechanisms using RNAi, siRNA, or miRNAs

replicating in animals, plants, microbes, and/or insects. Important areas include, but not limited to:

- i. Assessment of environmental fate and/or persistence of these small RNA molecules, especially those modified to enhance stability; and/or
 - ii. Potential off target (within the organism), non-target (effects on other organisms), or other unintended effects of these small RNA molecules in animals and plants (including GE and non-GE plants); and ways to design RNAi, siRNAs, or miRNA to minimize or avoid such effects.
- h) Assessment of the effects of multiple engineered insects and/or nematode resistance genes (e.g., *Bacillus thuringiensis* and RNAi) in a plant on non-target arthropod species and communities; and/or
- i) Research to understand the frequency and mechanisms by which pests or diseases overcome plant pest or disease resistance traits conferred by engineered genes (including where relevant how this compares to resistance to traditional approaches). Proposals on pest resistance management are not excluded from the program, but any such proposals submitted should describe clear and significant connection with biotechnology and environmental risk assessment/management.
- j) Research evaluating the relative efficacy and potential hazards of various biotechnology and non-biotechnology approaches used alone or in combination for mitigation of pests of quarantine significance (e.g., citrus greening, forest pests and others).
- k) Development and/or evaluation of high-throughput methodologies to assess pathogenicity, biocontrol properties or any other plant pest risk properties of novel strains of GE microorganisms such as but not limited to comparison of bioinformatic vs empirical assessment to determine these properties.

Standard Research Proposals must not exceed **\$500,000** total (including indirect costs) for project periods up to four years.

CONFERENCE PROPOSALS. Applicants to the BRAG program may request partial funding to organize a conference or workshop that brings together scientists, regulators, and other stakeholders to review science-based data relevant to gene flow and co-existence, emerging technologies related to biotechnology (such as genome editing and gene drives), risk assessment, or risk management of GE organisms released into the environment. To be eligible for funding, the steering committee for the proposed conference should include representatives from a variety of relevant and appropriate scientific disciplines. BRAG conference applications must include the following:

1. Describe the relevance of the proposed conference to biotechnology risk assessment in U.S. agriculture.
2. Explain the uniqueness and timeliness of the conference.
3. Outline the qualifications of the organizing committee and the appropriateness of the invited speakers to the topic areas to be covered.
4. State clearly the goals of the conference and the likely outcomes.
5. Explain the need for the various elements of the budget, provide a clear plan to disseminate the outcome of the conference to the public; and

6. Describe how the organizers will make up the total costs of the conference from other sources.

The goals for the conference should include sharing of scientific information and identification of gaps in knowledge, and/or public education and outreach, among others. Publication of the proceedings is highly encouraged, and a copy of any publications should be provided to NIFA.

Conference Proposals must not exceed **\$50,000** total and the conference must occur after August 1, 2022. Indirect costs are not allowed on conference grants.

PART II. AWARD INFORMATION

A. Available Funding

The anticipated amount available for BRAG in FY 2022 is approximately \$5,000,000.

This RFA is being released prior to the passage of an appropriations act for FY 2022. Enactment of additional continuing resolutions or an appropriations act may affect the availability or level of funding for this program. The anticipated amount available for grants in FY 2022 is approximately \$5,000,000.

USDA is not committed to fund any particular application or to make a specific number of awards. The [Automated Standard Application for Payments](#), operated by the Department of Treasury, Bureau of Fiscal Service, is the designated payment system for awards resulting from this RFA.

B. Types of Applications

NIFA will evaluate applications using the criteria described in [Part V](#) of this RFA. FY2021 applications are limited to the following types:

1. *New application*: New applications will be evaluated using the criteria described in [Part V](#) of this RFA and are subject to the due dates herein (see [Appendix III](#) for definition).
2. *Resubmitted application*: Resubmitted applications must include the response to the previous review panel summary and are subject to the same criteria and due dates herein. Resubmitted applicants must enter the NIFA-assigned proposal number of the previously submitted application in the *Federal Field (Field 4)* on the application form (see [Appendix III](#) for definition).

C. Project and Grant Types

The following describes the types of *projects* or *grants* that are eligible for funding:

1. Project Types. Applicants must propose one of the following:
 - a. **Standard Research Proposals**. Standard research proposals **should not exceed \$500,000 (including indirect cost)** for project periods up to four (4) years of support. Proposal requests exceeding these limits will be excluded from review.
 - b. **Conference Proposals**. Conference proposals **should not exceed \$50,000**. Indirect costs **are not allowed** on conference grants. Proposal requests exceeding these limits will be excluded from review.

The BRAG program will not support applications for postdoctoral fellowships. In addition, the BRAG program will not support applications in any of the following areas: food safety risk assessment or risk assessment; health risk assessment or risk assessment of humans or domestic food animals exposed to GE organisms, including clinical trials; methods for seed storage; commercial product development; product marketing strategies; or other research unrelated to environmental risk assessment or risk management.

2. Grant Types. Applicants must select the appropriate grant type under this RFA.
 - a. **Standard**. This is an award instrument by which NIFA agrees to support a specified level of effort for a predetermined project period without the announced intention of providing additional support at a future date.

b. Resubmission. This is a project application that has been submitted for consideration under the same program previously but has not been approved for an award under the program. For competitive programs, this type of application is evaluated in competition with other pending applications in the area to which it is assigned. Resubmissions are reviewed according to the same evaluation as new applications. In addition, applicants must respond to the previous panel review summaries, unless waived by NIFA.

D. Ethical Conduct of Funded Projects

In accordance with sections [2, 3, and 8 of 2 CFR Part 422](#), institutions that conduct USDA-funded extramural research must foster an atmosphere conducive to research integrity, bear primary responsibility for prevention and detection of research misconduct, and maintain and effectively communicate and train their staff regarding policies and procedures. In the event an application to NIFA results in an award, the Authorized Representative (AR) assures, through acceptance of the award that the institution will comply with the above requirements. Award recipients must, upon request, make available to NIFA the policies, procedures, and documentation to support the conduct of the training. See [Responsible and Ethical Conduct of Research](#) for further information.

PART III. ELIGIBILITY INFORMATION

A. Eligibility Requirements

Applicants for the BRAG are limited to public or private research or educational institutions or organizations and must meet all the requirements discussed in this RFA. Failure to meet the eligibility criteria by the application deadline may result in exclusion from consideration or, preclude NIFA from making an award. For those new to Federal financial assistance, NIFA's [Grants Overview](#) provides highly recommended information about grants and other resources to help understand the Federal awards process.

Duplicate or Multiple Submission – duplicate or multiple submissions are not allowed. NIFA will disqualify both applications if a lead project director submits duplicate or multiple submissions. For those new to Federal financial assistance, NIFA's [Grants Overview](#) provides highly recommended information about grants and other resources to help understand the Federal awards process.

B. Cost Sharing or Matching

No Match Required - The BRAG program has ***NO*** matching requirement. NIFA will not factor matching resources into the review process as an evaluation criterion.

C. Centers of Excellence

Pursuant to [Section 7214 of the Agricultural Act of 2014 \(Pub. L. 113-79\)](#), NIFA will recognize and prioritize COE applicants that carry out research, extension, and education activities that relate to the food and agricultural sciences. A COE is composed of one or more of the following entities that provide financial or in-kind support to the COE.

1. State agricultural experiment stations
2. Colleges and universities
3. University research foundations
4. Other research institutions and organizations
5. Federal agencies
6. National laboratories
7. Private organizations, foundations, or corporations
8. Individuals
9. Any group consisting of two or more of the entities described in (1) through (8).

PART IV. APPLICATION AND SUBMISSION

A. Letter of Intent Instructions

Applicants are **highly encouraged** to submit a “Letter of Intent to Submit an Application” by the Letter of Intent (LOI) request date specified in this RFA. This does not obligate the applicant in any way but provides useful information to the BRAG program regarding the project’s fit with the program and assists in preparing for application review. Applicants who do not submit a letter of intent by the specified request date are still allowed to submit an application by the application due date specified in the RFA. We request a LOI for all grant types, except Conference Grant type. Please follow the guidelines below for LOI submission

1. The Letter of Intent must adhere to the following formatting guidelines:
 - a. Font size must be at least 12 point.
 - b. Margins must be at least one (1) inch in all directions.
 - c. Line spacing must not exceed six (6) lines of text per vertical inch; and
 - d. Page size must be letter (i.e., 8.5 inches × 11 inches).
2. The Letter of Intent is limited to two (2) pages.
 - a. Provide the following on Page 1:
 - i. the name, professional title, department, institution, and e-mail address of the lead project director (PD) and name, professional title, department, and institution of all collaborating investigators; and
 - ii. the one (1) Program Area that is most closely addressed in the application
 - b. Provide the following on Page 2:
 - i. a descriptive title
 - ii. rationale and one (1) specific program area the project best aligns with
 - iii. overall hypothesis or goal
 - iv. specific objectives
 - v. approach and
 - vi. potential impact and expected outcomes for federal regulatory agencies related to biotechnology.
3. NIFA will only accept LOI in the portable document format (PDF). Attach the PDF LOI to an e-mail addressed to Dr. Neerja Tyagi (neerja.tyagi1@usda.gov). In the e-mail subject line, write: Letter of Intent HX _ [PDs Last Name].
4. NIFA discourages the submission of more than one (1) LOI per lead project director to a program.
5. Scientific program staff will review LOIs to plan for appropriate expertise for the peer review panel and to ensure that proposed projects fit appropriately within the Program Areas.
6. Please notify the main Program Area Contact of any changes to key project personnel, title, or objectives between the submission of the LOI and the full application.

B. Method of Application

Applicants must apply to this RFA electronically; no other method or response is accepted. The electronic application for this RFA and additional resources are available on [Grants.gov](https://www.grants.gov) and [Grants 101](#). **Table 3** provides instructions on how to obtain an electronic application. **Part III** of the [NIFA Grants.gov Application Guide](#) (Application Guide) contains detailed information regarding the [Grants.gov](https://www.grants.gov) registration process.

Table 3. Steps to Obtain Application Materials

Steps	Action
Step One: Register	<i>New Users</i> to Grants.gov must register early with Grants.gov prior to submitting an application (Register Here).
Step Two: Download Adobe	Download and Install Adobe Reader (see Adobe Software Compatibility for basic system requirements).
Step Three: Find Application	Using this funding opportunity number: USDA-NIFA-BRAP-008702 , search for application here: Opportunity Package .
Step Four: Assess Readiness	Contact an AR prior to starting an application to assess the organization's readiness to submit an electronic application.

Table 4: Help and Resources

Grants.gov Support	NIFA Support
Grants.gov Online Support Telephone support: 800-518-4726 Toll-Free or 606-545-5035 Email support: support@grants.gov Self-service customer-based support: Grants.gov iPortal Key Information: Customer service business Hours 24/7, except federal holidays .	Email: grantapplicationquestions@usda.gov Key Information: Business hours: Monday thru Friday, 7a.m. – 5p.m. ET, except federal holidays

C. Content and Form of the Application

The [Application Guide](#) is part of the corresponding application package for this RFA. The RFA overrides the [Application Guide](#) if there is a discrepancy between the two documents. NIFA will accept subsequent submissions to an application until the application deadline. However, applicants that do not meet the application requirements, to include partial applications, risk being excluded from NIFA's review. NIFA will assign a proposal number to all applications that meet the requirements of this RFA. Applicants must refer to the proposal number when corresponding with NIFA. **Table 5** outlines other key instructions for applicants.

Table 5: Key Application Instructions

Instruction	References (All references are to the <u>Application Guide</u>)
Attachments must be in a portable document format (PDF) format.	Part IV
Check the manifest of submitted files to verify attachments are in the correct format.	Part IV
Conduct an administrative review of the application before submission.	Part IV
Follow the submission instructions.	Part V
Provide an accurate email address, where designated, on the SF-424 R&R.	Part V
Contact the Grants.gov helpdesk for technical support and keep a record of the correspondence.	N/A
Contact NIFA if applicant does not received correspondence from NIFA regarding an application within 30 days of the application deadline.	N/A

SF 424 R&R Cover Sheet. See **Part V** of the [Application Guide](#) for the required certifications and assurances.

SF 424 R&R Project/Performance Site Location(s). See **Part V** of the [Application Guide](#).

R&R Other Project Information Form. See **Part V** of the [Application Guide](#).

1. Field 7. Project Summary (PS)/Abstract. The PS must show how the project goals align with the project goals of the BRAG. See **Part V** of the [Application Guide](#) for instructions and suggested templates.
2. Field 8. Project Narrative (PN). The PN shall not exceed 18 pages of written text regardless of whether it is single- or double-spaced. We have established this maximum (18 pages) including figures and tables to ensure fair and equitable competition. Applicants requesting consideration of COE status must include their justification at the end of their PN and within the page limits provided for the PN. The PN must include all the following:
 - a. Introduction: Include a clear statement of the long-term goal(s) and supporting objectives of the proposed activities. Summarize the body of knowledge or other past activities that substantiate the need for the proposed project. Describe ongoing or recently completed significant activities that relate to the proposed project including

- the work of the key project personnel. Include preliminary data/information pertinent to the proposed project. In addition, this section should include in-depth information on the following, when applicable:
- i. Estimates of the magnitude of the issues and their relevance to stakeholders and to federal regulatory agencies.
 - ii. Reasons for performing the work at the proposed institution.
- b. Rationale and significance: The rationale for the proposed project should be concisely presented. The project's specific relationship and relevance to the program area in which an application is submitted (see Part I, C.) and its specific relationship and relevance to potential regulatory issues of United States biotechnology research should be shown clearly.
- c. Objectives: All applications must include a statement(s) of specific aims of the proposed effort in clear, concise, complete, and logically arranged terms.
- d. Experimental Plan: The hypotheses or questions being asked and the methodology to be applied to the proposed project should be stated explicitly. Specifically, this section must include:
- i. a description of the investigations and/or experiments proposed and the sequence in which the investigations or experiments are to be performed.
 - ii. techniques/methods to be used in carrying out the proposed project, including the feasibility of the techniques.
 - iii. experimental unit, replication, and sample sizes for each experimental group
 - iv. results expected.
 - v. means by which experimental data will be analyzed or interpreted, using power analyses, when appropriate.
 - vi. pitfalls that may be encountered; limitations to proposed procedures; and
 - vii. a project timetable that outlines all the important phases of the project as a function of time, year by year, for the entire project, including periods beyond the grant funding period.
- e. Data Management Plan (DMP): Two (2) page limit. Title the attachment as 'Data Management Plan' and save file as 'DataManagementPlan'. The required DMP should clearly articulate how the project director (PD) and co-PDs plan to manage and disseminate data generated by the project. NIFA and reviewers will consider the DMP during the merit review process. NIFA is aware of the need to provide flexibility in assessing DMPs. The DMP should contain the following components:
- i. *Expected Data Type*. Describe the type of data (e.g., digital, non-digital), how will they be generated, and whether the data are primary or metadata. Research examples include lab work, field work and surveys.
 - ii. *Data Format*. For data to be readily accessible and usable, it is critical to use the existing appropriate community-recognized standard, and machine-readable format. If the data will be managed in domain-specific workspaces or submitted to public databases (see section c and d) indicate that their required formats will be followed. Regardless of the format used, the data set must contain enough information to allow independent use of the data.
 - iii. *Data Storage and Preservation*. Data must be stored in a safe environment with adequate measures taken for its long-term preservation. Applicants must describe the plans for storing and preserving the data during and after the

project and specify the data workspaces and repositories if they exist. Databases or data repositories for long-term preservation may be the same that are used to provide Data Sharing and Public Access (see section d). Estimate how much data will be preserved and state the planned retention period. Include an outline of strategies, tools, and contingency plans that will be used to avoid data loss, degradation, or damage.

- iv. *Data Sharing and Public Access.* Describe your data access and sharing procedures during and after the grant (e.g., publication or public release). Name specific repositories and catalogs as appropriate. Outline any restrictions such as copyright, confidentiality, patent, appropriate credit, disclaimers, or conditions for use of the data by other parties.
- v. *Roles and Responsibilities.* Who will ensure DMP implementation? This is particularly important for multi-investigator and multi-institutional projects. Provide a contingency plan in case key personnel leave the project. Also, what resources will be needed for the DMP? If funds are needed, have they been added to the budget request and budget narrative? Projects must budget sufficient resources to develop and implement the proposed DMP.
- f. Centers of Excellence Justification; Applicants requesting consideration of COE status must include their justification at the end of their Project Narratives and within the page limits provided for the project narratives; and
- g. For Resubmissions: The response to previous review must not exceed one-page and must be included at the beginning of project narrative document. (This does not count towards the 18-page limit for the project narrative).

3. Field 12, Add Other Attachments. See **Part V** of the [Application Guide](#).

R&R Senior/Key Person Profile (Expanded). See **Part V** of the [Application Guide](#) for profile requirements, details about the biographical sketch, and suggested support templates.

R&R Personal Data. This information is voluntary and is not a precondition of award (see **Part V** of the [Application Guide](#)).

R&R Budget. See **Part V** of the [Application Guide](#).

Indirect costs (IDC) – See [Part IV § C](#) of this RFA for funding restrictions regarding indirect cost, and **Part V** of the [Application Guide](#) for additional information.

Data Management Plan. A DMP is required for this program. Applicants should clearly articulate how the project director (PD) and co-PDs plan to manage and disseminate the data generated by the project. The DMP will be considered during the merit review process (see [Part V § B](#) of this RFA, [NIFA’s Data Management Plan](#)).

Supplemental Information Form. See **Part V** of the [Application Guide](#).

1. Field 2. Program to which the applicant is applying. Enter the program name (Biotechnology Risk Assessment) and the program code (HX). Accurate entry is critical.
2. Field 8. Conflict of Interest List. See **Part V** of the [Application Guide](#).

Representations Regarding Felony Conviction and Tax Delinquent Status for Corporate Applicants. This is required for corporate applicants. See **Part VI § 2** of the [Application Guide](#) for a description of the term, “corporation.”

D. Funding Restrictions

Indirect Cost (IDC) not to exceed 30 percent of Total Federal Funds Awarded (TFFA) of the recipient. [Section 1462\(a\) and \(c\) of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 \(NARETPA\)](#) limits IDC for the overall award to 30 percent of Total Federal Funds Awarded (TFFA) under a research, education, or extension grant. The maximum IDC rate allowed under the award is determined by calculating the amount of IDC using:

1. the sum of an institution’s negotiated indirect cost rate and the indirect cost rate charged by sub-awardees, if any; or
2. 30 percent of TFFA.

The maximum allowable IDC rate under the award, including the IDC charged by the sub-awardee(s), if any, is the lesser of the two rates.

If the result of number one is the lesser of the two rates, the grant recipient is allowed to charge the negotiated IDC rate on the prime award and the sub-award(s), if any. Any sub-awards would be subject to the sub-awardee’s negotiated IDC rate. The sub-awardee may charge its negotiated IDC rate on its portion of the award, provided the sum of the IDC rate charged under the award by the prime awardee and the sub-awardee(s) does not exceed 30 percent of the TFFA.

If the result of number two is the lesser of the two rates, then the maximum IDC rate allowed for the overall award, including any sub-award(s), is limited to 30 percent of the TFFA. That is, the IDC of the prime awardee plus the sum of the IDC charged by the sub-awardee(s), if any, may not exceed 30 percent of the TFFA.

In the event of an award, the prime awardee is responsible for ensuring the maximum indirect cost allowed for the award is not exceeded when combining IDC for the Federal portion (i.e., prime and sub-awardee(s)) and any applicable cost-sharing (see [7 CFR 3430.52\(b\)](#)). Amounts exceeding the maximum allowable IDC are considered unallowable. See sections [408 and 410 of 2 CFR 200](#).

Successful applicants must not use grant funds awarded under the authority of this RFA to renovate or refurbish research, education, or extension space; purchase or install fixed equipment in such space; or to plan, repair, rehabilitate, acquire, or construct buildings or facilities.

PART V. APPLICATION REVIEW REQUIREMENTS

A. NIFA's Evaluation Process

NIFA evaluates each application in a two-part process. First, we screen each application to ensure that it meets the administrative requirements set forth in this RFA. All administrative requirements must be met in order for the application to proceed to the next level of review. Second, a scientific peer-review process will be used to technically evaluate applications that have met the administrative requirements using a review panel (see [NIFA Peer Review Process](#)).

Scientific Peer Review Process:

NIFA selects reviewers for the review panel based upon their training and experience in relevant scientific, extension, or education fields, taking into account the following factors:

1. the level of relevant formal scientific, technical education, or extension experience of the individual, as well as the extent to which an individual is engaged in relevant research, education, or extension activities.
2. the need to include experts from various areas of specialization within relevant scientific, education, or extension fields.
3. the need to include other experts (e.g., producers, range or forest managers/operators, and consumers) who can assess relevance of the applications to targeted audiences and to program needs.
4. the need to include experts from a variety of organizational types (e.g., colleges, universities, industry, state and Federal agencies, and private profit and non-profit organizations) and geographic locations.
5. the need to maintain a balanced composition with regard to minority and female representation and an equitable age distribution; and
6. the need to include reviewers who can judge the effective usefulness of each application to producers and the general public.

After each peer review panel has completed its deliberations, the responsible program staff of NIFA will recommend that your project is either approved for support from currently available funds or declined due to insufficient funds or unfavorable review.

NIFA reserves the right to negotiate with the PD/PI and/or the submitting organization or institution regarding project revisions (e.g., reductions in the scope of work, funding level, period, or method of support) prior to recommending any project for funding.

After the review process has been completed, NIFA sends copies of reviews, *not* including the identity of reviewers, and a summary (if applicable) of the review panel comments to the PD.

Conflicts of interest. NIFA takes extreme care to prevent any actual or perceived conflicts of interest that may influence the review or evaluation (see [NIFA Peer Review Process for Competitive Grant Applications](#)).

B. Evaluation Criteria

NIFA will use the following criteria to evaluate this RFA:

1. Scientific merit of the proposal.
 - a) Novelty, innovation, uniqueness, and originality.
 - b) Conceptual adequacy of the research and suitability of the hypothesis, as applicable.
 - c) Clarity and delineation of objective.
 - d) Adequacy of the description of the undertaking and suitability and feasibility of methodology.
 - e) Demonstration of feasibility through preliminary data.
 - f) Probability of success of project is appropriate given the scientific originality; and
 - g) Appropriateness to federal regulatory agencies interested in biotechnology and environmental risk assessment.
2. Qualifications of proposed project personnel and adequacy of facilities
 - a) Training and demonstrated awareness of previous and alternative approaches to problem identified in the proposal, and performance record and/or potential for future accomplishments.
 - b) Time allocated for systemic attainment of objectives.
 - c) Institutional experience and competence in subject area; and
 - d) Adequacy of available or obtainable support personnel, facilities, and instrumentation.
3. Relevance of project to solving biotechnology regulatory uncertainty for United States agriculture.
 - a) Scientific contribution of research in leading to important discoveries or scientific breakthroughs in the BRAG program areas; and
 - b) Relevance of the risk assessment research to agriculture and the environment
4. Centers of Excellence Status

All eligible applicants will be competitively peer reviewed (as described in [Part V §§ A and B](#) of this RFA) and ranked in accordance with the evaluation criteria. Those that rank highly meritorious and requested to be considered as a COE will be further evaluated by the peer panel to determine whether they have met the standards to be a COE ([Part III § C](#) and [Part IV § C](#)). In instances where they are found to be equally meritorious with the application of a non-COE, based on peer review, selection for funding will be weighed in favor of applicants meeting the COE criteria. NIFA will effectively use the COE prioritization as a “tie breaker.” Applicants that rank highly meritorious but who did not request consideration as a COE or who are not deemed to have met the COE standards may still receive funding.

In addition, the applicant’s Notice of Award will reflect that, for the particular grant program, the applicant meets all of the requirements of a COE. Entities recognized as a COE will maintain that distinction for the duration of their period of performance or as identified in the terms and conditions of that award.

Criteria for Evaluating Scientific Research Conference Applications:

1. Relevance and timeliness of topics and selection of appropriate speakers.
2. General format of the conference, especially about its appropriateness for fostering scientific exchange and/or public understanding.

3. Provisions for wide participation from the scientific and regulatory community and others, as appropriate.
4. Qualifications of the organizing committee.
5. Appropriateness of the budget requested.
6. Qualifications of project personnel; and
7. Dissemination of proceedings of the conference to the public.

C. Centers of Excellence

In addition to evaluating applicants using the criterion listed in [Part V § B](#) of this RFA, NIFA will use the COE standards described in this RFA to evaluate applicants that rank highly meritorious and requested to be considered as a COE. In instances where applicants are found to be equally meritorious with the application of a non-COE applicant, NIFA will prioritize the COE applicant meeting the COE criteria. NIFA will effectively use the COE prioritization as a “tie breaker.” Applicants that rank highly meritorious but who did not request consideration as a COE or who are not deemed to have met the COE standards may still receive funding. Applicants that meet the COE requirements will have the COE designation in their notice of award. Entities recognized as COE will maintain that distinction for the duration of their period of performance or as identified in the terms and conditions of that award.

D. Organizational Management Information

Applicants must submit specific management information relating to an applicant prior to an award and update the information as needed. Applicants may only have to update their information if they had previously provided the information under this or another NIFA program. NIFA provides the requisite forms during the pre-award process. Although an applicant may be eligible for award under this program, there are factors that may exclude an applicant from receiving federal financial and nonfinancial assistance and benefits under this program (e.g., debarment or suspension of an individual, or a determination that an applicant is not responsible).

E. Application Disposition

Applicants may withdraw at any time before NIFA makes a final funding decision. NIFA will retain all applications, including withdrawn applications and unfunded applications.

PART VI AWARD ADMINISTRATION

A. General

Within the limit of funds authorized, the NIFA awarding official will make grants to responsible and eligible applicants whose applications are judged most meritorious under the procedures set forth in this RFA. The date specified by the NIFA awarding official as the effective date of the grant must be no later than September 30 of the federal fiscal year in which the project is approved for support and funds are appropriated for such purpose, unless otherwise permitted by law. The project need not be initiated on the grant effective date, but as soon thereafter as practical so that project goals may be attained within the funded project period. All funds granted by NIFA under this RFA may be used only for the purpose for which they are granted in accordance with the approved application and budget, regulations, terms and conditions of the award, applicable federal cost principles, USDA assistance regulations, and [NIFA General Awards Administration Provisions, 7 CFR part 3430, subparts A through E](#).

Award Notice. The award document will provide pertinent instructions and information as described in [2 CFR 200.211](#) (see [NIFA's Terms and Conditions](#)).

B. Administrative and National Policy Requirements

Several federal statutes and regulations apply to grant applications and the projects outlined in this RFA (some are listed here: [Federal Regulations](#)). Unless specifically noted by statute or award-specific requirements, [NIFA Policy Guide](#) applies to all NIFA awards.

PART VII OTHER INFORMATION

A. Use of Funds and Changes in Budget

Delegation of fiscal responsibility. Unless the terms and conditions of the award state otherwise, awardees may not in whole or in part delegate or transfer to another person, institution, or organization the responsibility for use or expenditure of award funds.

Changes in Budget or Project Plans. In accordance with [2 CFR 200.308](#), awardees must request prior approval from NIFA for the following program or budget-related reasons (the awardee is subject to the terms and conditions identified in the award):

1. Change in the scope or the objective of the project or program without prior written approval (even if there is no associated budget revision requiring).
2. Change in a key person specified in the application or the federal award.
3. Disengagement from the project for more than three months, or a 25 percent reduction in time devoted to the project.
4. Inclusion of costs that require prior approval in accordance with [2 CFR 200 Subpart E \(Cost Principles\)](#), or [45 CFR Part 75 Appendix IX, \(Principles for Determining Costs Applicable to Research and Development under Awards and Contracts with Hospitals\)](#), or [48 CFR](#), unless waived by the federal awarding agency,
5. [48 CFR Part 31, Contract Cost Principles and Procedures](#);
6. Transfer of funds budgeted for participant support costs to other categories of expense ([2 CFR 200.456 Participant support costs](#)).
7. Sub-awarding, transferring or contracting out of any work under a federal award, including fixed amount sub-awards (see [2 CFR 200.333, Fixed Amount Sub-awards](#)), unless described in the application and funded in the approved federal awards. This provision does not apply to the acquisition of supplies, material, equipment, or general support services.
8. Changes in the approved cost-sharing or matching provided by the non-federal entity; and
9. The need for additional federal funds to complete the project.

B. Confidential Aspects of Applications and Awards

When an application results in an award, it becomes a part of NIFA transaction records, which are available to the public. Information that the Secretary of Agriculture determines to be confidential, privileged, or proprietary in nature will be held in confidence to the extent permitted by law. Therefore, applicants should clearly mark any information within the application they wish to have considered as confidential, privileged, or proprietary. NIFA will retain a copy of an application that does not result in an award for three years. Such an application will be released only with the consent of the applicant or to the extent required by law. An applicant may withdraw at any time prior to the final action thereon.

C. Regulatory Information

This program is not subject to the provisions of [Executive Order 12372](#), which requires intergovernmental consultation with state and local officials. Under the provisions of the [Paperwork Reduction Act of 1995 \(44 U.S.C. Chapter 35\)](#), the collection of information requirements contained in this notice have been approved under [OMB Document No. 0524-0039](#).

APPENDIX I: AGENCY CONTACT

Program Contacts

Name	Email	Telephone
Dr. John Erickson	john.erickson@usda.gov	(816)-283-6422
Dr. Frank Siewerdt	frank.siewerdt@usda.gov	(816) 329-9745
Dr. Kari Perez	kari.perez@usda.gov	(816) 550-8047
Dr. Jack Okamuro	jack.okamuro@usda.gov	(301) 504-5912
Dr. Neerja Tyagi	neerja.tyagi1@usda.gov	

For administrative questions related to

- Grants.gov, see Part IV of this RFA
- Other RFA or application questions, please email grantapplicationquestions@usda.gov
- Awards under this RFA, please email awards@usda.gov

NIFA's Mailing Address:

National Institute of Food and Agriculture
U.S. Department of Agriculture
P.O. Box 419205, MS 10000
Kansas City, MO 64141-6205

Courier/Package Delivery Address:

National Institute of Food and Agriculture
United States Department of Agriculture
2312 East Bannister Road, MS 10000
Kansas City, MO 64141-3061

APPENDIX II: GLOSSARY OF TERMS

Name	Acronyms
Agricultural Research, Extension, and Education Reform Act of 1998	AREERA
Animal and Plant Health Inspection Service - Biotechnology Regulatory Services	APHIS-BRS
Authorized Representative	AR
Biotechnology Risk Assessment Grant	BRAG
Catalog of Federal Domestic Assistance	CFDA
Center of Excellence	COE
Data Management Plan	DMP
Department of Health and Human Services	DHHS
Environmental Protection Agency	EPA
Food and Drug Administration	FDA
Genetically engineered	GE
National Institute of Food and Agriculture	NIFA
Request for Application	RFA
Research, Education, and Economics	REE
United States Department of Agriculture	USDA

APPENDIX III: DEFINITIONS

[Refer to 7 CFR 3430 Competitive and Noncompetitive Non-formula Federal Assistance Programs – General Award Administrative Provisions](#) for additional definitions.

Continuation Award:

An award instrument by which NIFA agrees to support a specified level of effort for a predetermined period of time with a statement of intention to provide additional support at a future date, provided that performance has been satisfactory, appropriations are available for this purpose, and continued support would be in the best interest of the federal government and the public.

Matching:

The process through which a grant recipient match awarded USDA funds with cash and in-kind contributions on a dollar-for-dollar basis. The matching funds must derive from non-Federal sources.

New Application:

An application not previously submitted to a program.

Renewal Application:

A project application that seeks additional funding for a project beyond the period that was approved in an original or amended award.

Resubmitted Application:

A project application that was previously submitted to a program, but the application was not funded.

Resubmitted Renewal Application:

A project application that requests additional funding for a project beyond the period that was approved in the original award. This is an application that had previously been submitted for renewal to but not funded.