

Biotechnology Risk Assessment Research Grants Program

MODIFICATION # 2: Cover Page and Pages 2, 5, 16, 17 and 24 (2/4/19)

Fiscal Year (FY) 2019 Request for Applications (RFA)

LETTER OF INTENT **RECEIPT DATE:** December 12, 2018

APPLICATION DEADLINE: **February 27, 2019**

ELIGIBILITY: See Part III, A of RFA

APPROXIMATE AWARD AMOUNT: \$3.5 MILLION



United States
Department of
Agriculture

National Institute
of Food and
Agriculture

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE; U.S. DEPARTMENT OF AGRICULTURE

BIOTECHNOLOGY RISK ASSESSMENT RESEARCH GRANTS PROGRAM

INITIAL ANNOUNCEMENT

CATALOG OF FEDERAL DOMESTIC ASSISTANCE: This program is listed in the Assistance Listings under the Catalog of Federal Domestic Assistance number 10.219.

DATES: A Letter of Intent (LOI) **should** be received by **5:00 p.m. Eastern Time on December 12, 2018**. Applications must be received by **5:00 p.m. Eastern Time on February 27, 2019**. Applications received after this deadline will normally not be considered for funding (see Part IV, C of this RFA). Comments regarding this request for applications (RFA) are requested within six (6) months from the issuance of this notice. Comments received after that date will be considered to the extent practicable.

STAKEHOLDER INPUT: We at the National Institute of Food and Agriculture (NIFA) seek your comments about this RFA. We will consider your comments when we develop the next RFA for the program, if applicable, and we'll use them to 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)). Submit your written stakeholder comments by the deadline set forth in the DATES portion of this notice via email to Policy@nifa.usda.gov. (This email address is only for receiving comments regarding this RFA and *not* for requesting information or forms.) In your comments, please state that you are responding to the Biotechnology Risk Assessment Research Grants Program RFA.

Visit the [NIFA website](#) to access a factsheet on the Center of Excellence (COE) designation process, including COE criteria, and a list of programs offering COE opportunities. You may also review a recording of COE outreach and COE implementation webinars on the site. We will update COE webpages as appropriate.

EXECUTIVE SUMMARY: NIFA requests applications for the Biotechnology Risk Assessment Research Grants (BRAG) Program for fiscal year (FY) 2019 to support environmental assessment research concerning the introduction of genetically engineered (GE) organisms into the environment. The anticipated amount available for grants in FY 2019 is approximately \$3.5 million. This RFA is being released prior to the passage of an appropriations act for FY 2019. Enactment of additional continuing resolutions or an appropriations act may affect the availability or level of funding for this program.

This notice identifies the objectives for BRAG projects, deadline dates, funding information, eligibility criteria for projects and applicants, and application forms and associated instructions needed to apply for a BRAG grant.

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PART I—FUNDING OPPORTUNITY DESCRIPTION

A. Legislative Authority

Authority for the BRAG Program is contained in section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921) and amended in section 7210 of the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 7901) (Pub. L. 107-171). In accordance with the legislative authority in the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 7901), 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-Agricultural Research Service (ARS) and Forest Service (FS) provide annual funding for the BRAG program.

The administrative regulations for this program are found at 7 CFR 3415 and 7 CFR 3430.

B. Purpose and Priorities

The Biotechnology Risk Assessment Research Grants (BRAG) Program is aligned with the USDA Strategic Plan (<https://www.usda.gov/sites/default/files/documents/usda-strategic-plan-2018-2022.pdf>) and specifically addresses Strategic Goal 1: Promote American Agriculture Products and Exports Sustainable Agricultural, Objective 3.1, Expand International Marketing and Opportunities; Objective 3.2: Prevent or Resolve Barriers to Trade That Hinder U.S. Food and Agricultural Exports, Strategic Goal 7: Provide All Americans Access to Safe, Nutritious, and Secure Food Supply, Objective 7.1, Prevent Foodborne Illness and Protection Public Health.

The purpose of the BRAG Program is to support the generation of new information that will assist Federal regulatory agencies in making science-based decisions about the environmental effects of introducing genetically engineered (GE) organisms by recombinant nucleic acid techniques. Such organisms can include plants, microorganisms (including fungi, bacteria, and viruses), arthropods, fish, birds, mammals, and other animals excluding humans. Investigations of effects on both managed and natural environments are relevant. The BRAG program accomplishes its purpose by providing Federal regulatory agencies with relevant scientific information.

The BRAG Program receives input regarding its program priorities through multiple regulatory agencies that have an interest in the environmental risk related to the introduction of GE organisms. These regulatory agencies include, but are not limited to, 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).

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 (4) 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 above and 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 to include 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 Director(s) (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 areas:

1. Standard Research Proposals
2. Conference Proposals

C. Program Area Description

Program Area Code – HX

Letters of Intent Receipt Date – Wednesday, December 12, 2018 (5:00 p.m., ET)

Application Deadline – Wednesday, **February 27, 2019** (5:00 p.m., ET)

Proposed Budget Requests –

Standard Research Proposals **must not exceed \$500,000** total (including indirect costs) for project periods up to four (4) years.

Conference Proposals **must not exceed \$25,000** total (indirect costs are not allowed on conference grants).

Program Federal Agency Collaboration –

NIFA will competitively award research grants to support biotechnology regulation, thereby helping to addressing 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 (1) 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 of their application which SINGLE standard research program area aligns best with their proposed project.**

STANDARD RESEARCH PROPOSALS

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 (1) of the following five (5) 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 for assuring confinement of GE organisms during field trials, particularly insects and microbes;
- 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 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;
- 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 spread, such as birds, rodents, aquatic species, arthropods and other invertebrates. This area may include:
 - Basic biological information about the non-modified species that is important for risk assessment and population models, particularly information about dispersal and behavior,
 - Studies on genotype and phenotype stability over multiple generations,
 - Comparative mating competence or reproductive studies,
 - Comparative behavior and biological studies, including studies addressing whether traits introduced by genetic engineering can alter host range or ecological interactions of organisms such as birds, aquatic species, arthropods and other invertebrates;
- e) 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, to assure confinement of field trials. This would include dormancy of crop, sexually compatible weedy species, and hybrids of the crop and weedy relatives; 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 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 micro-organisms 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 expression of and phenotypes conferred by genetic modification, to inform understanding of the characteristics and potential outcomes of gene transfer;
- d) Basic research on the genes related to weediness and their loci in the genome of weedy relatives of crop plants; and/or
- e) Data acquisition and modeling of GE organisms or engineered gene escape into the environment, including modeling to identify parameters that influence gene dispersal and its consequences.

4. **Environmental Impacts of GE relative to Non-GE Organisms in the Context of Production Systems**

Environmental assessment research on production systems which compare the relative impacts of animals, plants, and micro-organisms 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 as compared to non-GE organisms on agricultural, aquatic, or forest ecosystems (e.g. on community structures of agro- or forest ecosystems) or unmanaged ecosystems.
- Important focus areas are:

- The population dynamics and ecological impacts of various types of beneficial organisms;
 - Defining the magnitude and types of changes in communities or indicator species that could trigger concerns regarding ecosystem impacts;
 - How the biology and ecology of indicator taxa are influenced by geography, seasonal fluctuations, species, etc.);
- c) Assessment of how the introduction of GE organisms alters the impact of agriculture on the rural environment, such as altered land use practices, species displacement, soil erosion, effects on water quality, or other geographically dispersed events. Comparative 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:
- Soil health, fertilizer, pesticide, and soil amendment inputs;
 - Changes in toxicant and pesticide residue levels;
 - Prevalence and distribution of weeds, including those with single or multiple herbicide resistance;
 - Prevalence, distribution, and damage from pests and pathogens, including emergence of resistance;
 - Land use related to yield and productivity; and/or
- e) Identification and experimental assessment of potential adverse environmental impacts of large-scale growth of GE crops, with emphasis on plants used for bioenergy and/or bio-based products (e.g., sorghum, *Camelina*, sugarcane, eukaryotic algae, or perennial species such as trees and some grasses), 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:
- 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;
 - Strategies for conducting large scale GE field studies with minimal environmental risk;
 - Landscape level studies to assess environmental impacts of land use changes and/or ecosystem function and services;
 - 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;

- 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
- 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 off-target phenotypic effects in GE organisms developed using genome editing technology or other genetic engineering techniques and potential hazards or adverse effects to the environment associated with these off-target phenotypic effects;
- b) Research evaluating the potential hazards or adverse effects of GE livestock intended to be reared under commercial conditions, 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 drive, release of insect carry dominant lethal, etc.) on target populations or non-target species that interact with the targeted species, especially when incorporating biologically realistic parameters (e.g. of resistance evolution, numbers of individuals released, etc.);
- f) Comparison of the types and frequencies of nucleic acid changes introduced into important crop genomes, via genetic engineering techniques versus other plant breeding techniques. These studies should support the assessment of potential unintended effects that may occur from genetic engineering compared to other breeding techniques. Proposed projects must be comparative studies designed to analyze and compare statistically relevant data concerning the types and frequencies of genomic sequence changes and associated unintended phenotypic variation resulting from:
 - Insertion of DNA with one (1) or more widely used genetic engineering techniques (e.g., particle bombardment, *Agrobacterium*-mediated transformation), or off target effects of genome editing technologies (e.g., Zinc finger nucleases, TALENS, and CRISPR-Cas9) compared to one (1) or more other mutation-generating plant breeding techniques (e.g., irradiation or chemical mutagenesis, somatic cell culture and clonal propagation, ploidy alterations, wide interspecies or inter-generic crosses, induced structural changes in chromosomes);

- g) Research focused on the environmental effects of introducing RNA interference transgenes or other gene silencing mechanisms using RNAi, siRNA, or miRNA as replicating in animals, plants, microbes, and/or insects. Important areas include, but not limited to:
- Assessment of environmental fate and/or persistence of these small RNA molecules; and/or
 - 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);
- h) Assessment of the effects of multiple engineered insect 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 how pests or diseases overcome plant pest or disease resistance traits conferred by engineered genes (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).

Standard Research Proposals must not exceed \$500,000 total (including indirect costs) for project periods up to four (4) 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), 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 the means by which 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 \$25,000 total and the conference must occur after July 12, 2019. Indirect costs are not allowed on conference grants.

PART II – AWARD INFORMATION

A. Available Funding

The anticipated amount available for BRAG grants in FY 2019 is approximately \$3.5 million. This RFA is being released prior to the passage of an appropriations act for FY 2019. Enactment of additional continuing resolutions or an appropriations act may affect the availability or level of funding for this program.

There is no commitment by USDA to fund any particular application or to make a specific number of awards.

The Automated Standard Applications for Payment System (ASAP), operated by the Department of Treasury's Bureau of the Fiscal Service, is the designated payment system for awards resulting from this RFA. For more information see https://www.fiscal.treasury.gov/fsservices/gov/pmt/asap/asap_home.htm.

B. Types of Applications

In FY 2019, you may **only** submit an application to the BRAG program as one (1) of the following grant types of requests:

New application. This is a project application that has not been previously submitted to the BRAG program. We will review all new applications competitively using the screening for administrative requirements, review panel evaluation of proposals using evaluation criteria and selection process described in Part V—Application Review Requirements.

Resubmitted application. This is an application that had previously been submitted to the NIFA but not funded. Project Directors (PDs) must respond to the previous review panel summary (see Response to Previous Review, Part IV). We must receive resubmitted applications by the relevant due dates. We will evaluate resubmitted applications in competition with other pending applications in the appropriate area to which they are assigned and review them according to the same evaluation criteria (Part V, B) as new applications. If you are submitting a resubmitted application, you must enter the NIFA-assigned proposal number of the previously-submitted application in the Federal field (Field 4 on the form).

C. Project and Grant Types

NIFA is soliciting applications for the BRAG program under the following project types:

1. Standard Research Proposals

- a) Standard research proposals **should not exceed \$500,000 (including indirect cost)** for project periods up to four (4) years of support.
- b) Proposal requests exceeding these limits will be excluded from review.

2. Conference Proposals

- a) Conference proposals **should not exceed \$25,000. Indirect costs are not allowed on conference grants.**
- b) 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.

Grant Types

The following is a list of available grant types 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. Responsible and Ethical Conduct of Research

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 shall, upon request, make available to NIFA the policies, procedures, and documentation to support the conduct of the training.

For information about the Responsible and Ethical Conduct of Research, see <https://nifa.usda.gov/responsible-and-ethical-conduct-research>.

PART III—ELIGIBILITY INFORMATION

A. Eligible Applicants

Applications may only be submitted by United States public or private research or educational institutions or organizations, including federal research laboratories. Failure to meet an eligibility criterion by the application deadline may result in the application being excluded from consideration or, even though an application may be reviewed, will preclude NIFA from making an award.

B. Cost Sharing or Matching

The Agriculture Improvement Act of 2018 (HR 2) removed the matching requirements for some NIFA competitive grants imposed by the Agricultural Act of 2014. Therefore, there are changes to the matching requirements for some funds awarded in 2019.

For FY 2019, NIFA does not require matching support for the BRAG program and matching resources will not be factored into the review process as evaluation criteria.

C. Centers of Excellence

Pursuant to Section 7214 of the Agricultural Act of 2014 (Pub. L. 113-79), beginning in Fiscal Year 2015, for applicable competitive research and extension programs, NIFA will recognize and provide priority in the receipt of funding to applications from “centers of excellence” that carry out research, extension, and education activities that relate to the food and agricultural sciences. NIFA held listening sessions in July 2014 and accepted written comments from stakeholders to inform NIFA’s implementation of the COE provision. Information from the webinars and a summary of the input are available on NIFA’s website at <https://nifa.usda.gov/centers-excellence>.

A COE is composed of one (1) 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; or
9. Any group consisting of two (2) or more of the entities described in (1) through (9).

COE designation is available only to standard grant applicants. Part IV, B., 3. of this RFA contains additional requirements for COE consideration.

PART IV—APPLICATION AND SUBMISSION INFORMATION

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
 - 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) On Page 1, provide only the following information:
 - 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
 - the **one** (1) Program Area that is most closely addressed in the application
 - b) On Page 2, include:
 - a descriptive title
 - rationale and one (1) specific program area the project best aligns with
 - overall hypothesis or goal
 - specific objectives
 - approach
 - 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. Shing Kwok (skwok@nifa.usda.gov). In the e-mail subject line, write: Letter of Intent HX _ [PDs Last Name].
4. We discourage the submission of more than one (1) LOI per applicant 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. You must 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.

The Letter of Intent **is highly encouraged and the receipt date** is December 12, 2018 at 5:00 pm ET.

B. Electronic Application Package and Content and Form of Application Submission

Only electronic applications may be submitted via Grants.gov to NIFA in response to this RFA. We urge you to submit early to the Grants.gov system. For information about the pre-award phase of the grant lifecycle see <https://www.grants.gov/web/grants/learn-grants/grants-101/pre-award-phase.html>.

New Users of Grants.gov

Prior to preparing an application, we recommend that the Project Director/Principal Investigator (PD/PI) first contact an Authorized Representative (AR, also referred to as Authorized Organizational Representative, or AOR) to determine if the organization is prepared to submit electronic applications through Grants.gov. If not (e.g., the institution/organization is new to the electronic grant application process through Grants.gov), then the one-time registration process must be completed PRIOR to submitting an application. It can take as long as two (2) weeks to complete the registration process so it is critical to begin as soon as possible. In such situations, the AR should go to **“Register,” in the top right corner of the Grants.gov web page (or go to <https://www.grants.gov/web/grants/register.html>), for information on registering the institution/organization with Grants.gov.** Part II, 1 of the NIFA Grants.gov Application Guide contains detailed information regarding the registration process. Refer to item 2, below, to locate the “NIFA Grants.gov Application Guide.”

Steps to Obtain Application Package Materials

To receive application materials:

1. You must download and install a version of [Adobe Reader](#) compatible with Grants.gov to access, complete, and submit applications. For basic system requirements and download instructions, see <https://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html>. Grants.gov has a test package that will help you determine whether your current version of Adobe Reader is compatible.
2. To obtain the application package from Grants.gov, go to <https://www.grants.gov/web/grants/applicants/download-application-package.html> and enter the funding opportunity number where appropriate:

Funding Opportunity Number: USDA-NIFA-BRAP-006674.

Click “Search.” On the displayed page, click the corresponding link to continue. A Grant Application Package is tied to a particular funding opportunity. You may move forms amongst different Grant Application Packages but you may ONLY submit an application to the particular funding opportunity to which the Grant Application Package is associated.

Contained within the application package is the “NIFA Grants.gov Application Guide.” This guide contains an introduction and general Grants.gov instructions, information about how to use a Grant Application Package in Grants.gov, and instructions on how to complete the application forms.

If you require assistance to access the application package (e.g., downloading or navigating Adobe forms) **or submitting the application**, refer to resources available on the Grants.gov website (<https://www.grants.gov/web/grants/support.html>). Grants.gov assistance is also available at:

Grants.gov customer support

800-518-4726 Toll-Free or 606-545-5035

Business Hours: 24 hours a day, 7 days a week. Closed on [federal holidays](#).

Email: support@grants.gov

Grants.gov iPortal (see <https://grants-portal.psc.gov/Welcome.aspx?pt=Grants>): Top 10 requested help topics (FAQs), Searchable knowledge base, self-service ticketing and ticket status, and live web chat (available 7 a.m. - 9 p.m. ET).

Have the following information available when contacting Grants.gov:

- a) Funding Opportunity Number (FON)
- b) Name of agency you are applying to
- c) Specific area of concern

Electronic applications are to be prepared following Parts V and VI of the NIFA Grants.gov Application Guide. This guide is part of the corresponding application package (see Section A of this part). The following is **additional information** you need to prepare an application in response to this RFA. **If there is discrepancy between the two (2) documents, the information contained in this RFA is overriding.**

Note the attachment requirements (e.g., PDF) in Part III, Section 3 of the guide. ANY PROPOSALS THAT ARE NON-COMPLIANT WITH THE REQUIREMENTS (e.g., content format, PDF file format, file name restrictions, and no password protected files) WILL BE AT RISK OF BEING EXCLUDED FROM NIFA REVIEW. Grants.gov does not check for NIFA required attachments or whether attachments are in PDF format; see Part III, Section 6.1 of the guide for how to check the manifest of submitted files. **Partial applications will be excluded from NIFA review. We will accept subsequent submissions of an application until close of business on the closing date in the RFA (see Part V, 2.1 of the NIFA Grants.gov Application Guide for further information).**

For any questions related to the preparation of an application, review the NIFA Grants.gov Application Guide and the applicable RFA. If assistance is still needed for preparing application forms content, contact:

Email: electronic@nifa.usda.gov

Phone: 202-401-5048

Business hours: Monday through Friday, 7 a.m. – 5 p.m. ET, excluding [federal holidays](#).

1. SF 424 R&R Cover Sheet

Information related to the questions on this form is dealt with in detail in Part V, 2 of the NIFA Grants.gov Application Guide. See Part V, Section 2.18 of the NIFA Grants.gov Application Guide for the required certifications and assurances (e.g., Prohibition Against Entities Requiring Certain Internal Confidentiality Agreements).

2. SF 424 R&R Project/Performance Site Location(s)

Detailed information related to the questions on this form is available in Part V, 3 of the NIFA Grants.gov Application Guide.

3. R&R Other Project Information Form

Detailed information related to the questions on this form is available in Part V, 4 of the NIFA Grants.gov Application Guide.

a) Field 7. Project Summary/Abstract.

The summary should also include the relevance of the project to the goals of BRAG. See Part V. 4.7 of NIFA Grants.gov Application Guide for further instructions and a link to a suggested template. The use of this template is highly encouraged.

b) Field 8. Project Narrative.

NOTE: The Project Narrative shall not exceed 18 pages of written text regardless of whether it is single- or double-spaced. We have established this maximum (18 pages) to ensure fair and equitable competition. 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. The Project Narrative must include all of the following:

- **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.
- **Objectives**: All applications must include a statement(s) of specific aims of the proposed effort in clear, concise, complete, and logically arranged terms.

- 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.

- 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.

- Center of Excellence Justification for Research Grant Type
 Designation of Center of Excellence (COE) is only for **research** grant type. For consideration as a COE, you must provide a brief justification statement on the last page of the Project Narrative, and within the page limits provided, which describes how you meet the standards of a COE, based on the following criteria:
 - i. The ability of the COE to ensure coordination and cost effectiveness by reducing unnecessarily duplicative efforts in the research, teaching, and extension activities outlined in this application;
 - ii. In addition to any applicable matching requirements, the ability of the COE to leverage available resources by using public-private partnerships among agricultural industry groups, institutions of higher education, and the federal government in the proposed research and/or extension activities outlined in this application. Resources leveraged should be commensurate with the size of the award;
 - iii. The Planned scope and capability of the COE to implement teaching initiatives that increase awareness and effectively disseminate solutions to target audiences through extension activities of the proposed research and/or extension activity outlined in this application; and

- iv. The ability or capacity of the COE to increase the economic returns to rural communities by identifying, attracting, and directing funds to high-priority agricultural issues in support of and as a result of the implementation of the proposed research and/or extension activity outlined in this application.

Additionally, where practicable (not required), COE applicants should describe proposed efforts to improve teaching capacity and infrastructure at colleges and universities (including land-grant colleges and universities, cooperating forestry schools, certified Non-Land Grant Colleges of Agriculture (NLGCA) (list of certified NLGCA is available at <https://nifa.usda.gov/resource/nlgca-list>), and schools of veterinary medicine).

- **Response to Previous Review**

This requirement only applies to Resubmitted Applications as described in Part II, B. The Project Narrative attachment is to include two (2) components: 1) a one-page response to the previous review (containing the previous proposal number in the first line) titled “Response to Preview Review” as the first page of the attachment and 2) the 18 page Narrative, as required (see Part IV, C. 3.b., above). The one-page “Response to Previous Review” does not count against the 18-page limit of the Project Narrative.

c) Field 9. Bibliography & References Cited – PDF Attachment. No Page Limit.

Title the attachment as ‘Bibliography & References Cited’ in the document header and save file as ‘BibliographyReferencesCited’.

All work cited in the text should be referenced in this section of the application. All references must be complete; include titles and all co-authors; conform to an acceptable journal format; and be listed in alphabetical order using the last name of the first author or listed by number in the order of citation.

d) Field 12. Add Other Attachments

See Part V. Section 4.12 of the NIFA Grants.gov Application Guide (Field 12 on the form) for instructions for this field.

- **Data Management Plan (DMP)** – PDF Attachment. Two (2) Page Limit. Required for Research applications. Title the attachment as ‘Data Management Plan’ and save file as ‘DataManagementPlan’.

The 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.

4. R&R Senior/Key Person Profile (Expanded)

Detailed information related to the questions on this form is available in Part V, 5 of the NIFA Grants.gov Application Guide. This section of the guide includes instructions about senior/key person profile requirements, and details about the biographical sketch and the current and pending support, including a link to a suggested template for the current and pending support.

Biographical Sketch - The following are additional instructions of information to include:

- a) Author identifier (ORCID, <https://orcid.org>) of the researcher if available.
- b) Digital Object Identifier (DOI) of all publications where possible.

You may also include a list of data publications or published data products relevant to the

proposed project, following recommended data citation format.

5. R&R Personal Data

As noted in Part V, 6 of the NIFA Grants.gov Application Guide, the submission of this information is voluntary and is not a precondition of award. Part V.6 also notes the importance and use of the information.

However, NIFA strongly encourages applicants to provide the requested information to help NIFA identify and address any inequities based on gender, race, ethnicity, or disability of its proposed PDs/PIs and co-PDs/PIs. Information not submitted will seriously undermine the statistical validity, and therefore the usefulness, of information received from others. The information you submit will be kept confidential and will be used only for tracking and statistical purposes necessary to meet the demands of the agency and will not be part of the review process.

6. R&R Budget

Detailed information related to the questions on this form is available in Part V, 7 of the NIFA Grants.gov Application Guide.

Beginning the first year of funding, the PD of a funded project (excluding conference proposal awardees) will be required to attend an annual one- to two-day PD meeting in the metropolitan Washington, DC area or another location (to be determined at a later date) for the duration of the award. Reasonable travel expenses should be included as part of the project budget.

Indirect Costs

For further information and instructions regarding indirect costs, refer to Part V, section 7.9 of the NIFA Grants.gov Application Guide. For indirect cost funding restrictions, refer to Part IV, D. of this RFA.

7. Supplemental Information Form

Detailed information related to the questions on this form is available in Part VI, 1 of the NIFA Grants.gov Application Guide.

- a) **Field 2. Program to which you are applying.** Enter the program code name (i.e., enter “**Biotechnology Risk Assessment**”) and the program code (i.e., enter **HX**”). Note that accurate entry of the program code is very important for proper and timely processing of an application.

- b) **Field 8. Conflict of Interest List.** See Part VI, 1.8 of the NIFA Grants.gov Application Guide for further instructions and a link to a suggested template.

8. Representations Regarding Felony Conviction and Tax Delinquent Status for Corporate Applicants

This is a required form for corporate applicants. See Part VI, 2 of the NIFA Grants.gov Application Guide for a description of the term, “corporation,” and detailed information related to the questions on this form.

C. Submission Dates and Times

We recommend that you conduct an administrative review of the application before submission of it via Grants.gov to ensure that it complies with all preparation instructions. An application checklist is included in Part VII of the NIFA Grants.gov Application Guide to assist with this review.

1. Letter of Intent (LOI)

LOI **receipt date (highly encouraged): Wednesday, December 12, 2018 at 5:00 pm ET.** See Part IV for submission instructions.

2. Full Application

Application deadline: **Wednesday, February 27, 2019 at 5:00 p.m. ET.** A LOI **should be submitted** prior to submission of an application. See Part IV, A. for further information regarding the LOI.

3. Data Management Plan

See Part IV for data management instructions

While you may use the checklist to check the application for completeness, the application should be checked for the following required item(s). The list includes:

- Project summary/Abstract
- Project Narrative
- Bibliography & References Cited
- Data Management Plan
- Facilities & Other Resources
- Curriculum Vitae
- Conflict of Interest Lists
- Current and Pending support
- Budget
- Budget Justification
- Felony and Tax Certification Form

This is not an exhaustive list of required items; it only serves to highlight items that may be overlooked. **Failure to include any of the three critical documents of Project summary/Abstract, Project Narrative, or Bibliography & References Cited sections as PDF attachments will result in the application not being reviewed or considered for funding by NIFA.**

Instructions for submitting an application are included in Part IV, Section 1.9 of the NIFA Grants.gov Application Guide.

Applications received after this deadline will normally not be considered for funding.

If you have trouble submitting an application to Grants.gov, you should FIRST contact the Grants.gov Help Desk to resolve any problems. Keep a record of any such correspondence. See Part IV. A for Grants.gov contact information.

We send email correspondence to the AR regarding the status of submitted applications. We strongly encourage you to provide accurate email addresses, where designated, on the SF-424 R&R Application for Federal Assistance.

If the AR has not received correspondence **from NIFA** regarding a submitted application within 30 days of the established deadline, contact the Agency Contact identified in Part VII of the RFA and request the proposal number assigned to the application. **Failure to do so may result in the application not being considered for funding by the peer review panel. Once the application has been assigned a proposal number, you should cite this number on all future correspondence.**

D. Funding Restrictions

Section 713 of the Consolidated Appropriations Act, 2018 (Pub. L. 115-141) limits indirect costs to 30 percent of the total federal funds provided (or 42.857 percent of total direct costs) under each award. Similar language may be included in the FY 2019 appropriation, therefore, when preparing budgets, you should limit your request for the recovery of indirect costs to the lesser of your institution's official negotiated indirect cost rate or the equivalent of 30 percent of total Federal funds awarded. See Part V section 7.9 of the NIFA Grants.gov Application Guide for further indirect cost information.

Funds made available for grants under the BRAG Program must comply with the legislative authority.

The use of grant funds to plan, acquire, or construct a building or facility is not allowed under this program. With prior approval, and in accordance with the cost principles set forth in 2 CFR part 200, some grant funds may be used for minor alterations, renovations, or repairs deemed necessary to retrofit existing teaching or research spaces in order to carry out a funded project. However, requests to use grant funds for such purposes must demonstrate that the work is essential to achieving the major purpose of the project. Grant funds may not be used for endowment investing.

E. Other Submission Requirements

You should follow the submission requirements noted in Part IV, Section 1.9 in the document entitled "NIFA Grants.gov Application Guide."

For information about the **status of a submitted application**, see Part III, Section 6 of the NIFA Grants.gov Application Guide

PART V—APPLICATION REVIEW REQUIREMENTS

A. General

We evaluate each application in a two-part process. First, we screen each application to ensure that it meets the administrative requirements as set forth in this RFA. Second, a technical review panel will evaluate applications that meet the administrative requirements.

We select reviewers 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 the BRAG Program will recommend that your project be approved for support from currently available funds or be declined due to insufficient funds or unfavorable review.

The BRAG Program reserves the right to negotiate with the PD/PI and/or with 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.

We will send copies of reviews, *not* including the identity of reviewers, and a summary of the panel comments to the PD after the review process has been completed.

B. Evaluation Criteria

A reviewer's written evaluation entails two levels of assessment. First, the reviewer summarizes how well the application addressed each evaluation criterion. After the application has been assessed for strengths and weaknesses of each criterion, the reviewer then evaluates the overall likelihood that the project will have significant outcome and impact. These written reviews are used to begin panel discussions with other reviewers serving on the peer review panel. Through these discussions, peer review panelists come to consensus on the final rating and ranking of proposals. A complete description of NIFA's peer review process can be found at the NIFA website:

<https://nifa.usda.gov/resource/nifa-peer-review-process-competitive-grant-applications>.

Please be advised that the evaluation criteria has equal weight.

We will use the evaluation criteria below to review applications submitted in response to this RFA:

The evaluation criteria identified in [7 CFR 3415.15](#) (see below) will be used to review all applications submitted in response to this RFA except applications that seek funding for conferences.

Criteria for Evaluating Standard Research Applications

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 with regard to 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. Conflicts of Interest and Confidentiality

During the peer evaluation process, we take extreme care to prevent any actual or perceived conflicts of interest that may impact review or evaluation. See <https://nifa.usda.gov/resource/nifa-peer-review-process-competitive-grant-applications> for further information about conflicts of interest and confidentiality as related to the peer review process.

D. Organizational Management Information

Specific management information relating to an applicant shall be submitted one-time, with updates on an as-needed basis. This requirement is part of the responsibility determined prior to the award of a grant identified under this RFA, if such information has not been provided previously under this or another NIFA program. We will provide you copies of forms recommended for use in fulfilling these requirements as part of the pre-award process. Although an applicant may be eligible based on its status as one (1) of these entities, 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 involved or a

determination that an applicant is not responsible based on submitted organizational management information).

E. Application Disposition

An application may be withdrawn at any time before a final funding decision is made regarding the application. Each application that is not selected for funding, including those that are withdrawn, will be retained by the BRAG Program for a period of three (3) years.

PART VI—AWARD ADMINISTRATION

A. General

Within the limit of funds available for such purpose, the NIFA awarding official shall make grants to those responsible, 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 shall 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 at 7 CFR part 3430, subparts A through E.

B. Award Notice

The award document will provide pertinent instructions and information including, at a minimum, the information described in [2 CFR 200.210](#).

See <https://nifa.usda.gov/terms-and-conditions> to view current NIFA award terms and conditions.

C. Administrative and National Policy Requirements

Several federal statutes and regulations apply to grant applications considered for review and to project grants awarded under this program. These may include, but are not limited to, the ones listed on the NIFA web page – <http://nifa.usda.gov/federal-regulations>.

NIFA Federal Assistance Policy Guide—a compendium of basic NIFA policies and procedures that apply to all NIFA awards, unless there are statutory, regulatory, or award-specific requirements to the contrary—is available at <http://nifa.usda.gov/policy-guide>.

Responsible and Ethical Conduct of Research

Refer to Part II, D for more information.

D. Expected Program Outputs and Reporting Requirements

The output and reporting requirements are included in the award terms and conditions (see <https://nifa.usda.gov/terms-and-conditions> for information about NIFA award terms). If there are any program or award-specific award terms, they will be identified in the award.

Grantees are required to use REEport, NIFA’s electronic, web-based inventory system to submit an initial project initiation which documents expected products and outcomes of the project.

Additionally, annual progress report documenting realized project outcomes must be submitted to the REEport system. The web-based system facilitates an electronic workflow between grantees and NIFA for project accomplishments to be easily searchable and allows for public access to information on Federally-funded projects. The details of these reporting requirements, including those specific to the annual and final technical reports, are included in the award terms and conditions and will also be provided by the National Program Leaders of the BRAG Program.

Project Directors are expected to participate in a one- to two-day PD meeting (excluding conference proposal awardees) in the metropolitan Washington, DC area or another location (to be determined at a later date). An oral briefing for representatives of regulatory agencies may be scheduled during this time. Reasonable travel expenses may be claimed as part of the project budget.

PART VII—AGENCY CONTACTS

Applicants and other interested parties are encouraged to contact:

Primary Programmatic Contact –

Dr. Shing F. Kwok, National Program Leader
U.S. Department of Agriculture
National Institute of Food and Agriculture
Institute of Food Production and Sustainability
800 9th St., SW; Washington, DC 20024
Telephone: (202) 401-6060
Fax: (202) 401-6071
Email: skwok@nifa.usda.gov

Additional Programmatic Contacts

Dr. Lakshmi Matukumalli, National Program Leader
U.S. Department of Agriculture
National Institute of Food and Agriculture
Institute of Food Production and Sustainability
800 9th St., SW; Washington, DC 20024
Telephone: (202)-401-1766
Email: lmatumalli@nifa.usda.gov

Dr. Jack Okamuro, National Program Leader
U.S. Department of Agriculture
Agricultural Research Service
George Washington Carver Center
5601 Sunnyside Avenue, Room 4-2220
Beltsville, MD 20705-5139
Telephone: (301) 504-5912
Mobile: (202) 285 – 9520
Email: jack.okamuro@ars.usda.gov

Administrative/Business Contact –

Mrs. Rochelle McCrea; Team Leader, Team I
U.S. Department of Agriculture
National Institute of Food and Agriculture
Office of Grants and Financial Management
1400 Independence Ave., SW; STOP 2271
Washington, DC 20250-2271
Telephone: (202) 401–2880
Fax: (202) 401–6271
Email: rmccrea@nifa.usda.gov

PART VIII—OTHER INFORMATION

A. Use of Funds; Changes

1. 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.

2. 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:

- a) Change in the scope or the objective of the project or program (even if there is no associated budget revision requiring prior written approval).
- b) Change in a key person specified in the application or the federal award.
- c) The disengagement from the project for more than three (3) months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.
- d) The inclusion, unless waived by the federal award agency, of costs that require prior approval in accordance with 2 CFR 200 Subpart E – Cost Principles of this part 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 Part 31, “Contract Cost Principles and Procedures,” as applicable.
- e) The transfer of funds budgeted for participant support costs as defined in §200.75 Participant support costs to other categories of expense.
- f) Unless described in the application and funded in the approved federal awards, the subawarding, transferring or contracting out of any work under a federal award, including fixed amount subawards as described in §200.332 Fixed amount subawards. This provision does not apply to the acquisition of supplies, material, equipment, or general support services.
- g) Changes in the approved cost-sharing or matching provided by the non-federal entity.
- h) The need arises for additional federal funds to complete the project.

The awardee will be subject to the terms and conditions identified in the award. See <https://nifa.usda.gov/terms-and-conditions> for information about NIFA award terms.

B. Confidential Aspects of Applications and Awards

When an application results in an award, it becomes a part of the record of NIFA transactions, available to the public upon specific request. Information that the Secretary of Agriculture determines to be of a confidential, privileged, or proprietary nature will be held in confidence to the extent permitted by law. Therefore, any information that the applicant wishes to have considered as confidential, privileged, or proprietary should be clearly marked within the

application. We will retain for three (3) years a copy of an application that does not result in an award. Such an application will be released only with the consent of the applicant or to the extent required by law. An application may be withdrawn 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.

D. Definitions

Refer to [7 CFR 3430, Competitive and Noncompetitive Non-formula Financial Assistance Programs--General Award Administrative Provisions](#), for applicable definitions for this NIFA grant program.

Partnership requires that all partners have a substantial involvement in the project throughout the life of the project. If a partnership between multiple entities is proposed, the proposal must clearly identify the following:

1. A narrative of each entity's clearly established role in the project;
2. How each entity involved as a partner on the project will contribute to execution of project objectives, determine experimental design, develop the project work plan and time table, and submit collaborative, timely reports; and
3. A comprehensive project budget that reflects each entity's financial or in-kind contribution to the total project budget costs.

E. Materials Available on the Internet

The BRAG Program information will be made available on the NIFA web site at <http://nifa.usda.gov/program/biotechnology-risk-assessment-research-grants-program>. The following are among the materials available on the web page:

1. More information about the BRAG Program
2. Partnerships
3. Requests for Applications
4. Abstracts of recently Funded Projects