

Biotechnology Risk Assessment Research Grants Program

MODIFICATION: On page 2 and 12 (1/8/2016). Updated Appropriation
Language.

2016 Request for Applications (RFA)

LETTER OF INTENT RECEIPT DATE: February 12, 2016

APPLICATION DEADLINE: April 15, 2016

ELIGIBILITY: See Part III, A of RFA



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 Catalog of Federal Domestic Assistance under **10.219**.

DATES: Letter of Intent (LOI) should be received by 5:00 p.m., Eastern Time on February 12, 2016. Applications must be received by **5:00 p.m. Eastern Time on April 15, 2016.**

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 6 months from the issuance of this notice. Comments received after that date will be considered to the extent practicable.

STAKEHOLDER INPUT: The National Institute of Food and Agriculture (NIFA) seeks your comments about this RFA. We will consider the 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 written stakeholder comments by the deadline set forth in the DATES portion of this Notice via e-mail to: Policy@nifa.usda.gov. (This e-mail address is intended only for receiving comments regarding this RFA and not 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 in fiscal year 2016. You can also review a recording of COE outreach webinars held in February and March of 2015 from the site. The COE webpages will be updated throughout FY 2016 with additional information, such as a summary of comments received from stakeholders.

EXECUTIVE SUMMARY: NIFA requests applications for the Biotechnology Risk Assessment Research Grants (BRAG) Program for fiscal year (FY) 2016 to support environmental assessment research concerning the introduction of genetically engineered (GE) organisms into the environment. The anticipated appropriated amount available for NIFA to support this program in FY 2016 is approximately \$4 million.

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

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PART I—FUNDING OPPORTUNITY DESCRIPTION

A. Legislative Authority and Background

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 (USDA) jointly administer 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 Grants (BRAG) program directly aligns with the Research, Education, and Economics Action Plan (March 2014 version) (http://www.ree.usda.gov/ree/news/USDA_2014_REE_Action_Plan_08-2014_Final.pdf) and specifically addresses: Goal 1 – Sustainable Intensification of Agricultural Production, Subgoals 1A, 1B, and 1C (which focus on Crop and Animal Production, Crop and Animal Health, and Crop and Animal Genetics, Genomics, Genetic Resources, and Biotechnology, respectively); Goal 2 - Responding to Climate and Energy Needs, Subgoal 2B (which focuses on Bioenergy/Biofuels and Biobased Products). The BRAG program is also aligned with the NIFA Strategic plan (2014-2018) (http://nifa.usda.gov/about/pdfs/strat_plan_2014.pdf), specifically addressing Strategic Goal 1 (Science), Advance Our Nation’s Ability to Fight Hunger and Ensure Global Food Security (Subgoal 1.1).

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 organisms genetically engineered (GE) 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). In addition, the BRAG program seeks input on research priorities from USDA’s Advisory Committee on Biotechnology & 21st Century Agriculture (AC21) – <http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=AC21Main.xml>.

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 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.

NIFA is soliciting applications for the Biotechnology Risk Assessment Research Grants Program (BRAG) under the following areas:

- (1) Priority Research Proposals
- (2) Standard Research Proposals
- (3) Conference Proposals

C. Program Area Description

Program Area Code – HX

Letters of Intent Receipt - Friday, February 12, 2016 (5:00 p.m., ET)

Application Deadline – Friday, April 15, 2016 (5:00 p.m., ET)

Proposed Budget Requests –

Priority Research Proposals **must not exceed \$1 million** total (including indirect costs) for project periods up to 4 years.

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

Conference Proposals **must not exceed \$25,000** total (no indirect costs are allowed on conference grants).

Program Federal Agency Collaboration –

NIFA and ARS 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. In addition, research that is relevant to risk assessment and can simultaneously inform the development of approaches for co-existence is useful** (http://www.usda.gov/documents/ac21_report-enhancing-coexistence.pdf). 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 priority or standard research program areas (see below) or seek funding for a conference/workshop. In addition, applicants **MUST state in the beginning of their Project Summary which SINGLE priority or standard program area aligns best with their proposed project.**

PRIORITY RESEARCH PROPOSALS

A priority research project must provide viable solutions to the highest priority issues in biotechnology risk assessment research through either applied or fundamental research.

Areas of interest to the BRAG program for a priority grant are:

1. Comparison between Transformation-associated Genomic Variation and Genomic Variation Introduced by Non-genetic Engineering Approaches in Plants

Comparison of the types and frequencies of nucleic acid changes introduced into plant genomes, via genetic insertion/modification techniques versus other plant breeding techniques. Proposed projects must be comparative studies designed to analyze and compare data concerning the types and frequencies of genomic sequence changes and associated unintended phenotypic variation resulting from:

- a) insertion of DNA with one 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**

- b) one 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).

Proposed projects must be conducted in an important crop species which can include specialty crops and clonally propagated crops. Experimental designs must generate statistically relevant data. These studies should support the assessment of potential unintended effects that may occur from genetic engineering compared to other breeding techniques.

The use of the word “phenotypic variation” above specifically refers to the introduction of unintended changes to the existing phenotype and does NOT include the intended new phenotype introduced. The focus of the project is on the unintended consequences of DNA insertion/sequence modification and not on the consequences of the specific DNA inserted/modified.

2. Development of a Risk Assessment Framework for the Environmental Impacts of GE crops at the Landscape Level

Identification and experimental assessment of potential environmental impacts of large-scale growth of GE crops, with emphasis on plants used for biofuels (e.g., perennial species such as trees or grasses, camelina, sorghum, sugarcane, eukaryotic algae etc.), to support the development of a risk assessment framework. For the purposes of this priority area, large-scale refers to cultivation on 100 or more acres. Project must address multiple BRAG topic areas, preferentially chosen from (but not limited to) the following:

- a) Biological and ecological baseline studies associated with GE perennial species that will aid in the development of risk assessment methodologies;
- b) Strategies for conducting large scale GE field studies with minimal environmental risk;
- c) Landscape level studies to assess environmental impacts of land use changes and/or ecosystem function and services;
- d) 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;
- e) Assessment of the likelihood and impact of gene flow to related organisms under various management strategies;
- f) Weediness or invasiveness of the GE organism relative to non-GE parent organism; and/or
- g) Basic biology and ecology of the unmodified parent organism, including fitness characteristics.

Priority Research Proposals must not exceed \$1 million (including indirect costs) for project periods up to four years.

STANDARD RESEARCH PROPOSALS

Standard research proposals address issues related to newly developed GE organisms that are animals, plants (e.g., trees and other perennials, including biofuel crops are especially sought), 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 for confinement of field trials of GE organisms;
- b) Development of practical management methodologies for reducing the spread and persistence of GE organisms into natural and managed environments;
- c) Development or evaluation of effective bio-confinement strategies, including molecular and/or genetic techniques, to limit gene transfer (gene flow) or outcrossing to sexually compatible organisms;
- d) Mitigation measures to limit gene introgression when GE organisms are released or escaped into the environment, physical containment fails, or biological containment is unavailable;
- e) Ecological effects of technologies for reducing the undesired spread of GE organisms;
- f) Evaluation of safeguards (e.g. reversal drives, immunization) for controlling the spread of gene drives during research to understand the effect of the desired genetic change on organisms and populations; and/or
- g) Explore risk mitigation strategies to ameliorate environmental impacts associated with certain GE organisms.

2. Methods to Monitor and Understand the Dispersal of GE Organisms

Research designed to develop methods to monitor and understand the dispersal of GE organisms. Potential areas of research include, but are not limited to:

- a) Survivability profile and/or fitness of GE organisms in the wild (for plants) or GE organisms as compared to their non-GE counterparts (for animals);
- b) Information on dormancy in the seed bank affecting persistence of grains (e.g. wheat, barley, rice and canola), particularly variety x environment 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;
- c) Strategies for large-scale deployment or field studies of GE organisms, with special reference to those considerations that may not be revealed through small-scale evaluation and tests;
- d) Assessing the effects of transgene(s) in engineered animal species that may easily spread,

such as birds, aquatic species, arthropods and other invertebrates. This area may include:

- Studies on genotype and phenotype stability over multiple generations,
 - Comparative mating competence or reproductive studies,
 - Comparative behavior and biological studies, including studies addressing whether transgenes can alter host range or ecological interactions;
- e) Understanding and predicting the behavior of gene drives in organisms when released into the environment; especially the identification of the key factors impacting survival, spread in populations; or
- f) Development and/or evaluation of tools for assessing weediness or invasiveness of GE plants relative to unmodified parent organisms.

3. Gene Transfer to Domesticated and Wild Relatives

Research designed to further existing knowledge with the characteristics, rates, and mechanisms of gene transfer (gene flow) 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 outcrossing to sexually compatible species and to genes that have a high potential for altering the fitness of the recipient organism for its environment. For plants, preference will be given to studies with species that have sexually compatible wild relatives in the United States. Potential areas of research include, but are not limited to:

- a) Impacts of gene flow from GE plants, particularly perennials (*e.g.* trees), insects, animals, or micro-organisms to related organisms, communities, or ecosystems;
- b) Fate and stability (persistence) of transgenes that have been introgressed by outcrossing into populations of non-GE organisms, and the degree to which they confer a selective advantage or disadvantage upon the carriers, especially with regard to transgenes that confer fitness (*e.g.* enhanced growth or abiotic stress tolerance) in wild populations;
- c) Assessing the influence of genetic background on the expression of and phenotypes conferred by regulatory genes, to inform understanding of the characteristics and potential outcomes of gene transfer; and/or
- d) Data acquisition and modeling of GE organisms or transgene escape into the environment, including modeling to identify parameters that influence gene dispersal and its consequences, with a particular interest in insect-mediated gene movement between plants.

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

Environmental assessment research which compares the relative impacts of animals, plants, and micro-organisms modified through genetic engineering to other types of production systems. Potential areas of research include, but are not limited to:

- a) Assessment of the influence of GE *as compared to* non-GE organisms on agricultural or forest ecosystems (*e.g.*, on community structures of agro- or forest ecosystems). Important focus areas are:

- The presence and function of various types of beneficial organisms,
 - Defining the magnitude of changes in indicator species or communities that could trigger concerns regarding ecosystem impacts,
 - How the biology and ecology of indicator taxa are influenced by geography, seasonal fluctuations, species, etc.); and/or
- b) Assessment of how the introduction of GE organisms alters the impact of agriculture on the rural environment, such as altered land use practices or other aspects of human ecology, 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); and/or
- c) 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, and/or
 - Land use related to yield and productivity.

5. Other Research Topics designed to further the purposes of this program

Other areas of research designed to further the purposes of the BRAG Program. Potential areas of research include, but are not limited to:

- a) 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) at the landscape level.
- b) Assessment of the impacts of genetic engineering on plant-pest interactions, including impacts on the plants themselves and/or on plant-pest populations, **including research** to understand how pests or diseases overcome transgene conferred resistance.
- c) The effects of multiple transgenic resistance genes on non-target species. Proposals on pest resistance management are not excluded from the program, but any such proposals submitted should describe a clear and significant connection with biotechnology and environmental risk assessment/management.

- d) Research addressing off-target genotypic and/or phenotypic effects in GE organisms developed using genome editing technology;
- e) Research evaluating the risks and the need for containment of GE livestock reared under commercial conditions;
- f) Research evaluating the risks and levels of containment needed for GE animals intended for release into the environment (e.g., population control).

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, 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 should: 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, 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 must occur after July 15, 2016. No indirect costs are allowed on conference grants

PART II—AWARD INFORMATION

A. Available Funding

The anticipated appropriated amount available for NIFA to support this program in FY 2016 is approximately \$4 million. The funds will be awarded through a grant. There is no commitment by USDA to fund any particular application or to make a specific number of awards.

Awards issued as a result of this RFA will have designated the Automated Standard Applications for Payment System (ASAP), operated by the Department of Treasury's Bureau of the Fiscal Service, as the payment system for funds. For more information see <http://fms.treas.gov/index1.html>.

B. Types of Applications

In FY 2016, you may only submit a new application to the BRAG Program as one of the following 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 selection process and evaluation criteria described in Part V—Application Review Requirements.

Resubmitted application. This is an application that had previously been submitted to the BRAG Program but not funded. Project Directors (PDs) must respond to the previous review panel summary (see Response to Previous Review, Part IV). Resubmitted applications must be received by the relevant due dates, will be evaluated in competition with other pending applications in appropriate area to which they are assigned, and will be reviewed according to the same evaluation criteria as new applications.

C. Project Types

NIFA is soliciting applications for the BRAG Program under the following project type:

(1) Priority Research Proposals

- Priority research proposals submitted to the BRAG program **should not exceed \$1 million (including indirect costs)** for project periods up to 4 years of support.
- Proposal requests exceeding these limits will be excluded from review.

(2) Standard Research Proposals

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

(3) Conference Proposals

- Conference proposals **should not exceed \$25,000. No indirect costs are 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 management; health risk assessment or risk management 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.

D. Responsible and Ethical Conduct of Research

See <http://nifa.usda.gov/responsible-and-ethical-conduct-research> for further information.

PART III—ELIGIBILITY INFORMATION

A. Eligible Applicants

Applications may only be submitted by United States public or private research or educational institution or organization. Award recipients may subcontract to organizations not eligible to apply provided such organizations are necessary for the conduct of the project. Failure to meet an eligibility criterion by the time of 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

In accordance with section 1492 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3371), as added by section 7128 of the Agricultural Act of 2014 (Pub. L. 113-79), for grants awarded after October 1, 2014, the recipient of an award from the BRAG program must provide funds, in-kind contributions, or a combination of both, from sources other than funds provided through such grant in an amount that is at least equal to the amount awarded by NIFA unless one of the exemptions described herein is applicable. Note that NIFA included information at http://www.nifa.usda.gov/business/awards/matching_require.html to further assist you in determining if you must meet the new matching requirement.

The matching funds requirement does not apply to grants awarded:

1. To a research agency of the United States Department of Agriculture (USDA); or
2. To an entity eligible to receive funds under a capacity and infrastructure program (as defined in section 251(f)(1)(C) of the Department of Agriculture Reorganization Act of 1994, 7 U.S.C. 6971(f)(1)(C)), including a partner (see Part VIII, E. Definitions for definition of partnership) of such an entity.

Entities eligible to receive funds under a capacity and infrastructure program and exempt from the matching funds requirement include:

- a. 1862 Land-grant Institutions, including State Agricultural Experiment Stations receiving funding under the Hatch Act of 1887
- b. 1890 Land-grant Institutions
- c. 1994 Land-grant Institutions
- d. Entities eligible to receive funds under the Continuing Animal Health and Disease, Food Security, and Stewardship Research, Education, and Extension Program Funds — Capacity and Infrastructure Program (CIP)
- e. Hispanic-Serving Agricultural Colleges and Universities (HSACU)
- f. Insular Area Schools Eligible to Receive Funds from the Distance Education/Resident Instruction Grant Programs
- g. Entities eligible to receive funds under the McIntire-Stennis Cooperative Forestry Program Funds

- h. Non-Land Grant Colleges of Agriculture (NLGCA) - (for exemption from the new matching requirement, these applications must include NLGCA certification, see instructions for requesting certification at <http://www.nifa.usda.gov/form/form.html>, and for attaching the certification in Part IV, C. of this RFA)
- i. Recipients of funds under a program established under section 1417(b) of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3152(b)), including: (1) 1890 Institution Teaching, Research, and Extension Capacity Building Grants Program; (2) Higher Education Challenge Grants Program; (3) Higher Education Multicultural Scholars Program; and (4) Food and Agricultural Sciences National Needs Graduate and Postgraduate Fellowship Grants Program
- j. Individual public or private, nonprofit Alaska Native-Serving and Native Hawaiian-Serving Institutions of higher education (see 20 U.S.C. 1059d).

A proposal submitted in response to this RFA may indicate that the work will be completed by multiple entities as a collaborative partnership. All partners must have a substantial involvement in the project throughout the life of the project. If a partnership among 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, determination of experimental design, development of the project work plan and time table, and submission of collaborative, timely reports; and
- 3) A comprehensive project budget that reflects each entity's financial or third party in-kind contribution (see section 2 of 7 CFR 3430 or section 96 of 2 CFR part 200) to the total project budget costs.

If a proposal indicates that the work on the project will be completed by multiple entities as partners, and at least one entity is exempt from the matching requirement under #2 above, the entire project will be exempt from the matching requirement regardless of whether all entities involved are otherwise exempt. Any partner entity can serve as the lead entity on the project. All partners must be significantly involved in the project.

After proposals have been recommended for award, NIFA will determine if the submitted proposal and proposed division of work reflects substantial involvement of all entities involved. If a proposal is recommended for award to a lead entity not otherwise exempt from the matching requirement and the proposal does not reflect substantial involvement of at least one partner that is exempt under #2 above, then the matching requirement will apply. Exemption from the matching requirement for an entity not otherwise exempt is limited to the project for which it is a partner.

Waiver of Match - NIFA may waive the matching funds requirement for a recipient for one year with respect to a competitive grant that involves research or extension activities that are consistent

with the priorities established by the National Agricultural Research, Education, Extension and Economics Advisory Board (NAREEEAB) for the year involved. To determine whether proposed activities are consistent with the priorities of the NAREEEAB, please refer to the [2014 Research, Education and Economics Action Plan](#). Instructions for requesting a waiver are included in Part IV, C. of this RFA.

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 be recognizing and providing priority in the receipt of funding to applications from “centers of excellence” that have been established for purposes of carrying out research, extension, and education activities relating to the food and agricultural sciences. In July of 2014, NIFA held listening sessions and accepted written comments from stakeholders to inform NIFA’s implementation of the centers of excellence (COE) provision. Information from the webinars and a summary of the input gathered are available on NIFA’s website at <http://nifa.usda.gov/resource/centers-excellence-webinars>.

A COE is composed of 1 or more of the following entities that provide financial or in-kind support to the center of excellence. Therefore, an eligible applicant who wishes to be considered as a center of excellence must be one of the following entities that provides financial or in-kind support to the Center being proposed, as described in the grant application.

- (A) State agricultural experiment stations;
- (B) colleges and universities;
- (C) university research foundations;
- (D) other research institutions and organizations;
- (E) Federal agencies;
- (F) national laboratories;
- (G) private organizations, foundations, or corporations;
- (H) individuals; or
- (I) any group consisting of 2 or more of the entities described in (A) through (H).

Only standard and priority grant applicants may be considered for COE designation. See Part IV, C. of this RFA for additional requirements that eligible applicants must meet to be considered a center of excellence.

PART IV—APPLICATION AND SUBMISSION INFORMATION

A. Letter of Intent Instructions

Applicants are encouraged to submit a “Letter of Intent to Submit an Application” by the Letter of Intent due date specified in this RFA. This does not obligate the applicant in any way, but will provide useful information to NIFA in preparing for application review.

Applicants who do not submit a letter of intent by the specified due date are still allowed to submit an application by the application due date specified in the RFA. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows program staff to estimate the potential review workload and plan the review.

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 inch in all directions
 - c. Line spacing must not exceed six 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 pages** for all research grant types.
 - a. On Page 1, provide **only** the following information:
 - 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
 - ii. the one Program Area that is most closely addressed in the application
 - b. On Page 2, include:
 - i. a descriptive title
 - ii. rationale
 - iii. overall hypothesis or goal
 - iv. specific objectives
 - v. approach
 - vi. potential impact and expected outcomes for federal regulatory agencies

3. When submitting LOI, 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 [Program Area Code] _ [PDs Last Name].

4. A Letter of Intent is requested for all grant types, except Conference Grant applications.

5. Submission of more than one Letter of Intent to a program is discouraged.

6. Letters of Intent will be reviewed by scientific program staff in order to plan for appropriate expertise for the peer review panel and ensure that the proposed project fits appropriately within the Program Area Priorities.

7. You must notify the appropriate 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 due date is February 12, 2016 at 5:00 pm ET.

B. Electronic Application Package

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 an overview of the Grants.gov application process see <http://www.grants.gov/web/grants/applicants/grant-application-process.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 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 <http://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 <http://www.grants.gov/web/grants/support/technical-support/software/adobe-reader-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 <http://www.grants.gov/web/grants/applicants/apply-for-grants.html>. Under Step 1 click on “Download a Grant Application Package,” and enter the funding opportunity number

Funding Opportunity Number: USDA-NIFA-BRAP-005435

in the appropriate box and click “Download Package.” From the search results, click “Download” to access the application package.

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 (<http://www.grants.gov/web/grants/applicants/applicant-resources.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). Get help now!

Have the following information available when contacting Grants.gov:

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

C. Content and Form of Application Submission

You should prepare electronic applications 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** needed to prepare an application in response to this RFA. **If there is discrepancy between the two 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 that 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.

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

Information related to the questions on this form is dealt with in detail in Part V, 3. of the NIFA Grants.gov Application Guide.

3. R&R Other Project Information Form

Information related to the questions on this form is dealt with in detail 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.

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. The Project Narrative must include all of the following:

(1) 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:

- Estimates of the magnitude of the issues and their relevance to stakeholders and to federal regulatory agencies.
- Reasons for performing the work at the proposed institution.

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

(3) 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. Any novel ideas or contributions that the proposed project offers should also be discussed in this section.

(4) 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:

- a description of the investigations and/or experiments proposed and the sequence in which the investigations or experiments are to be performed;
- techniques/methods to be used in carrying out the proposed project, including the feasibility of the techniques;
- results expected;
- means by which experimental data will be analyzed or interpreted;
- pitfalls that may be encountered
- limitations to proposed procedures, and;
- 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.

In the experimental plan, you must explain fully any materials, procedures, situations, or activities that may be hazardous to personnel (whether or not they are directly related to a particular phase of the proposed project), along with an outline of precautions to be exercised to avoid or mitigate the effects of such hazards.

(5) Center of Excellence Justification

Only standard and priority grant applicants may be considered for center of excellence (COE) designation.

In addition to meeting the other requirements detailed in Part IV, C., of this Request for Application (RFA), eligible applicants who wish to be considered as centers of excellence must provide a brief justification statement, on the last page of the Project Narratives and within the page limits provided, describing how they meet the standards of a center of excellence, based on the following criteria:

(A) the ability of the center of excellence to ensure coordination and cost effectiveness by reducing unnecessarily duplicative efforts regarding research, teaching, and extension in the implementation of the proposed research and/or extension activity outlined in this application;

(B) in addition to any applicable matching requirements, the ability of the center of excellence to leverage available resources by using public-private partnerships among agricultural industry groups, institutions of higher education, and the Federal Government in the implementation of the proposed research and/or extension activity outlined in this application. Resources leveraged should be commensurate with the size of the award;

(C) the planned scope and capability of the center of excellence to implement teaching initiatives to increase awareness and effectively disseminate solutions to target audiences through extension activities in the implementation of the proposed research and/or extension activity outlined in this application; and

(D) the ability or capacity of the center of excellence 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), center of excellence 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 http://www.nifa.usda.gov/funding/pdfs/nlgca_colleges.pdf), and schools of veterinary medicine).

c. Field 9. Bibliography & References Cited. All work cited, including that of key personnel, should be referenced in this section of the application.

d. Field 12. Other Attachments:

1. Response to Previous Review. This requirement only applies to “Resubmitted Applications” PDs must respond to the previous review panel summary on no more than one (1) page, titled “RESPONSE TO PREVIOUS REVIEW.” Within the first sentence, the applicant must reference the previous submission’s *GRANTS.gov* number or *Proposal* number. Applicants must also include the questions raised by the previous reviewers and how they have addressed those comments in their resubmitted proposal.
2. Cooperation and Institutional Units Involved. Cooperative, multi-institutional and multidisciplinary applications are encouraged. Where applicable, each institutional unit contributing to the project and designate the lead institution or institutional unit should be identified and the programmatic roles, responsibilities and budget for each institutional partner clearly defined.
3. Appendices to Project Narrative. Appendices to the Project Narrative are allowed if they are directly germane to the proposed project. The addition of appendices should not be used to circumvent the text and/or figures and tables page limitations.
4. Collaborative Arrangements. If it will be necessary to enter into formal consulting or collaborative arrangements with others, such arrangements should be fully explained and justified. If the consultants or collaborators are known at the time of application, a vitae or resume and Statement of Work (SOW) should be provided. In addition, evidence (e.g., letter of support) should be provided indicating that the collaborators

involved have agreed to render these services. Additional information on consultants and collaborators must also be provided in the budget portion of the application.

5. Non-Land Grant College of Agriculture (NLGCA) Certification. PDF Attachment. Applicants claiming exemption from the new matching requirement as NLGCA, must attach the NLGCA certification letter they requested and received from NIFA. Title attachment 'NLGCA Certification' and save file as 'NLGCACertification'. To request certification as an NLGCA, complete the form at <http://www.nifa.usda.gov/form/form.html>. Note that certification can take up to 30 days from submission of request form. Please see part III Section 3.1 of the NIFA Grants.gov Application Guide for NIFA attachment specifications.

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

Information related to the questions on this form is dealt with in detail in Part V, 5. of the NIFA Grants.gov Application Guide. This section of the Guide includes information about the people who require a Senior/Key Person Profile, 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.

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.

6. R&R Budget

Information related to the questions on this form is dealt with in detail in Part V, 7. of the NIFA Grants.gov Application Guide.

Beginning the first year of funding, the PD of a funded project (excluding a 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.

Matching Funds

If you conclude that matching funds are not required as specified under Part III, B. Cost-Sharing or Matching, you must include a justification in the Budget Narrative. We will consider this justification when ascertaining final matching requirements or in determining if required matching can be waived. NIFA retains the right to make final determinations regarding matching requirements.

For grants that require matching funds as specified under Part III, B., the Budget Narrative should include written verification of commitments of matching support (including both cash and in-kind contributions) from third parties. Written verification means:

- (a) For any third party cash contributions, a separate pledge agreement for each donation, signed by the authorized representatives of the donor organization (and the applicant organization ONLY if provided after submission of the application) must include: (1)

The donor's name, address, and telephone number; (2) the name of the applicant organization; (3) the title of the project; (4) the dollar amount of the cash donation (the budget narrative must describe how the cash donation will be used); (5) a statement that the donor will pay the cash contribution during the grant period; and (6) whether the applicant can designate cash as the applicant deems necessary or the cash contribution has been designated to a particular budget item.

- (b) For any third party in-kind contributions, a separate pledge agreement for each contribution, signed by the authorized representatives of the donor organization (and the applicant organization ONLY if provided after submission of the application) must include: (1) The donor's name, address, and telephone number; (2) the name of the applicant organization; (3) the title of the project; (4) a good faith estimate of the current fair market value of the third party in-kind contribution and a description of how the fair market value was determined; and (5) a statement that the donor will make the contribution during the grant period.

Summarize on a separate page the sources and amount of all matching support from outside the applicant institution and place that information in the proposal as part of the Budget Narrative. You must place all pledge agreements in the proposal immediately following the summary of matching support.

Establish the value of applicant contributions in accordance with applicable cost principles. Refer to 2 CFR Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards", for further guidance and other requirements relating to matching and allowable costs.

7. Supplemental Information Form

Information related to the questions on this form is dealt with in detail 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. **Applications with inaccurate program codes will not be reviewed and will not be considered for funding.**
- a. **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.

D. Submission Dates and Times

1. Letter of Intent

See Part IV for submission instructions and deadline

2. Full Application

A LOI is encouraged prior to submission of an applications. See Part IV, A for further information regarding the LOI

Prior to electronic submission of the application via Grants.gov, it is strongly recommended that an administrative review be conducted to ensure that an application complies with all application preparation instructions. An application checklist is included in Part VII of the NIFA Grants.gov Application Guide to assist with this review. **Instructions for submitting an application are included in Part IV, Section 1.9 of the NIFA Grants.gov Application Guide.**

Applications must be received by Grants.gov by **5:00 p.m. Eastern Time on April 15, 2016.** 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. Therefore, applicants are strongly encouraged to provide accurate e-mail 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 applicable 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, this number should be cited on all future correspondence.**

E. Funding Restrictions

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 220 (Circular No. A-21), 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 alterations, renovations, or repairs are essential to achieving the major purpose of the project. Grant funds may not be used for endowment investing.

Section 715 of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) limits indirect costs to 30 percent of the total Federal funds provided under each award. 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.

F. 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 2-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: (a) 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; (b) the need to include as reviewers experts from various areas of specialization within relevant scientific, education, or extension fields; (c) the need to include as reviewers 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; (d) the need to include as reviewers 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; (e) the need to maintain a balanced composition of reviewers with regard to minority and female representation and an equitable age distribution; and (f) the need to include reviewers who can judge the effective usefulness of each application to producers and the general public.

When each peer review panel has completed its deliberations, the responsible program staff of BRAG will recommend that the project: (a) be approved for support from currently available funds or (b) be declined due to insufficient funds or unfavorable review.

BRAG 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.

B. Evaluation Criteria

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 Priority and Standard Research Applications:

1. Scientific merit of the proposal.
 - Conceptual adequacy of hypothesis;
 - Clarity and delineation of objective; Adequacy of the description of the undertaking and suitability and feasibility of methodology;
 - Demonstration of feasibility through preliminary data;

- Probability of success of project;
 - Novelty, uniqueness and originality; and
 - Appropriateness to regulation of biotechnology and risk assessment.
2. Qualifications of proposed project personnel and adequacy of facilities.
 - Training and demonstrated awareness of previous and alternative approaches to the problem identified in the proposal, and performance record and/or potential for future accomplishments;
 - Time allocated for systematic attainment of objectives;
 - Institutional experience and competence in subject area; and
 - Adequacy of available or obtainable support personnel, facilities, and instrumentation.
 3. Relevance of project to solving biotechnology regulatory uncertainty for United States agriculture.
 - Scientific contribution of research in leading to important discoveries or significant breakthroughs in announced program areas; and
 - Relevance of the risk assessment research to agriculture and environmental
 4. Center 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 center of excellence will be further evaluated by the peer panel to determine whether they have met the standards to be centers of excellence (Part III D. and Part IV C.). In instances where they are found to be equally meritorious with the application of a non-center of excellence, based on peer review, selection for funding will be weighed in favor of applicants meeting the center of excellence criteria. NIFA will effectively use the center of excellence prioritization as a “tie breaker”. Applicants that rank highly meritorious but who did not request consideration as a center of excellence or who are not deemed to have met the centers of excellence 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 center of excellence. Entities recognized as centers of excellence 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; and
6. Qualifications of project personnel.

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 http://www.nifa.usda.gov/business/competitive_peer_review.html 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 on a one time basis, with updates on an as needed basis. This requirement is part of the responsibility determination 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 preaward process. Although an applicant may be eligible based on its status as one 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 BRAG for a period of three 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:

- (1) Legal name and address of performing organization or institution to which the director has issued an award under the terms of this request for applications;
- (2) Title of project;
- (3) Name(s) and institution(s) of PDs chosen to direct and control approved activities;
- (4) Identifying award number and the Federal Agency Identification Number assigned by NIFA;
- (5) Project period, specifying the amount of time NIFA intends to support the project without requiring recompetition for funds;
- (6) Total amount of financial assistance approved for the award;
- (7) Legal authority(ies) under which the award is issued;
- (8) Appropriate Catalog of Federal Domestic Assistance (CFDA) number;
- (9) Applicable award terms and conditions (see <http://www.nifa.usda.gov/business/awards/awardterms.html> to view NIFA award terms and conditions);
- (10) Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the award; and

(11) Other information or provisions deemed necessary by NIFA to carry out its respective awarding activities or to accomplish the purpose of a particular award.

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

Please refer to Part II, C. for more information.

D. Expected Program Outputs and Reporting Requirements

The output and reporting requirements are included in the award terms and conditions (see <http://www.nifa.usda.gov/business/awards/awardterms.html> for information about NIFA award terms). If there are any program or award-specific award terms, those, if any, will be identified in the award.

Grantees are 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 electronic 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.

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 CONTACT

Applicants and other interested parties are encouraged to contact:

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
E-mail: skwok@nifa.usda.gov

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
Fax: (202) 401-6071
E-mail: imatukumalli@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
E-mail: jack.okamuro@ars.usda.gov

Administrative/Business Contact –

Mr. Duane Alphas; Team Leader, Team II, Section II
U.S. Department of Agriculture
National Institute of Food and Agriculture
Office of Grants and Financial Management
1400 Independence Avenue SW, Stop 2201 Washington, DC 20250-2201
Telephone: (202) 401-4326
Fax: (202) 401-6271
E-mail: dalphs@nifa.usda.gov

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
E-mail: rmccrea@nifa.usda.gov

PART VIII—OTHER INFORMATION

A. Access to Review Information

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

B. 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 Project Plans

a. The permissible changes by the awardee, PD(s), or other key project personnel in the approved project shall be limited to changes in methodology, techniques, or other similar aspects of the project to expedite achievement of the project's approved goals. If the awardee or the PD(s) is uncertain as to whether a change complies with this provision, the question must be referred to the Authorized Departmental Officer (ADO) for a final determination. The ADO is the signatory of the award document, not the program contact.

b. The awardee must request, and the ADO must approve in writing, all changes in approved goals or objectives prior to effecting such changes. In no event shall requests be approved for changes that are outside the scope of the original approved project.

c. The awardee must request, and the ADO must approve in writing, all changes in approved project leadership or the replacement or reassignment of other key project personnel, prior to effecting such changes.

d. The awardee must request, and the ADO must approve in writing, all transfers of actual performance of the substantive programmatic work in whole or in part and provisions for payment of funds, whether or not federal funds are involved, prior to instituting such transfers, unless prescribed otherwise in the terms and conditions of the award.

e. The project period may be extended without additional financial support, for such additional period(s) necessary to complete or fulfill the purposes of an approved project, but in no case shall the total project period exceed any applicable statutory limit or expiring appropriation limitation. The terms and conditions of award include information about no-cost extensions of the award and when ADO's prior approval is necessary.

f. Changes in Approved Budget: Unless stated otherwise in the terms and conditions of award, changes in an approved budget must be requested by the awardee and approved in writing by the

ADO prior to instituting such changes, if the revision will involve transfers or expenditures of amounts requiring prior approval as set forth in the applicable Federal cost principles, Departmental regulations, or award.

C. 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 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. The original copy of an application that does not result in an award will be retained by the Agency for a period of three years. Other copies will be destroyed. 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.

D. Regulatory Information

For the reasons set forth in the final Rule related Notice to 2 CFR part 415, subpart C , this program is excluded from the scope of the 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.

E. Definitions

Please 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 should 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, determination of experimental design, development of the project work plan and time table, and submission of 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.

F. Materials Available on the Internet

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 BRAG
2. Partnerships
3. Requests for Applications
4. BRAG Abstracts of Funded Projects
5. Project Director Meeting Booklets