

## § 3402.24

international study or thesis/dissertation research allowance and/or institutional adherence to program guidelines.

(3) Exit Information shall be completed and submitted to HEP by the Project Director for each Fellow supported by a grant as soon as a Fellow either: Graduates; is officially terminated from the Fellowship or the academic program due to unsatisfactory academic progress; or voluntarily withdraws from the Fellowship or the academic program. If a Fellow has not completed all degree requirements at the end of the five-year grant duration, HEP may request a preliminary exit report. In such a case, a final exit report shall be required at a later date. When a final exit report for each Fellow supported by a grant has been accepted by HEP, the grantee will have satisfied the requirement of a final performance report for the grant. Additional follow-up reports to track Fellows' career patterns may be requested.

(b) All grantees (supplemental international, graduate, and postdoctoral) shall submit initial project information and annual and summary reports to NIFA' Current Research Information System (CRIS). The CRIS database contains narrative project information, progress/impact statements, and final technical reports that are made available to the public. For applications recommended for funding, instructions on preparation and submission of project documentation will be provided to the applicant by the agency contact. Documentation must be submitted to CRIS before NIFA funds will be released. Project reports will be requested by the CRIS office when required. For more information about CRIS, visit <http://cris.nifa.usda.gov>.

### § 3402.24 Evaluation of program.

Grantees should be aware that HEP may, as a part of its own program evaluation activities, carry out in-depth evaluations of assisted activities through independent third parties. Thus, grantees should be prepared to cooperate with evaluators retained by HEP to analyze both the institutional context and the impact of any supported project.

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### PART 3403—SMALL BUSINESS INNOVATION RESEARCH GRANTS PROGRAM

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#### Subpart A—General Information

##### § 3403.1 Applicability of regulations.

(a) The regulations of this part apply to small business innovation research grants awarded under the general authority of section 630 of the Act making appropriations for Agriculture, Rural Development, and Related Agencies' programs for fiscal year ending 1987, and for other purposes as made applicable by section 101(a) of Pub. L. 99-591, 100 Stat. 3341, and the provisions of the Small Business Innovation Development Act of 1982, as amended (15

U.S.C. 638), and the Small Business Innovation Research Program Reauthorization Act of 2000, Pub. L. 106-554, which extends the SBIR Program through September 30, 2008. The Small Business Innovation Development Act of 1982, as amended, mandates that each Federal agency with an annual extramural budget for research or research and development in excess of \$100 million participate in a Small Business Innovation Research (SBIR) program by reserving a statutory percentage of its annual extramural budget for award to small business concerns for research or research and development in order to stimulate technological innovation, use small business to meet Federal research and development needs, increase private sector commercialization of innovations derived from Federal research and development, and foster and encourage the participation of socially and economically disadvantaged small business concerns and women-owned small business concerns in technological innovation. The Department will participate in this program through the issuance of competitive research grants which will be administered by the Office of Extramural Programs, NIFA.

(b) The regulations of this part do not apply to research grants awarded by the Department under any other authority.

#### § 3403.2 Definitions.

As used in this part:

*Ad hoc reviewers* means experts or consultants, qualified by training and experience in particular scientific or technical fields to render expert advice on the scientific technical merit of the grant applications in those fields, who review on an individual basis one or several of the eligible proposals submitted to this program in their area of expertise and who submit to the Department written evaluations of such proposals.

*Applicant* is the organizational entity that, at the time of award, will qualify as a small business concern and that submits a grant application for a funding agreement under the SBIR Program.

*Authorized departmental officer (ADO)* means the Secretary or any employee

of the Department who has the authority to issue or modify grant instruments on behalf of the Secretary. The ADO is also referred to as the Funding Agreement Officer.

*Authorized organizational representative (AOR)* means the president, director, or chief executive officer or other designated official of the applicant organization who has the authority to commit the resources of the organization.

*Budget Period* means the interval of time into which the project period is divided for budgetary and reporting purposes.

*Commercialization* is the process of developing marketable products or services and producing and delivering products or services for sale (whether by the originating party or by others) to Government or commercial markets.

*Department* means the U.S. Department of Agriculture.

*Essentially equivalent work* occurs when:

(1) Substantially the same research is proposed for funding in more than one grant application submitted to the same Federal agency;

(2) Substantially the same research is submitted to two or more different Federal agencies for review and funding consideration; or

(3) A specific research objective and the research design for accomplishing an objective are the same or closely related in two or more proposals or awards, regardless of the funding source.

*Funding agreement* is any contract, grant, or cooperative agreement entered into between any Federal agency and any small business concern for the performance of experimental, developmental, or research work, including products or services funded in whole or in part by the Federal Government.

*A grant* is a financial assistance mechanism providing money, property, or both to an eligible entity to carry out the approved project or activity, and substantial programmatic involvement by Government is not anticipated.

*Grantee* means the small business concern designated in the grant award

document as the responsible legal entity to whom the grant is awarded under this part.

*Innovation* is something new or improved, having marketable potential including:

- (1) Development of new technologies;
- (2) Refinement of existing technologies; or
- (3) Development of new applications for existing technologies.

*Intellectual property* means the separate and distinct types of intangible property that are referred to collectively as “intellectual property,” including but not limited to: Patents, trademarks, copyrights, trade secrets, SBIR technical data (as defined in this section), ideas, designs, know-how, business, technical and research methods, other types of intangible business assets, and all types of intangible assets either proposed or generated by a small business concern as a result of its participation in the SBIR Program.

*Joint venture* is an association of concerns with interests in any degree or proportion by way of contract, express or implied, consorting to engage in and carry out a single specific business venture for joint profit, for which purpose they combine their efforts, property, money, skill, or knowledge, but not on a continuing or permanent basis for conducting business generally. A joint venture is viewed as a business entity in determining power to control its management.

*NIFA* means the National Institute of Food and Agriculture.

*Outcomes* are the measure of long-term, eventual, program impact.

*Outputs* are the measures of near-term program impact.

*Peer review group* means experts or consultants, qualified by training and experience in particular scientific or technical fields to give expert advice on the scientific and technical merit of grant applications to those fields, who assemble as a group to discuss and evaluate all of the eligible proposals submitted to this program in their area of expertise.

*Principal investigator/project director* is the one individual designated by the applicant to provide the scientific and technical direction to a project supported by the funding agreement.

*Professional Employer Organization* is an organization that provides an integrated approach to the management and administration of the human resources and employer risk of its clients, by contractually assuming substantial employer rights, responsibilities, and risk, through the establishment and maintenance of an employer relationship with the workers assigned to its clients.

*Program solicitation* is a formal request for proposals whereby an agency notifies the small business community of its research or research and development needs and interests in broad and selected areas, as appropriate to the agency, and requests proposals from small business concerns in response to these needs and interests.

*Project period* means the total length of time that is approved by the Department for conducting the research project as outlined in an approved grant application.

*Prototype* is a model of something to be further developed, which includes designs, protocols, questionnaires, software, and devices.

*Research or research and development (R/R&D)* means any activity which is:

- (1) A systematic, intensive study directed toward greater knowledge or understanding of the subject studied;
- (2) A systematic study directed specifically toward applying new knowledge to meet a recognized need; or
- (3) A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

*Research project grant* means the award by the Department of funds to a grantee to assist in meeting the costs of conducting for the benefit of the public an identified project which is intended and designed to establish, discover, elucidate, or confirm information or the underlying mechanisms relating to a research topic area identified in the annual solicitation of applications.

*Research project grant* means the award by the Department of funds to a grantee to assist in meeting the costs of conducting for the benefit of the public an identified project which is intended and designed to establish, discover, elucidate, or confirm information or the underlying mechanisms relating to a research topic area identified in the annual solicitation of applications.

*SBIR Participants* are business concerns that have received SBIR awards or that have submitted SBIR proposals/applications.

*SBIR Technical Data* is defined as all data generated during the performance of an SBIR award.

*SBIR Technical Data Rights* are the rights a small business concern obtains in data generated during the performance of any SBIR award that an awardee delivers to the Government during or upon completion of a Federally-funded project, and to which the government receives a license.

*Small business concern* (SBC) means a concern that, on the date of award for both Phase I and Phase II funding agreements:

(1) Is organized for profit, with a place of business located in the United States, which operates primarily within the United States, or which makes a significant contribution to the United States economy through the payment of taxes or use of American products, materials or labor;

(2) Is in the legal form of an individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative, except that where the form is a joint venture, there can be no more than 49 percent participation by foreign business entities in the joint venture;

(3) Is at least 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States, except in the case of a joint venture, where each entity in the venture must be 51 percent owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in the United States; and

(4) Has, including its affiliates, not more than 500 employees. The term "affiliates" is defined in greater detail in 13 CFR 121.103. The term "number of employees" is defined in 13 CFR 121.106.

*Socially and economically disadvantaged small business concern* is defined in 13 CFR part 124-8(A) Business Development/Small Disadvantaged Business Status Determinations, §124.103 (Who is socially disadvantaged?) and §124.104 (Who is economically disadvantaged?).

*United States* means the 50 states, the territories and possessions of the Federal Government, the Commonwealth of Puerto Rico, the District of Columbia, the Republic of the Marshall Is-

lands, the Federated States of Micronesia, and the Republic of Palau.

*Women-owned small business concern* means a small business concern that is at least 51 percent owned by one or more women, or in the case of any publicly owned business, at least 51 percent of the stock is owned by women, and women control the management and daily business operations.

[72 FR 20703, Apr. 26, 2007, as amended at 76 FR 4808, Jan. 27, 2011]

### § 3403.3 Eligibility requirements.

(a) *Eligibility of organization.* (1) To receive SBIR funds, each awardee of a SBIR Phase I or Phase II must qualify as a small business concern.

(2) For Phase I, a minimum of two-thirds of the research or analytical effort, as measured by the budget, must be performed by the awardee. Occasionally, deviations from this requirement may occur, and must be approved in writing by the ADO after consultation with the agency SBIR National Program Leader.

(3) For Phase II, a minimum of one-half of the research or analytical effort, as measured by the budget, must be performed by the awardee. Occasionally, deviations from this requirement may occur, and must be approved in writing by the ADO after consultation with the agency SBIR National Program Leader.

(4) For both Phase I and Phase II, the primary employment of the principal investigator must be with the SBC at the time of award and during the conduct of the proposed project. Primary employment means that more than one-half of the principal investigator's time is spent in the employ of the SBC. This precludes full-time employment with another organization. Occasionally, deviations from this requirement may occur, and must be approved in writing by the ADO after consultation with the agency SBIR National Program Leader. Further, an SBC may replace the principal investigator on an SBIR Phase I or Phase II award, subject to approval in writing by the ADO after consultation with the SBIR National Program Leader. For purposes of the SBIR Program, personnel obtained through a Professional Employer Organization or other similar personnel

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leasing company must be considered employees of the awardee. This is consistent with SBA's size regulations, 13 CFR 121.106—Small Business Size Regulations.

(5) For both Phase I and Phase II, the R/R&D must be performed in the United States. However, based on a rare and unique circumstance, ADO approval may be granted to perform a particular portion of the research or research and development work outside of the United States, for example, if a supply of material or other item or project requirement is not available in the United States. The ADO, after consultation with the agency SBIR National Program Leader, must approve each such specific condition in writing.

(b) [Reserved]

#### Subpart B—Program Description

##### § 3403.4 Three-phase program.

The Small Business Innovation Research Grants Program is carried out in three separate phases described in this section. The first two phases are designed to assist USDA in meeting its research or research and development objectives and will be supported with SBIR Program funds. The purpose of the third phase is to pursue the commercial applications or objectives of the research carried out in Phases I and II through the use of private or Federal non-SBIR funds.

(a) *Phase I.* Phase I involves a solicitation of grant applications (hereinafter referred to as proposals) to conduct feasibility-related experimental research and development related to described agency requirements. These requirements, as defined by agency topics contained in the solicitation, may be general or narrow in scope, depending on USDA needs. The object of this phase is to determine the scientific and technical merit and feasibility of the proposed effort and the quality of performance of the small business concern with a relatively small agency investment before consideration of further Federal support in Phase II.

(b) *Phase II* is the principal research or research and development effort in which the results from Phase I are expanded upon and further pursued, nor-

mally for a period not to exceed 24 months. Only SBIR awardees in Phase I are eligible to participate in Phase II. This includes those awardees identified via a "novated" or "successor in interest" or similarly-revised funding agreement, or those that have reorganized with the same key staff, regardless of whether they have been assigned a different tax identification number. For each Phase I project funded, the awardee may apply for a Phase II award only once. Phase I awardees who for valid reasons cannot apply for Phase II support in the next fiscal year funding cycle may normally apply for support no later than the second fiscal year funding cycle.

(c) *Phase III* refers to work that derives from, extends, or logically concludes effort(s) performed under prior SBIR funding agreements, but is funded by sources other than the SBIR Program. Phase III work is typically oriented towards commercialization of SBIR research or technology. This portion of a project is funded by a non-SBIR source through the use of a follow-on funding commitment. A follow-on funding commitment is an agreement between the small business concern and a provider of the follow-on capital for a specified amount of funds to be made available to the small business concern for future development of their effort upon achieving certain mutually agreed upon technical objectives.

#### Subpart C—Preparation of Proposals

##### § 3403.5 Program solicitation.

(a) *Phase I.* A program solicitation requesting Phase I proposals will be prepared each fiscal year in which funds are made available for this purpose. This solicitation will contain information sufficient to enable eligible applicants to prepare grant proposals and will include descriptions of specific research topic areas which the Department will support during the fiscal year involved. A notice of solicitation, and the entire contents of the program solicitation will be published, at a minimum, on the agency's Web site.

(b) *Phase II.* For each fiscal year in which funds are made available for this

purpose, the Department will send correspondence requesting Phase II proposals from the Phase I grantees eligible to apply for Phase II funding in that fiscal year. The correspondence will contain information sufficient to enable eligible applicants to prepare grant proposals.

#### § 3403.6 Content of proposals.

(a) The proposed research must be responsive to one of the USDA program interests stated in the research topic descriptions of the program solicitation.

(b) Proposals must cover only scientific/technological research activities. A small business concern must not propose product development, technical assistance, demonstration projects, classified research, or patent applications. Many of the research projects supported by the SBIR program lead to the development of new products based upon the research results obtained during the project. However, projects that seek funding solely for product development where no research is involved, *i.e.*, funds are needed to permit the development of a project based on previously completed research, will not be accepted. Literature surveys should be conducted prior to preparing proposals for submission and must not be proposed as a part of the SBIR Phase I or Phase II effort. Proposals principally for the development of proven concepts toward commercialization or for market research should not be submitted since such efforts are considered the responsibility of the private sector and therefore are not supported by USDA.

(c) A proposal must be limited to only one topic. The same proposal may not be submitted under more than one topic as defined in the solicitation. However, an organization may submit separate proposals on the same topic. Where similar research is discussed under more than one topic, the proposer should choose that topic whose description appears most relevant to the proposer's research concept. USDA will not consider funding duplicate (essentially equivalent work) proposals. In addition, essentially equivalent work funded by another entity will be

returned to the applicant without review.

#### § 3403.7 Proposal format for phase I applications.

(a) The following items relate to Phase I applications. Further instructions or descriptions for these items as well as any additional items to be included will be provided in the annual solicitation, as necessary.

(1) *SF-424 R&R Cover*. Applicants must submit basic proposal identification information on the first page of the proposals. Applicants must also certify on the first page of the proposals that they meet the definition of a small business concern as stated in the solicitation, and must certify as to whether or not they qualify as socially and economically disadvantaged small business concerns, or women-owned small business concerns.

(2) *Project Summary/Abstract*. The technical abstract should include a brief description of the problem or opportunity, project objectives, and a description of the effort. Anticipated results and potential commercial applications of the proposed research also should be summarized in the space provided. Keywords should characterize the most important aspects of the project. The project summary of successful proposals may be published by USDA and therefore should not contain proprietary information.

(3) *Project Narrative*. The main body of the proposal should include:

- (i) Identification and significance of the problem or opportunity.
- (ii) Background and rationale.
- (iii) Relationship with future research or research and development.
- (iv) Phase I technical objectives.
- (v) Phase I work plan.
- (vi) Related research or research and development.

(vii) References. For each reference cited in the Proposal, provide the complete name for each author, the date of publication, the full title of the article, name of the journal, etc.

(4) *Key personnel and bibliography*. Identify key personnel involved in the effort, including information on their directly related education and experience. For each key person, provide a chronological list of the most recent

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representative publications in the topic area.

(5) *Facilities and equipment.* Describe the types, location, and availability of instrumentation and physical facilities necessary to carry out the work proposed. Items of equipment to be purchased must be fully justified under this section.

(6) *Outside services.* Involvement of university or other consultants in the planning and research stages of the project as consultants or through subcontracting arrangements is permitted and may be particularly helpful to small business concerns that have not previously received Federal research awards. If such involvement is intended, it should be described in detail.

(7) *Satisfying the public interest.* Specify how the proposed research will satisfy one or more of the following objectives:

- (i) Develops sustainable agriculture production systems;
- (ii) Protects natural resources and the environment;
- (iii) Creates a safe, nutritious and affordable food supply;
- (iv) Develops value-added food and non-food products from agricultural materials;
- (v) Enhances global competitiveness; and
- (vi) Enhances economic opportunity and quality of life, especially for people in rural areas.

(8) *Potential post applications.* Briefly describe the commercialization potential of the proposed research. Indicate whether and by what means there appears to be a potential for the Federal Government to use the proposed research. Include a brief description of the proposing company (e.g., date founded, number of employees) and its field of interest. What are the major competitive products in this field, and what advantages will the proposed research have over existing technology (in application, performance, technique, efficiency or cost)?

(9) *Similar Proposals or Awards.* (i) **WARNING**—While it is permissible with proposal notification to submit identical proposals containing a significant amount of essentially equivalent work for consideration under numerous Federal program solicitations,

it is unlawful to enter into funding agreements requiring essentially equivalent work. If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award. If an applicant elects to submit identical proposals or proposals containing a significant amount of essentially equivalent work under other Federal program solicitations, a statement must be included in each such proposal indicating:

(A) Name and address of the agency(ies) to which the proposal was submitted, or will be submitted, or from which an award is expected or has been received.

(B) Date of actual or anticipated proposal submission or date of award, as appropriate.

(C) Title of proposal or award, identifying number assigned to the solicitation or proposal by the agency involved, and the date the proposal(s) were submitted or the award was received.

(D) Applicable research topic area for each proposal submitted or award received.

(E) Titles of research projects.

(F) Name and title of principal investigator for each proposal submitted or award received.

(ii) *USDA will not make awards that duplicate research funded (or to be funded) by other Federal agencies.*

(10) *Cost breakdown on proposal budget.* Complete a budget form for the phase under which you are currently applying. (An applicant for Phase I funding should not submit both Phase I and Phase II budgets.) A budget narrative with supporting detail for each budget category must be included.

(11) *Special Considerations.* If the proposed research will include laboratory animals or human subjects at risk, the applicant may be required to have the research plan reviewed and approved by an Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) prior to commencing actual substantive work. If such approval is required, USDA may not release funds for the award until proper documentation is submitted and accepted by USDA. It is suggested that applicants contact local universities,

colleges, or nonprofit research organizations which have established reviewing mechanisms to have this service performed.

(12) *Proprietary information.* (i) If proprietary information is provided by an applicant in a proposal which constitutes a trade secret, proprietary commercial or financial information, confidential personal information, or data affecting the national security, it will be treated in confidence to the extent permitted by law. This information must be clearly marked by the applicant with the term "confidential proprietary information" and the following legend must appear on the title page of the proposal: "These data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than evaluation of this proposal. If a funding agreement is awarded to this applicant as a result of or in connection with the submission of these data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the funding agreement and pursuant to applicable law. This restriction does not limit the Government's right to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction are contained on pages \_\_\_ of this proposal."

(ii) USDA, by law, is required to make the final decision as to whether the information is required to be kept in confidence. Information contained in unsuccessful proposals will remain the property of the applicant. However, USDA will retain for three years one copy of all proposals received; extra copies will be destroyed. Public release of information for any proposal submitted will be subject to existing statutory and regulatory requirements. Any proposal which is funded will be considered an integral part of the award and normally will be made available to the public upon request through the Freedom of Information Act, except for designated proprietary information.

(iii) The inclusion of proprietary information is discouraged unless it is necessary for the proper evaluation of the proposal. If proprietary informa-

tion is to be included, it should be limited, set apart from other text on a separate page, and keyed to the text by numbers. It should be confined to a few critical technical items which, if disclosed, could jeopardize the obtaining of foreign or domestic patents. Trade secrets, salaries, or other information which could jeopardize commercial competitiveness should be similarly keyed and presented on a separate page. Proposals or reports which attempt to restrict dissemination of large amounts of information may be found unacceptable by USDA.

(13) *Rights in data developed under SBIR funding agreement.* The legend (or statements) in the SBIR datarights clause included in the SBIR award must be affixed to any submissions of technical data. Where such legend is affixed, rights in technical data, including software developed under the terms of any funding agreement resulting from a proposal submitted in response to the program solicitation shall remain with the grantee. The Government may not use, modify, reproduce, release, perform, display, or disclose technical data or computer software marked with this legend for 4 years. After expiration of the 4-year period, the Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for Government purposes, and is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these data by third parties, except that any such data that is also protected and referenced under a subsequent SBIR award shall remain protected through the protection of that subsequent SBIR award.

(14) *Patents and Inventions.* Allocation of rights to inventions shall be in accordance with 35 U.S.C. 202 through 206 and the Department of Commerce implementing regulations entitled "Rights to Inventions Made by Non-profit Organizations and Small Business Firms under Government Grants, Contracts and Cooperative Agreements" at 37 CFR part 401. These regulations provide that small businesses normally may retain the principal worldwide patent rights to any invention developed with USDA support. USDA receives a royalty-free license



for Federal Government use, reserves the right to require the patentee to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it domestically. To the extent authorized by 35 U.S.C. 205, USDA will not make public any information disclosing a USDA-supported invention for a four-year period. SBIR awardees must report inventions to the awarding agency within two months of the inventor's report to the awardee. The reporting of inventions shall be made through submission to Interagency Edison as specified in the terms and conditions of the grant.

(15) *Organizational management information.* Before the award of an SBIR funding agreement, USDA requires the submission of certain organizational management, personnel, and financial information to assure responsibility of the applicant. This information is not required unless a project is recommended for funding, and then it is submitted on a one-time basis only. However, new information should be submitted if a small business concern has undergone significant changes in organization, personnel, finance or policies, including those relating to civil rights.

(16) *Documentation of commercialization record of firms with multiple phase II awards.* A small business concern submitting a proposal for a Phase I award that has received more than 15 Phase II SBIR awards during the preceding five fiscal years must document the extent to which it was able to secure Phase III funding to develop concepts resulting from previous Phase II SBIR awards.

(b) [Reserved]

#### § 3403.8 Proposal format for phase II applications.

(a) The following items relate to Phase II applications. Further instructions or descriptions for these items as well as any additional items to be included will be identified in the annual program solicitation as necessary. See § 3403.9.

(1) *SF-424 R&R cover sheet.* Follow instructions found in § 3403.7(a)(1).

(2) *Project summary.* Follow instructions found at § 3403.7(a)(2).

(3) *Phase I results.* The proposal should contain an extensive section that lists Phase I objectives and makes detailed presentation of the Phase I results. This section should establish the degree to which Phase I objectives were met and feasibility of the proposed research project was established.

(4) *Proposal.* Since Phase II is the principal research and development effort, proposals should be more comprehensive than those submitted under Phase I. However, the outline and information contained in § 3403.7(a)(3)–(9) and § 3403.7(a)(11)–(14) should be followed, tailoring the information requested to the Phase II project.

(5) *Cost breakdown on proposal budget.* For Phase II, a detailed budget is required for each year of requested support. In addition, a summary budget is required detailing the requested support for the overall project period. A budget narrative, with supporting budget detail for each budget category must be included.

(6) *Organizational management information.* Each Phase II awardee will be asked to submit an updated statement of financial condition (such as the latest audit report, financial statements or balance sheet) and report any changes in management or principals.

(7) *Commercialization Plan.* A succinct commercialization plan must be included in each SBIR Phase II proposal moving toward commercialization. Elements of a commercialization plan may include the following:

(i) *Company information.* Focused objectives/core competencies; size; specialization area(s); products with significant sales; and history of previous Federal and non-Federal funding; regulatory experience; and subsequent commercialization.

(ii) *Customer and competition.* Clear description of key technology objectives, current competition, and advantages compared to competing products or services; description of hurdles to acceptance of the innovation.

(iii) *Market.* Milestone, target dates, analyses of market size, and estimated market share after first year sales and after five years; explanation of plan to obtain market share.

(iv) *Intellectual property.* Patent status, technology lead, trade secrets or

other demonstration of a plan to achieve sufficient protection to realize the commercialization state and attain at least a temporary competitive advantage.

(v) *Financing*. Plans for securing necessary funding in Phase III.

(vi) *Assistance and mentoring*. Plans for securing needed technical or business assistance through mentoring, partnering, or through arrangements with state assistance programs, Small Business Development Centers, Federally-funded research laboratories, manufacturing extension Partnership Centers, or other assistance providers.

(8) *Data Collection*. Each Phase II applicant will be required to provide information to the Tech-Net Database System (<http://technet.sba.gov>) per OMB No. 3245-03356. The following are examples of the data to be entered by applicants into Tech-Net:

(i) Any business concern or subsidiary established for the commercial application of a product or service for which an SBIR award is made;

(ii) Revenue from the sale of new products or services resulting from the research conducted under each Phase II award;

(iii) Additional investment from any source, other than Phase I or Phase II awards, to further the research and development conducted under each Phase II award; and

(iv) Updates to information in the Tech-Net database for any prior Phase II award received by the small business concern.

(b) [Reserved]

### Subpart D—Submission and Evaluation of Proposals

#### § 3403.9 Submission of proposals.

The SBIR program solicitation for Phase I proposals and the correspondence requesting Phase II proposals will provide the deadline date for submitting proposals, and instructions for submitting the proposal to NIFA for funding consideration.

#### § 3403.10 Proposal review.

(a) The receipt of all proposals will be acknowledged.

(b) All Phase I and II proposals will be evaluated and judged on a competi-

tive basis. Proposals will be initially screened to determine responsiveness. Proposals passing this initial screening will be technically evaluated by scientists to determine the most promising technical and scientific approaches. Each proposal will be judged on its own merit. USDA is under no obligation to fund any proposal or any specific number of proposals in a given topic. It also may elect to fund several or none of the proposed approaches to the same topic or subtopic.

(c) Phase I and II proposal evaluation criteria will be published in the “Method of Selection and Evaluation Criteria” section of the program solicitation.

(d) External peer reviewers may be used during the technical evaluation stage of this process. Selections will be made from among recognized specialists who are uniquely qualified by training and experience in their respective fields to render expert advice on the merit of proposals received. It is anticipated that such experts will include those located in universities, government, and nonprofit research organizations. If possible, USDA intends that peer review groups shall be balanced with minority and female representation and with an equitable age distribution.

(e) Reviewers will base their conclusions and recommendations on information contained in the Phase I or Phase II proposal. It cannot be assumed that reviewers are acquainted with any experiments referred to within a proposal, with key individuals, or with the firm itself. Therefore, the proposals should be self-contained and written with the care and thoroughness accorded papers for publication.

(f) Final decisions will be made by USDA based upon the rating assigned by reviewers in consideration of the technical and commercial potential of the application, duplication of research, any critical USDA requirements, resubmission and budget limitation. In the event that two or more proposals are of approximately equal merit, the existence of a cooperative research and development agreement (CRADA) with a USDA laboratory will

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be an important consideration. The existence of a follow-on funding commitment for continued development in Phase III will also be an important consideration. The value of any commitment will depend upon the degree of financial commitment made by investors, with the maximum value resulting from a signed agreement with reasonable terms for an amount at least equal to funding requested from USDA in Phase II.

**§ 3403.11 Availability of information.**

Information regarding the peer review process will be made available to the extent permitted under the Freedom of Information Act (5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a), the SBIR Policy Directive, and implementing Departmental and other Federal regulations. Implementing Departmental regulations are found at 7 CFR part 1.

**Subpart E—Supplementary Information**

**§ 3403.12 Terms and conditions of grant awards.**

Within the limit of funds available for such purposes, the Authorized Departmental Officer shall make research project grants to those responsible, eligible applicants whose proposals are judged most meritorious in the announced program areas under the evaluation criteria and procedures set forth in the annual program solicitation. The beginning of the project period shall be no later than September 30 of the Federal fiscal year in which the project is approved for support. All funds granted under this part shall be expended solely for the purpose for which funds are granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of award, the Federal Acquisition Regulations (48 CFR part 31), and the Department's Uniform Federal Assistance Regulations (7 CFR part 3015).

**§ 3403.13 Notice of grant awards.**

(a) The grant award document may include the following:

(1) Legal name and address of performing organization or institution;

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- (2) Title of project;
- (3) Name and institution of Project Director's chosen to direct and control approved activities;
- (4) Identifying grant number assigned by the Department;
- (5) Project period, specifying the amount of time the Department intends to support the project;
- (6) Total amount of Departmental financial assistance approved for the project period;
- (7) Legal authority(ies) under which the grant is awarded;
- (8) Appropriate Catalog of Federal Domestic Assistance (CFDA) number;
- (9) Applicable award terms and conditions;
- (10) Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the grant award; and
- (11) Other information or provisions deemed necessary by NIFA to carry out its respective granting activities or to accomplish the purpose of a particular grant.

(b) [Reserved]

**§ 3403.14 Use of funds; changes.**

(a) *Delegation of fiscal responsibility.* Unless the terms and conditions of the grant state otherwise, the grantee may not in whole or in part delegate or transfer to another person, institution, or organization the responsibility for use or expenditure of grant funds.

(b) *Changes in Project Plans.* (1) The permissible changes by the grantee, Project Director, or other key project personnel in the approved project grant 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 grantee or the Project Director (PD) 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 signatory of the award document is the ADO, not the program contact.

(2) Changes in approved goals or objectives shall be requested by the grantee and, in consultation with the NIFA SBIR National Program Leader, approved in writing by the ADO prior to effecting such changes. In no event

shall requests for such changes be approved which are outside the scope of the original approved project.

(3) Changes in approved project leadership or the replacement or reassignment of other key project personnel shall be requested by the grantee and, in consultation with the NIFA SBIR National Program Leader, approved in writing by the ADO prior to effecting such changes.

(4) 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, shall be requested by the grantee and, in consultation with the NIFA SBIR National Program Leader, approved in writing by the ADO prior to effecting such transfers, unless prescribed otherwise in the terms and conditions of the grant.

(c) *Changes in Project Period.* The project period may be extended by NIFA without additional financial support, for such additional period(s) as the ADO determines may be necessary to complete or fulfill the purposes of an approved project provided Federal funds remain. Any extension of time shall be conditioned upon prior request by the grantee and approval in writing by the ADO unless otherwise noted in the award terms and conditions. In such cases the extension will not normally exceed 12 months. The Phase I award will still be limited to the approved award amount, and the submission of a Phase II proposal will normally be delayed by no more than one year. The extension allows the grantee to continue expending the remaining Federal funds for the intended purpose over the extension period. In instances where no Federal funds remain, it is unnecessary to approve an extension since the purpose of the extension is to continue using Federal funds. The grantee may opt to continue the Phase I project after the grant's termination and closeout, however, the grantee would have to do so without additional Federal funds. In the latter case, no communication with USDA is necessary.

(d) *Changes in approved budget.* Changes in an approved budget must be requested by the grantee and approved in writing by the ADO prior to insti-

tuting 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 grant award.

(e) *Use of Change of Name and Novation Agreement.* (1) Occasionally, after an award has been made the name of the Awardee may change. NIFA requires execution of a "Change of Name Agreement" in such instances. The specific circumstances of each situation will determine which kind of agreement should be executed. This decision will be determined by the ADO.

(i) A Change of Name Agreement is a legal instrument executed by the Awardee and the Government that recognizes a change of the legal name of the Awardee without disturbing the original rights and obligations of the parties. If only a change of the Awardee's name is involved and the Government's and Awardee's rights and obligations remain unaffected, the parties should execute an agreement to reflect the name change.

(ii) In order to execute the actual Change of Name Agreement with USDA, the Awardee is required to submit the following information:

(A) The document effecting the name change, authenticated by a proper official of the State having jurisdiction;

(B) The opinion of the Grantee's legal counsel stating that the change of name was properly effected under applicable law and showing the effective date;

(C) A list of all affected awards between the Grantee and NIFA.

(iii) When NIFA is notified that a change of name has taken place, the ADO will request the aforementioned information from the Grantee. Upon receipt and review of this information, parties will properly execute a Change of Name Agreement and the appropriate changes will be made to the Agency's records. The following suggested format for an agreement may be adapted for specific cases:

**CHANGE OF NAME AGREEMENT**

THE ABC CORPORATION (Grantee), a corporation duly organized and existing under the laws of \_\_\_\_\_ (insert State), and the NATIONAL INSTITUTE OF FOOD AND AGRICULTURE, USDA (Government) enter into this Agreement as of \_\_\_\_\_ (insert

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date when the change of name became effective under applicable State law).

(a) THE PARTIES AGREE TO THE FOLLOWING FACTS:

1. The Government, represented by the ADO, has entered into certain awards with XYZ CORPORATION, namely \_\_\_\_\_ (insert award number or delete "namely" and insert "as shown in the attached list marked 'Exhibit A' and incorporated in this Agreement by reference.") The term "the awards," as used in this Agreement, means the above awards and all other awards, including all modifications, made by the Government and the Grantee before the effective date of this Agreement (whether or not performance and payment have been completed and releases executed if the Government or the Grantee has any remaining rights, duties, or obligations under these awards.)

2. The XYZ CORPORATION, by an amendment to its certificate of incorporation, dated \_\_\_\_\_, 20\_\_\_\_, has changed its corporate name to ABC CORPORATION.

3. This amendment accomplishes a change of corporate name only and all rights and obligations of the Government and of the Grantee under the awards are unaffected by this change.

4. Documentary evidence of this change of corporate name has been filed with the Government.

(b) IN CONSIDERATION OF THESE FACTS, THE PARTIES AGREE THAT:

1. The awards covered by this Agreement are amended by substituting the name "ABC CORPORATION" for the name "XYZ CORPORATION" wherever it appears in the awards; and

2. Each party has executed this Agreement as of the day and year first above written.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE, USDA

BY: \_\_\_\_\_  
TITLE: \_\_\_\_\_

ABC CORPORATION

BY: \_\_\_\_\_  
TITLE: \_\_\_\_\_

CERTIFICATE

I, \_\_\_\_\_, certify that I am the Secretary of ABC CORPORATION, that \_\_\_\_\_, who signed this Agreement for this corporation, was then \_\_\_\_\_ of this corporation; and that this Agreement was duly signed for and on behalf of this corporation by authority of its governing body and within the scope of its corporation powers.

WITNESS MY HAND, and the seal of this corporation, this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

BY: \_\_\_\_\_

(CORPORATE SEAL)

(2) From time to time the legal entity performing the research under the award may have to be changed. In such instances, USDA will ensure that all parties properly execute a Novation Agreement (Successor in Interest Agreement).

(i) A Novation Agreement is a legal instrument executed by the Grantee (transferor), the successor in interest (transferee), and the Government by which, among other things, the transferor guarantees performance of the award, the transferee assumes all obligations under the award, and the Government recognizes the transfer of the award and related assets. This occurs when the third party's interest in the award arises out of the transfer of all the Grantee's assets or the entire portion of the assets involved in performing the award. Examples include, but are not limited to: the sale of these assets with a provision for assuming liabilities; the transfer of these assets incident to a merger or corporate consolidation; and the incorporation of a proprietorship or partnership, or the formation of a partnership.

(ii) When a Grantee asks the Government to recognize a successor in interest, the responsible ADO shall obtain the following from the Grantee:

(A) An authenticated copy of the instrument effecting the transfer of assets; e.g., bill of sale, certificate of merger, contract, deed, agreement, or court decree;

(B) A list of all affected awards;

(C) A certified copy of each resolution of the corporate parties' boards of directors authorizing the transfer of assets;

(D) A certified copy of the minutes of each corporate party's stockholder meeting necessary to approve the transfer of assets;

(E) The opinion of legal counsel for the transferor and transferee stating that the transfer was properly effected under applicable law and the effective date of transfer;

(F) An authenticated copy of the transferee's certificate and articles of incorporation, if a corporation was formed for the purpose of receiving the assets involved in performing the Government award;

(G) Evidence of transferee's capability to perform the award; and

(H) Balance sheets of the transferor and transferee as of the dates immediately before and after the transfer of assets, certified for accuracy by independent accountants.

(iii) The ADO will review the Agency's financial records concerning the correct cash-on-hand balances held by the transferor to ensure that they are properly accounted for in the transfer process. If recognizing a successor in interest to a Government award is consistent with the Government's interest, the ADO will prepare a Novation Agreement for execution by all three parties. The agreement will provide that:

(A) The transferee assumes all the transferor's obligations under the award(s);

(B) The transferor waives all rights under the award against the Government;

(C) The transferor guarantees performance of the award by the transferee (a satisfactory performance bond may be accepted instead of the guarantee); and

(D) Nothing in the agreement shall relieve the transferor or transferee from compliance with any Federal law.

(E) The following suggested format for an agreement may be adapted for specific cases:

**NOVATION AGREEMENT (SUCCESSOR IN INTEREST AGREEMENT)**

THE ABC CORPORATION (Transferor), a corporation duly organized and existing under the laws of \_\_\_\_\_ (insert state) with its principal office in \_\_\_\_\_ (insert city); the XYZ CORPORATION (Transferee), a corporation duly organized and existing under the laws of \_\_\_\_\_ (insert state) with its principal office in \_\_\_\_\_ (insert city); and the NATIONAL INSTITUTE OF FOOD AND AGRICULTURE, USDA (Government) enter into this Agreement as of \_\_\_\_\_ (insert the date transfer of assets became effective under applicable State law).

**(a) THE PARTIES AGREE TO THE FOLLOWING FACTS:**

1. The Government, represented by the ADO has entered into certain awards with the Transferor, namely: \_\_\_\_\_ (insert award number or delete "namely" and insert "as shown in the attached list marked 'Exhibit A' and incorporated in this Agreement by reference.") The term "the awards," as

used in this Agreement, means the above awards and all other awards, including all modifications, made between the Government and Transferor before the effective date of this Agreement (whether or not performance and payment have been completed and releases executed if the Government or the Transferor has any remaining rights, duties, or obligations under these awards.) Included in the term "award" are also all modifications made under the terms and conditions of these awards between the Government and the Transferor, on or after the effective date of this Agreement.

2. As of \_\_\_\_\_, 20\_\_\_\_, the Transferor has transferred to the Transferee all the assets of the Transferor by virtue of a \_\_\_\_\_ (insert terms or legal transaction involved) between the Transferor and the Transferee.

3. The Transferee has acquired all the assets of the Transferor by virtue of the above transfer.

4. The Transferee has assumed all obligations and liabilities of the Transferor under the awards by virtue of the above transfer.

5. The Transferee is in a position to fully perform all obligations that may exist under the awards.

6. It is consistent with the Government's interest to recognize the Transferee as the successor party to the awards.

7. Evidence of the above transfer has been filed with the Government.

**(b) IN CONSIDERATION OF THESE FACTS, THE PARTIES AGREE THAT BY THIS AGREEMENT:**

1. The Transferor confirms the transfer to the Transferee, and waives any claims and rights against the Government that it now has or may have in the future in connection with the awards.

2. The Transferee agrees to be bound by and to perform each award in accordance with the conditions contained in the awards. The Transferee also assumes all obligations and liabilities of, and all claims against, the Transferor under the awards as if the Transferee were the original party to the awards.

3. The Transferee ratifies all previous actions taken by the Transferor with respect to the awards, with the same force and effect as if the action had been taken by the Transferee.

4. The Government recognizes the Transferee as the Transferor's successor in interest in and to the awards. The Transferee by this Agreement becomes entitled to all rights, titles, and interests of the Transferor in and to the awards as if the Transferee were the original party to the awards. Following the effective date of this Agreement, the term Grantee, as used in the awards, shall refer to the Transferee.

5. Except as expressly provided in this Agreement, nothing in it shall be construed

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as a waiver of any rights of the Government against the Transferor.

6. All payments and reimbursements previously made by the Government to the Transferor, and all other previous actions taken by the Government under the awards, shall be considered to have discharged those parts of the Government's obligations under the awards. All payments and reimbursements made by the Government after the date of this Agreement in the name of or to the Transferor shall have the same force and effect as if made to the Transferee, and shall constitute a complete discharge of the Government's obligations under the awards, to the extent of the amounts paid or reimbursed.

7. The Transferor and the Transferee agree that the Government is not obligated to pay or reimburse either of them for, or otherwise give effect to, any costs, taxes, or other expenses, or any related increases, directly or indirectly arising out of or resulting from the transfer or this Agreement, other than those that the Government in the absence of this transfer or Agreement would have been obligated to pay or reimburse under the terms of the awards.

8. The Transferor guarantees payment of all liabilities and the performance of all obligations that the Transferee (i) assumes under this Agreement or (ii) may undertake in the future should these awards be modified under their terms and conditions. The Transferor waives notice of, and consents to, any such future modifications.

9. The awards shall remain in full force and effect, except as modified by this Agreement. Each party has executed this Agreement as of the day and year first above written.

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE, USDA

BY: \_\_\_\_\_

TITLE: \_\_\_\_\_

ABC CORPORATION

BY: \_\_\_\_\_

TITLE: \_\_\_\_\_

XYZ CORPORATION

BY: \_\_\_\_\_

TITLE: \_\_\_\_\_

CERTIFICATE

I, \_\_\_\_\_, certify that I am the Secretary of ABC CORPORATION, that \_\_\_\_\_, who signed this Agreement for this corporation, was then \_\_\_\_\_ of this corporation; and that this Agreement was duly signed for and on behalf of this corporation by authority of its governing body and within the scope of its corporation powers. WITNESS MY HAND, and the seal of this corporation, this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_

BY: \_\_\_\_\_

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(CORPORATE SEAL)

CERTIFICATE

I, \_\_\_\_\_, certify that I am the Secretary of XYZ CORPORATION, that \_\_\_\_\_, who signed this Agreement for this corporation, was then \_\_\_\_\_ of this corporation; and that this Agreement was duly signed for and on behalf of this corporation by authority of its governing body and within the scope of its corporation powers. WITNESS MY HAND, and the seal of this corporation, this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_

BY: \_\_\_\_\_

(CORPORATE SEAL)

§ 3403.15 Other Federal statutes and regulations that apply.

Several other Federal statutes and regulations apply to grant proposals considered for review or to research project grants awarded under this part. These include but are not limited to:

7 CFR part 1, subpart A—USDA implementation of the Freedom of Information Act.

7 CFR part 1c—USDA implementation of the Federal Policy for the Protection of Human Subjects.

7 CFR part 3—USDA implementation of the Debt Collection Act.

7 CFR part 15, subpart A—USDA implementation of Title VI of the Civil Rights Act of 1964, as amended.

7 CFR part 331 and 9 CFR part 121—USDA implementation of the Agricultural Bioterrorism Protection Act of 2002.

7 CFR part 3015—USDA Uniform Federal Assistance Regulations, implementing OMB directives (i.e., OMB Circular Nos. A-21 and A-122) and incorporating provisions of 31 U.S.C. 6301-6308 (formerly the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. 95-224), as well as general policy requirements applicable to recipients of Departmental financial assistance.

7 CFR part 3017—USDA implementation of Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants).

7 CFR part 3018—USDA implementation of Restrictions on Lobbying. Imposes prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal

contracts, grants, cooperative agreements, and loans.

7 CFR part 3019—USDA implementation of OMB Circular A-110, Uniform Administrative Requirements for Grants and Other Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.

7 CFR part 3052—USDA implementation of OMB Circular No. A-133, Audits of States, Local Governments, and Non-profit Organizations.

7 CFR part 3407—NIFA procedures to implement the National Environmental Policy Act of 1969, as amended.

9 CFR parts 1, 2, 3, and 4—USDA implementation of the Act of August 24, 1966, Pub. L. 89-544, as amended (commonly known as the Laboratory Animal Welfare Act).

48 CFR part 31—Contract Cost Principles and Procedures of the Federal Acquisition Regulations.

29 U.S.C. 794 (section 504, Rehabilitation Act of 1973) and 7 CFR part 15b (USDA implementation of statute)—prohibiting discrimination based upon physical or mental handicap in Federally assisted programs.

35 U.S.C. 200 et seq.—Bayh-Dole Act, controlling allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in Federally assisted programs (implementing regulations are contained in 37 CFR part 401).

#### § 3403.16 Other considerations.

The Department may, with respect to any research project grant, impose additional conditions prior to or at the time of any award when, in the Department's judgment, such conditions are necessary to assure or protect advancement of the approved project, the interests of the public, or the conservation of grant funds.

### PART 3404—PUBLIC INFORMATION

Sec.

3404.1 General statement.

3404.2 Public inspection, copying, and indexing.

3404.3 Requests for records.

3404.4 Multitrack processing.

3404.5 Denials.

3404.6 Appeals.

AUTHORITY: 5 U.S.C. 301, 552; 7 CFR part 1, subpart A and appendix A thereto.

SOURCE: 66 FR 57842, Nov. 19, 2001, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 3404 appear at 76 FR 4808, Jan. 27, 2011.

#### § 3404.1 General statement.

This part is issued in accordance with the regulations of the Secretary of Agriculture in part 1, subpart A of this title and appendix A thereto, implementing the Freedom of Information Act (FOIA) (5 U.S.C. 552). The Secretary's regulations, as implemented by the regulations in this part, govern the availability of records of the National Institute of Food and Agriculture (NIFA) to the public.

#### § 3404.2 Public inspection, copying, and indexing.

5 U.S.C. 552(a)(2) requires that certain materials be made available for public inspection and copying and that a current index of these materials be published quarterly or otherwise be made available. Members of the public may request access to such materials maintained by NIFA at the following office: Information Staff, ARS, REE, USDA, Room 1-2248, Mail Stop 5128, 5601 Sunnyside Avenue, Beltsville, MD 20705-5128; Telephone (301) 504-1640 or (301) 504-1655; TTY-VOICE (301) 504-1743. Office hours are 8 a.m. to 4:30 p.m. Information maintained in our electronic reading room can be accessed at <http://www.ars.usda.gov/is/foia/#Electronic>.

#### § 3404.3 Requests for records.

Requests for records of NIFA under 5 U.S.C. 552(a)(3) shall be made in accordance with § 1.5 of this title and submitted to the FOIA Coordinator, Information Staff, ARS, REE, USDA, Room 1-2248, Mail Stop 5128, 5601 Sunnyside Avenue, Beltsville, MD 20705-5128; Telephone (301) 504-1640 or (301) 504-1655; TTY-VOICE (301) 504-1743; Facsimile (301) 504-1648; or E-mail [shutchison@ars.usda.gov](mailto:shutchison@ars.usda.gov). The FOIA Coordinator is delegated authority to make determinations regarding such requests in accordance with § 1.3(c) of this title.

[66 FR 57842, Nov. 19, 2001, as amended at 76 FR 4808, Jan. 27, 2011]