

DEPARTMENT OF AGRICULTURE**Cooperative State Research,
Education, and Extension Service****7 CFR Part 3403****Small Business Innovation Research
Grants Program; Administrative
Provisions**

AGENCY: Cooperative State Research, Education, and Extension Service, USDA.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Cooperative State Research, Education, and Extension Service (CSREES) proposes to amend its regulations relating to the administration of the Small Business Innovation Research (SBIR) Grants Program, which prescribe the procedures to be followed annually in the solicitation of research grant proposals, the evaluation of such proposals, and the award of competitive research grants under this program. This rule amends those regulations by identifying information that will be specified in the annual solicitation as opposed to this rule. CSREES is republishing these regulations in their entirety with the proposed amendments in order to enhance their use by the public and to ensure expeditious submission and processing of grant proposals.

DATES: Written comments are invited from interested individuals and organizations. To be considered in the formulation of a final rule, all relevant material must be received on or before April 10, 1997.

ADDRESSES: Written comments should be sent to Sally J. Rockey, Deputy Administrator, Competitive Research Grants and Awards Management, Cooperative State Research, Education, and Extension Service, U.S. Department of Agriculture, STOP 2240, 1400 Independence Avenue, SW., Washington, DC 20250-2240.

FOR FURTHER INFORMATION CONTACT: Sally J. Rockey at (202) 401-1766.

SUPPLEMENTARY INFORMATION:**Paperwork Reduction**

Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the collection of information requirements contained in this proposed rule have been approved under OMB Document Nos. 0524-0022, 0524-0025, and 0524-0026.

Classification

This proposed rule has been reviewed under Executive Order 12866, and it has

been determined that it is not a "significant regulatory action" rule because it will not have an annual effect on the economy of \$100 million or more or adversely and materially affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. This proposed rule will not create any serious inconsistencies or otherwise interfere with any actions taken or planned by another agency. It will not materially alter the budgetary impact of entitlements, grants, user fees or loan programs and does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or principles set forth in Executive Order No. 12866. In addition, the Department certifies that the proposed rule will not have a significant impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96-534 (5 U.S.C. 601 et seq.).

Regulatory Analysis

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. All State and local laws and regulations that are in conflict with this rule are preempted. No retroactive effect is to be given to this rule. This rule does not require administrative proceedings before parties may file suit in court.

Environmental Impact Statement

This proposed regulation does not significantly affect the environment. Therefore, an environmental impact statement is not required under the National Environmental Policy Act of 1969, as amended.

Catalog of Federal Domestic Assistance

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.212, Small Business Innovation Research (SBIR Program). For the reasons set forth in the Final Rule-related Notice to 7 CFR part 3015, subpart V, 48 FR 29115, June 24, 1983, and pursuant to the Notice found at 52 FR 22831, June 16, 1987, this program is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Background and Purpose

On June 10, 1988, the Department published a Final Rule in the Federal Register (53 FR 21966-21972), which established part 3403 of title 7, subtitle B, chapter XXXIV of the Code of Federal Regulations, for the purpose of administering the U.S. Department of Agriculture's Small Business Innovation Research (SBIR) Grants Program conducted under the authority of the

Small Business Innovation Development Act of 1982, as amended (15 U.S.C. 638) and section 630 of the Act making appropriations for Agriculture, Rural Development, and Related Agencies' programs for fiscal year ending September 30, 1987, and for other purposes, as made applicable by section 101(a) of Pub. L. 99-591, 100 Stat. 3341. This rule established and codified the procedures to be followed in the solicitation of competitive small business innovation research proposals, the evaluation of such proposals, and the award of grants under this program. On September 20, 1991, the Department published a Final Rule in the Federal Register (56 FR 47882-47889), which amended the Cooperative State Research Service (CSRS) regulations relating to the Small Business Innovation Research Grants Program. On December 30, 1994, the Department published a Final Rule in the Federal Register (59 FR 68072) which amended 7 CFR chapter XXXIV to reflect the abolishment of CSRS and the establishment of CSREES. On May 15, 1996, the Department published a Final Rule in the Federal Register (61 FR 25366) amending 7 CFR Chapter XXXIV by encouraging the individuals who are principally responsible for the scientific or technical direction of the proposed work to be designated as the principal investigator, making it a condition that Federal funds remain for an extension of a Phase I grant and that an extension will not normally exceed 12 months, requiring that when purchasing equipment or products with agreement funds that only American-made items are purchased to the extent possible, and making a few additional changes. These regulations are proposed to be amended as follows:

Authority: CSREES proposes to amend the authority citation from "5 U.S.C. 638" to "15 U.S.C. 638" to correct a technical error.

Section 3403.2. CSREES proposes to correct "in behalf of" to read "on behalf of" in the definition of "awarding official." In addition, CSREES proposes to revise the definition of "funding agreement" to include "concern" after "small business" and the definition of "Socially and economically disadvantaged individual" by removing the "or" before "Subcontinent Asian Americans" to be in accordance with the language of the January 1993 SBIR Policy Directive.

Section 3403.3. CSREES proposes to change references of a "firm" to "organization" in order to be consistent throughout the document. In addition, CSREES proposes to include "concern" after "small business" to be in

accordance with the language of the January 1993 SBIR Policy Directive.

Section 3403.6(d). CSREES proposes to delete the language in this section and replace it with a statement that the information will be identified in the annual solicitation.

Section 3403.7. CSREES proposes to add paragraph (a) and redesignate paragraphs (a) through (m) as paragraphs (1) through (13), paragraphs (c) (1) through (6) as subparagraphs (3) (i) through (vi), paragraphs (g) (1) and (2) as subparagraphs (7) (i) and (ii), paragraphs (h) (1) through (6) as subparagraphs (8) (i) through (vi), paragraphs (k) (1) through (3) as subparagraphs (11) (i) through (iii), and paragraphs (l) (1) and (2) as subparagraphs (12) (i) and (ii). Furthermore, CSREES proposes to add language to identify that further instructions or descriptions of the phase I proposal items as well as additional items will be provided in the annual solicitation, as necessary. As such, much of the instructions and descriptions of the phase I items are deleted from this section.

Section 3403.7(g). CSREES proposes to add an item (iii) to require the applicant to identify whether and by what means the proposed research will satisfy the public interest. This will assist in determining the potential success of potential commercial application.

Section 3403.7(j). CSREES proposes to add language to explain that if an Institutional Review Board (IRB) review is required that USDA must receive and accept the IRB approval before grant funds will be released to the grantee.

Section 3403.8. CSREES proposes to add paragraph (a) and redesignate paragraphs (a) through (h) as paragraphs (1) through (8) and paragraphs (h) (1) and (2) as subparagraphs (8) (i) and (ii). In addition, see proposed change described for § 3403.7. The same changes are proposed for phase II proposals as are proposed for phase I proposals.

Section 3403.10(b). CSREES proposes to add language to explain that the evaluation criteria will be identified in the annual solicitation.

Section 3403.11. CSREES proposes to delete this section due to the proposed change identified for § 3403.10(b).

Section 3403.12. CSREES proposes to delete paragraph (a) and add paragraph (b) to § 3403.10(e) due to the proposed change identified for § 3403.10(b).

Section 3403.13. CSREES proposes to redesignate § 3403.13 as § 3403.11.

Section 3403.14. CSREES proposes to redesignate § 3403.14 as § 3403.12.

Section 3403.15. CSREES proposes to redesignate § 3403.15 as § 3403.13.

Section 3403.16. CSREES proposes to redesignate § 3403.16 as § 3403.14. In addition, CSREES proposes to change references of "Department" to "Authorized Departmental Officer" to be more specific.

Section 3403.16(c). CSREES proposes to change the reference to a specific phase I dollar amount with "the approved award amount" since the phase I award amount may vary from one year to the next.

Section 3403.17. CSREES proposes to redesignate § 3403.17 as § 3403.15. In addition, CSREES proposes to add "9 CFR Parts 1, 2, 3, and 4—USDA Laboratory Animal Care Regulations" after the reference to 7 CFR part 3407 and before the reference to 48 CFR part 31.

Section 3403.18. CSREES proposes to redesignate § 3403.18 as § 3403.16.

CSREES proposes to republish title 7, subtitle B, chapter XXXIV, part 3403, in its entirety with the proposed aforementioned changes. This action will preclude making a separate amendment to these regulations and allow the regulations to appear in one document for easy access and reference by the public and CSREES.

List of Subjects in 7 CFR Part 3403

Grant programs—Agriculture, Grant administration. For the reasons set out in the preamble, title 7, subtitle B, chapter XXXIV, part 3403 of the Code of Federal Regulations is revised to read as follows:

PART 3403—SMALL BUSINESS INNOVATION RESEARCH GRANTS PROGRAM

Subpart A—General Information

Sec.

3403.1 Applicability of regulations.

3403.2 Definitions.

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3403.7 Proposal format for phase I applications.

3403.8 Proposal format for phase II applications.

3403.9 Submission of proposals.

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3403.10 Proposal review.

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3403.12 Terms and conditions of grant awards.

3403.13 Notice of grant awards.

3403.14 Use of funds; changes.

3403.15 Other Federal statutes and regulations that apply.

3403.16 Other Conditions.

Authority: 15 U.S.C. 638.

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 September 30, 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). 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 U.S. Department of Agriculture (USDA) will participate in this program through the issuance of competitive research grants which will be administered by the Office of Competitive Research Grants and Awards Management, Cooperative State Research, Education, and Extension Service (CSREES).

(b) The regulations of this part do not apply to research grants awarded by the Department of Agriculture 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 or technical merit of

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.

Awarding official means any officer or employee of the Department who has the authority to issue or modify research project grant instruments on behalf of the Department.

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

Commercialization means the process of developing markets and producing and delivering products or services for sale (whether by the originating party or by others); as used here, commercialization includes both government and commercial markets.

Department means the Department of Agriculture.

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 funded in whole or in part by the Federal Government.

Grantee means the small business concern designated in the grant award document as the responsible legal entity to whom a grant is awarded under this part.

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 in 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 means a single individual designated by the grantee in the grant application and approved by the Department who is responsible for the scientific or technical direction of the project. Therefore, the individual should have a scientific and technical background.

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 selected areas and invites proposals from small business concerns in response to those needs.

Project means the particular activity within the scope of one of the research topic areas identified in the annual solicitation of applications, which is

supported by a grant award under this part.

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.

Research or research and development (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.

Small business concern means a concern which at the time of award of phase I and phase II funding agreements meets the following criteria:

(1) Is organized for profit, independently owned or operated, is not dominant in the field in which it is proposing, has its principal place of business located in the United States, has a number of employees not exceeding 500 (full-time, part-time, temporary, or other) in all affiliated concerns owned or controlled by a single parent concern, and meets the other regulatory requirements outlined in 13 CFR part 121. Business concerns, other than licensed investment companies, or State development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when directly or indirectly one concern controls or has the power to control the other or third parties (or party) control or have the power to control both. Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR 121.401(a) through (m). The term "number of employees" is defined in 13 CFR 121.407. Business concerns include, but are not limited to, any individual, partnership, corporation,

joint venture, association, or cooperative.

(2) Is at least 51 percent owned, or in the case of a publicly owned business at least 51 percent of its voting stock is owned, by United States citizens or lawfully admitted permanent resident aliens.

Socially and economically disadvantaged small business concern is one that is:

(1) At least 51 percent owned by:

(i) An Indian tribe or a native Hawaiian organization, or

(ii) One or more socially and economically disadvantaged individuals; and

(2) Whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

Socially and economically disadvantaged individual is a member of any of the following groups: Black Americans, Hispanic Americans, Native Americans, Asian-Pacific Americans, Subcontinent Asian Americans, other groups designated from time to time by the Small Business Administration (SBA) to be socially disadvantaged, or any other individual found to be socially and economically disadvantaged by the SBA pursuant to section 8(a) of the Small Business Act, 15 U.S.C. 637(a).

Subcontract is any agreement, other than one involving an employer-employee relationship, entered into by a Federal Government funding agreement awardee requesting supplies or services required solely for the performance of the funding agreement.

United States means the fifty States, the territories and possessions of the United States, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.

Women-owned small business concern means a small business concern that is at least 51 percent owned by a woman or women who also control and operate it. Control as used in this context means exercising the power to make policy decisions. Operate as used in this context means being actively involved in the day-to-day management of the concern.

§ 3403.3 Eligibility requirements.

(a) *Eligibility of organization.* (1) Each organization submitting a proposal must qualify as a small business concern for research purposes, as defined in § 3403.2. Joint ventures and limited partnerships are eligible to apply for and to receive research grants under this program, provided that the entity created qualifies as a small business

concern in accordance with section 2(3) of the Small Business Act (15 U.S.C. 632) and as defined in § 3403.2 of this part. For both phase I and phase II the research must be performed in the United States.

(2) A minimum of two-thirds of the research or analytical work, as determined by budget expenditures, must be performed by the proposing organization under phase I grants. For phase II awards, a minimum of one-half of the research or analytical effort must be conducted by the proposing organization. The space used by the SBIR awardee to conduct the research must be space over which it has exclusive control for the period of the grant.

(b) *Eligibility of principal investigator.* (1) It is strongly suggested that the individual responsible for the scientific or technical direction of the project be designated as the principal investigator. In addition, the primary employment of the principal investigator must be with the proposing small business concern at the time of award and during the conduct of the proposed research.

Primary employment means that more than one-half of the principal investigator's time is spent in the employ of the small business concern. Primary employment with the small business applicant precludes full-time employment with another organization.

(2) If the proposed principal investigator is employed by another organization (e.g., university or another company) at the time of submission of the application, documentation must be submitted with the proposal from the principal investigator's current employer verifying that, in the event of an SBIR award, he/she will become a less-than half-time employee of such organization and will remain so for the duration of the SBIR project.

Subpart B—Program Description

§ 3403.4 Three-phase program.

The Small Business Innovation Research Grants Program will be carried out in three separate phases described in this section. The first two phases are designed to assist USDA in meeting its research and development objectives and will be supported with SBIR 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 is the initial stage in which the scientific and technical merit and feasibility of an idea related to one of the research areas described in the program solicitation is evaluated,

normally for a period not to exceed 6 months. In special cases, however, where a proposed research project requires more than 6 months to complete, a longer grant period may be considered. A proposer of a phase I project with an anticipated duration beyond 6 months should specify the length and duration in the proposal at the time of its submission to USDA in order for it to be considered at the time of award. (See § 3403.14(c) for changes in project period subsequent to award).

(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, normally for a period not to exceed 24 months. Only those small businesses previously receiving phase I awards are eligible to submit phase II proposals. 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 apply for support not later than the second fiscal year funding cycle.

(c) Phase III is to stimulate technological innovation and the national return on investment from research through the pursuit of commercial objectives resulting from the work supported by SBIR funding carried out in phases I and II. This portion of the project is performed by the small business concern and privately funded or Federally 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 follow-on capital for a specified amount of funds to be made available to the small business concern for further development of their effort upon achieving certain mutually agreed upon technical objectives during phase II.

Subpart C—Preparation and Submission of Proposals

§ 3403.5 Requests for proposals.

(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. The 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, forms to be completed and submitted with proposals, and special requirements. A notice will be published in the Federal

Register informing the public of the availability of the program solicitation.

(b) *Phase II.* For each fiscal year in which funds are made available for this purpose, the Department will send a letter requesting phase II proposals from the phase I grantees eligible to apply for phase II funding in that fiscal year. The letter will be accompanied by the solicitation which contains information sufficient to enable eligible applicants to prepare grant proposals and includes forms to be submitted with proposals as well as special requirements.

§ 3403.6 General 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. the 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. 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. Duplicate proposals will be returned to the applicant without review.

(d) The limitation on the length of phase I and phase II proposals, text instructions, and the formatting instructions will be identified in the annual solicitation.

§ 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) *Proposal cover sheet.* Photocopy and complete Form CSREES-667 in the program solicitation. The original of the proposal cover sheet must at a minimum contain the pen-and-ink signatures of the proposed principal investigator(s) and the authorized organizational official.

(2) *Project summary.* Photocopy and complete Form CSREES-668 in the program solicitation. 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, to be provided in the last block on the page, 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) *Technical content.* 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.

(4) *Key personnel and bibliography.* Identify key personnel involved in the effort, including information on their directly related education and experience.

(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) *Consultants.* Involvement of university or other consultants in the planning and research stages of the project is permitted and may be particularly helpful to small firms which have not previously received Federal research awards. If such involvement is intended, it should be described in detail.

(7) *Potential post application.* Briefly describe:

(i) Whether and by what means the proposed research appears to have potential commercial application;

(ii) Whether and by what means the proposed research appears to have potential use by the Federal Government; and

(iii) Whether and by what means the proposed research will satisfy the public interest.

(8) *Current and pending support.* If a proposal, substantially the same as the one being submitted, has been previously funded or is currently funded, pending, or about to be submitted to another Federal agency or to USDA in a separate action, the proposer must provide the following information:

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

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

(iii) Title of proposal or award, identifying number assigned by the agency involved, and the date of program solicitation under which the proposal was submitted or the award was received.

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

(v) Title of research project.

(vi) Name and title of principal investigator for each proposal submitted or award received. USDA will not make awards that duplicate research funded (or to be funded) by other Federal agencies.

(9) *Cost breakdown on proposal budget.* Photocopy and complete the budget form in the program solicitation only for the phase under which you are currently applying. (An applicant for phase I funding should not submit both phase I and II budgets.)

(10) *Research involving special considerations.* If the proposed research will involve recombinant DNA molecules, human subjects at risk, or laboratory animal care, the proposal must so indicate and include an assurance statement (Form CSREES-662) as the last page of the proposal. The original of the assurance statement must at a minimum contain the pen-and-ink signature of the authorized organizational official. In order to complete the assurance statement, the proposer may be required to have the research plan reviewed and approved by an appropriate "Institutional Review Board" (IRB) prior to commencing actual substantive work. If an IRB review is required, USDA will not release funds for an award until proper

documentation of the IRB approval is submitted to and accepted by USDA. It is suggested that proposers contact local universities, colleges, or nonprofit research organizations which have established such reviewing mechanisms to have this service performed.

(11) *Proprietary information.* (i) If a proposal contains proprietary information that 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, provided the information is clearly marked by the proposer with the term "confidential proprietary information" and provided the following legend appears in the designated area at the bottom of the proposal cover sheet (Form CSREES-667): *The following pages (specify) contain proprietary information which (name of proposing organization) requests not be released to persons outside the Government, except for purposes of evaluation.*

(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 proposer. However, USDA will retain for one year one file 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 except for designated proprietary information that is determined by USDA to be proprietary information.

(iii) The inclusion of proprietary information is discouraged unless it is necessary for the proper evaluation of the proposal. If proprietary information 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. Any other legend than that listed in paragraph (a)(11)(i) of this section may be unacceptable to USDA and may constitute grounds for return of the

proposal without further consideration. Without assuming any liability for inadvertent disclosure, USDA will limit dissemination of such information to its employees and, where necessary for the evaluation of the proposal, to outside reviewers on a confidential basis.

(12) *Rights in data developed under SBIR funding agreement.* The SBIR legislation provides for "retention of rights in data generated in the performance of the contract by the small business concern."

(i) The legislative history clarifies that the intent of the statute is to provide authority for the participating agency to protect technical data generated under the funding agreement, and to refrain from disclosing such data to competitors of the small business concern or from using the information to produce future technical procurement specifications that could harm the small business concern that discovered and developed the innovation until the small business concern has a reasonable chance to seek patent protection, if appropriate.

(ii) Therefore, except for program evaluation, participating agencies shall protect such technical data for a period of not less than 4 years from the completion of the project from which the data were generated unless the agencies obtain permission to disclose such data from the contractor or grantee. The government shall retain a royalty-free license for government use of any technical data delivered under an SBIR funding agreement whether patented or not.

(13) *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 the responsibility of the proposer. 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.

§ 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 solicitation, as necessary.

(1) *Proposal cover sheet.* Follow instructions found in § 3403.7(a)(1) of this part.

(2) *Project summary.* Follow instructions found in § 3403.7(a)(2) of this part.

(3) *Phase I results.* The proposal should contain an extensive section that lists the 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 contained in § 3403.7(a)(3) of this part 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.

(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).

(7) *Follow-on funding commitment.* If the proposer has obtained a contingent commitment for phase III follow-on funding, it should be forwarded with the phase II application.

(8) *Documentation of multiple phase II awards.* (i) An applicant that submits a proposal for a funding agreement for phase I and has received more than 15 phase II awards during the preceding 5 fiscal years, must document the extent to which it was able to secure phase III funding to develop concepts resulting from previous phase II awards. This documentation should include the name of the awarding agency, date of award, funding agreement number, topic or subtopic title, amount and date of phase II funding and commercialization status for each phase II award.

(ii) USDA shall collect and retain the information submitted under paragraph (a)(8)(i) of this section at least until the General Accounting Office submits the report required under section 106 of the Small Business Research and Development Enhancement Act of 1992.

§ 3403.9 Submission of proposals.

The program solicitation for phase I proposals and the letter requesting phase II proposals will provide the deadline date for submitting proposals, the number of copies to be submitted, and the address where proposals should be mailed or delivered.

Subpart D—Proposal Review and Evaluation

§ 3403.10 Proposal review.

(a) All research grant applications will be acknowledged.

(b) Phase I and phase II proposals will be judged competitively in a two-stage process, based primarily upon scientific or technical merit. First, each proposal will be screened by USDA scientists to ensure that it is responsive to stated requirements contained in the program solicitation. Proposals found to be responsive will be technically evaluated by peer scientists knowledgeable in the appropriate scientific field using the criteria identified in the annual solicitation, as appropriate. Proposals found to be nonresponsive will be returned to the proposing firm without review.

(c) Both internal and 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 non-profit research organizations. If possible, USDA intends that peer review groups shall be balanced with minority and female representation and with an equitable age distribution.

(d) Technical 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 proposal should be self-contained and written with the care and thoroughness accorded papers for publication.

(e) Final decisions will be made by USDA based upon the ratings assigned by reviewers and consideration of other factors, including the potential commercial application, possible duplication of other research, any critical USDA requirements, and budget limitation. In addition, the follow-on funding commitment will be a consideration for phase II proposals. In the event that two or more phase II proposals are of approximately equal technical merit, the follow-on funding commitment for continued development in phase III will be an important consideration. The value of the commitment will depend upon the degree of commitment made by non-Federal investors, with the maximum value resulting from a signed agreement

with reasonable terms for an amount at least equal to the 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 purpose, the awarding official 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 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 the funds are granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award, the Federal Acquisition Regulation (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 shall include, at a minimum, the following:

- (1) Legal name and address of performing organization.
- (2) Title of project.
- (3) Name(s) and address(es) of the Principal Investigator(s).
- (4) Identifying grant number assigned by the Department.
- (5) Project period, which specifies how long the Department intends to support the effort.
- (6) Total amount of Federal financial assistance approved for the project period.
- (7) Legal authorities under which the grant is awarded.
- (8) Approved budget plan for categorizing project funds to accomplish the stated purpose of the grant award.
- (9) Other information or provisions deemed necessary by the Department to carry out its granting activities or to accomplish the purpose of a particular research project grant.

(b) The notice of grant award, in the form of a letter, will provide pertinent instructions and information to the grantee which are not included in the grant award document described in paragraph (a) of this section.

§ 3403.14 Use of funds; changes.

(a) *Delegation of fiscal responsibility.* 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) *Change in project plans.* (1) The permissible changes by the grantee, principal investigator(s), or other key project personnel in the approved research project grant shall be limited to changes in methodology, techniques, or other aspects of the project to expedite achievement of the project's approved goals. If the grantee and/or the principal investigator(s) are 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.

(2) Changes in approved goals, or objectives, shall be requested by the grantee and 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 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 approved in writing by the ADO prior to effecting such transfers.

(c) *Changes in project period.* The project period may be extended by the ADO to complete or fulfill the purposes of an approved project provided Federal funds remain. The extension shall be conditioned upon a prior request by the grantee and approval in writing by the ADO. 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 be delayed by 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. However, the maximum delay for submission of a Phase II proposal remains as specified in § 3403.4(b).

(d) *Changes in approved budget.* Changes in an approved budget shall be requested by the grantee and approved in writing by the ADO prior to instituting such changes if the revision will:

- (1) Involve transfers of amounts budgeted for indirect costs to absorb an increase in direct costs;
- (2) Involve transfers of amounts budgeted for direct costs to accommodate changes in indirect cost rates negotiated during a budget period and not approved when a grant was awarded;
- (3) Result in a need or claim for the award of additional funds; or
- (4) Involve transfers or expenditures of amounts requiring prior approval as set forth in the Departmental regulations or in the grant award.

§ 3403.15 Other Federal statutes and regulations that apply.

Several other Federal statutes and/or 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 1.1—USDA implementation of 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 OMB Circular A-129, Managing Federal Credit Programs.

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

7 CFR part 3015—USDA Uniform Federal Assistance Regulations, implementing OMB directives where applicable (i.e., Circular Nos. A-102, A-110, A-87, 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, as amended—USDA implementation of Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants), as amended.

7 CFR part 3018—USDA implementation of New Restrictions on Lobbying. Imposes new prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans.

7 CFR part 3407—CSREES procedures to implement the National Environmental Policy Act.

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 Regulation.

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 conditions.

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.

Done at Washington, DC, this 4th day of March 1997.

B. H. Robinson,

Administrator, Cooperative State Research, Education, and Extension Service.

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