

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 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. CSREES proposes to publish these regulations in their entirety in order to enhance their use by the public and to ensure expeditious submission and processing of grant proposals.

(The CSREES was established by Pub. L. 103-354, the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994, and the functions of the Cooperative State Research Service (CSRS) were transferred to the CSREES by the Secretary of Agriculture in the Secretary's Memorandum 1010-1, October 20, 1994.)

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 September 18, 1995.

ADDRESSES: Written comments should be sent to Louise Ebaugh, Director, Awards Management Division, Cooperative State Research, Education, and Extension Service, U.S. Department

of Agriculture, AG Box 2245, Washington, D.C. 20250-2245.

FOR FURTHER INFORMATION CONTACT: Louise Ebaugh at (202) 401-5024.

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 final rule have been approved under OMB Document Nos. 0524-0022, 0524-0025, and 0524-0026.

Classification

This 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 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, it 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.). This rule has been reviewed in accordance with Executive Order No. 12778, Civil Justice Reform, and the required certification has been made to OMB. 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.

Regulatory Analysis

Not required for this rulemaking.

Environmental Impact Statement

This 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. No. 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. These regulations are proposed to be changed as follows:

Section 3403.1(a)

CSREES proposes to change "minority and disadvantaged participation" to "participation of socially and economically disadvantaged small business concerns and women-owned small business concerns". This change conforms with the provisions of Pub. L. Number 102-564, 15 U.S.C. 638(j)(2)(F), as implemented by the January 1993 SBIR Policy Directive.

Section 3403.2

Definitions—Alphabetized due to the following changes.

Section 3403.2(d)

CSREES proposes to add the definition for "commercialization," adopted in the January 1993 SBIR Policy Directive and to include in the

definition the production and delivery of products and services in order to encompass the objectives of all topic areas (i.e., Rural and Community Development). This definition is pertinent to the three-phase program since it is the underlying goal of the program.

Section 3403.2(q)

CSREES proposes to change "Minority and disadvantaged small business" to "Socially and economically disadvantaged small business concern" and to change the definition in accordance with the language of Pub. L. Number 102-564 and the January 1993 SBIR Policy Directive. This includes adding a separate definition of a "Socially and Economically Disadvantaged Individual".

Section 3403.2(i)

See proposed change for Section 3403.3(b).

Section 3403.2(s)

CSREES proposes to delete "the Commonwealth of the Northern Mariana Islands" since they now are a part of the Trust Territory of the Pacific Islands.

Section 3403.3(b)

CSREES proposes to add language to encourage the individuals who are principally responsible for the scientific or technical direction of the proposed work to be designated as the principal investigator.

Section 3403.4(a)

CSREES proposes to add language describing the procedure of how to obtain a grant period longer than 6 months at the time of a phase I award. In addition, the maximum award amount for a Phase I award is changed from \$50,000 to the current limit of \$55,000.

Section 3403.4(c)

CSREES proposes to add the following language to the beginning of the first sentence, "Phase III is to stimulate technological innovation and the national return on investment from research through the pursuit of commercial objectives * * *." to better describe the purpose of phase III.

Section 3403.6(b)

CSREES proposes to add language to adequately explain that proposals must cover only scientific/technological research activities and not activities for product development where no research is involved. This will allow a better understanding by applicants of what constitutes an acceptable proposal.

Section 3403.6(d)

CSREES proposes to change the page restrictions in order to conform with those listed in the January 1993 issue of the SBIR Policy Directive.

Section 3403.7(f)

CSREES proposes to reference § 3403.11(d) or § 3403.12(5), as appropriate since these sections relate to the information provided in § 3407(f).

Section 3403.7(i)(1)

CSREES proposes to request information on how the applicant established the level of compensation to assist CSREES in determining if the compensation is reasonable for the level of work to be performed.

Section 3403.7(i)(2)

CSREES proposes to add language regarding American-made equipment as expressed by Congress in the Small Business Research and Development Enhancement Act of 1992.

Section 3403.7(i)(6)

CSREES proposes to add language explaining that indirect costs may not exceed the lesser of the negotiated rate or the rate restricted by statute.

Section 3403.7(j)(1)

CSREES proposes to add a statement regarding the submission of an assurance Statement (Form CSRS-662) and that this form will not count as part of the 25-page limit for Phase I applicants or the 50-page limit for Phase II applicants since the page limit is to restrict the amount of the text. This action will clarify the requirements for applicants whose research involves recombinant DNA, living vertebrate animals and/or human subjects.

Section 3403.7(k)(1)

CSREES proposes to revise the language regarding proprietary data to conform with language currently used by CSREES.

Section 3403.7(k)(3)

CSREES proposes to delete reference to technical reports and to include as § 3403.7(1), Rights in Data Developed Under SBIR Funding Agreement.

Section 3404.7(l)

CSREES proposes to add language concerning retention of rights to data developed under SBIR projects by contractors or grantees as mandated by the Small Business Innovation Development Act of 1992.

Section 3403.7(m)

CSREES proposes to include personnel information as a part of

organizational management information and that new forms should be submitted if a small business has undergone significant changes in organization, personnel, finance, or policies including those relating to civil rights. This will allow CSREES to obtain the necessary information if a significant change occurs and not limit CSREES to the one-time basis only statement.

Section 3403.8(f)

CSREES proposes to add examples of an updated statement of financial condition to give the applicants a better understanding of what information is necessary.

Section 3403.8(h)

CSREES proposes to include the requirement of documentation of multiple Phase II awards as specified by Pub. L. No. 102-624 and outlined in the January 1993 SBIR Policy Directive.

Section 3403.16(c)

CSREES proposes to add language to this part which requires that some Federal funds remain unexpended in order to obtain a no-cost extension of time for a Phase I grant, that the extension will not normally exceed 12 months because any additional time would make the Phase I awardee ineligible to apply for a Phase II award, and to clarify the purpose of a no-cost extension.

Section 3403.17

CSREES proposes to add 7 CFR Part 1c—USDA implementation of the Federal Policy for the Protection of Human Subjects and 7 CFR Part 3407—CSREES implementation of the National Environmental Policy Act as regulations that apply to proposals considered or grants awarded under this program.

We propose to publish Title 7, Subtitle B, Chapter XXXIV, Part 3403, in its entirety by combining **Federal Register** 56 FR 47882-47889, dated September 20, 1991, together with changes made by **Federal Register** 56 FR 68072, December 30, 1994, 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.

3403.3 Eligibility requirements.

Subpart B—Program Description

3403.4 Three-phase program.

Subpart C—Preparation and Submission of Proposals

3403.5 Requests for proposals.

3403.6 General content of proposals.

3403.7 Proposal format for phase I applications.

3403.8 Proposal format for phase II applications.

3403.9 Submission of proposals.

Subpart D—Proposal Review and Evaluation

3403.10 Proposal review.

3403.11 Phase I evaluation criteria.

3403.12 Phase II evaluation criteria.

3403.13 Availability of information.

Subpart E—Supplementary Information

3403.14 Terms and conditions of grant awards.

3403.15 Notice of grant awards.

3403.16 Use of funds; changes.

3403.17 Other Federal statutes and regulations that apply.

3403.18 Other Conditions.

Authority: 5 U.S.C. 301; 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. Number 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:

(a) *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.

(b) *Awarding official* means any officer or employee of the Department who has the authority to issue or modify research project grant instruments in behalf of the Department.

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

(d) *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.

(e) *Department* means the Department of Agriculture.

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

(g) *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.

(h) *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.

(i) *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.

(j) *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.

(k) *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.

(l) *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.

(m) *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.

(n) *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.

(o) *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)-(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.

(p) *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.

(q) *Socially and economically disadvantaged individual* is a member of any of the following groups: Black Americans, Hispanic Americans, Native Americans, Asian-Pacific Americans, or 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).

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

(s) *United States* means the several 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.

(t) *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 firm.* (1) Each organization submitting a proposal must qualify as a small business for research purposes, as defined in § 3403.2(O). 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 in accordance with section 2(3) of the Small Business Act (15 U.S.C. 632) and as defined in § 3403.2(o) 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 firm. 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 firm 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. 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 below. The first two phases are designed to assist USDA in meeting its research and development objectives and will be supported with Federal 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, 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 § 3403.16(c) for changes in project period subsequent to award). In any case, a phase I award will be limited to \$55,000.

(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 Federally supported work carried out in phases I and II. This portion of the project is performed by the small business firm and privately 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 firm and a provider of follow-on capital for a specified amount of funds to be made available to the small business 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 firm 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) Phase I applicants should submit a research proposal of no more than 25 pages, including cover page, budget, and all proposal-related enclosures or attachments. The text must be prepared on only one side of the page using standard size (8½"×11"; 21.6 cm×27.9 cm) white paper, 2.5 cm margins and type no smaller than 11 point font size regardless of whether it is single or double spaced. In the interest of equity to all proposers, no additional attachments, appendixes, or references beyond the 25-page limitation will be considered in the proposal evaluation process, and proposals in excess of the 25-page limitation will not be considered for review or award. In addition, supplementary materials, revisions, and/or substitutions will not be accepted after the due date for proposals. Phase II applicants should submit a research proposal of no more than 50 pages, including cover page, budget, and all proposal-related enclosures or attachments.

§ 3403.7 Proposal format for phase I applications.

(a) *Cover sheet.* Photocopy and complete Form CSRS-667 in the program solicitation. The original of the cover sheet must at a minimum contain the pen-and-ink signatures of the proposed principal investigator(s) and the authorized organizational official. A proposal which does not contain the signature of the authorized organizational official will not be considered a legal document and will be returned to the proposing small business firm without review. All other copies of the proposal must also contain a cover sheet, but facsimile or photocopied signatures will be accepted. The title should be brief (80-character maximum), clear, specific designation of the research proposed. It will be used to provide information to Congress and also will be used in issuing press releases. Therefore, it should not contain highly technical words. In addition, phrases such as "investigation of" or "research on" should not be used.

(b) *Project summary.* Photocopy and complete Form CSRS-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.

(c) *Technical content.* The main body of the proposal should include:

(1) *Identification and significance of the problem or opportunity.* Clearly state the specific technical problem or opportunity addressed and its importance.

(2) *Background and rationale.* Indicate the overall background and technical approach to the problem or opportunity and the part that the proposed research plays in providing needed results.

(3) *Relationship with future research or research and development.* Discuss the significance of the phase I effort in providing a foundation for the phase II R&D effort. State the anticipated results of the approach if the project is successful (phases I and II). This should address:

(i) The technical, economic, social, and other benefits to the Nation and to users of the result such as the commercial sector, the Federal Government, or other researchers;

(ii) The estimated total cost of the approach relative to benefits; and, if appropriate,

(iii) Any specific policy issues or decisions which might be affected by the results.

(4) *Phase I technical objectives.* State the specific objectives of the phase I research or research and development effort, including the technical questions it will try to answer to determine the feasibility of the proposed approach.

(5) *Phase I work plan.* This work must provide an explicit, detailed description of the phase I research or research and development approach. The plan should indicate the tasks to be performed as well as how and where the work will be carried out. The phase I effort should attempt to determine the technical feasibility of the proposed concept. The work plan should be linked with the technical objectives of the research and the questions the effort is designed to answer. Therefore, it should flow logically from § 3403.7(c)(4) of this part.

This section should constitute a substantial portion of the total proposal.

(6) *Related research or research and development.* Describe the significant research or research and development activities from relevant literature that are directly related to the proposed effort, including any conducted by the principal investigator or by the proposing firm, how it relates to the proposed effort, and any planned coordination with outside sources. The proposer must persuade reviewers that he or she is aware of related research in the selected subject.

(d) *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 representative publications in the topic area during the preceding 5 years, including those in press. List the authors (in the same order as they appear on the paper), the full title, and the complete reference as these usually appear in journals. Where vitae are extensive, summaries that focus on most relevant experience or publications may be necessary to meet the proposal size limitation in phase I and phase II.

(e) *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.

(f) *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. Proposals must include letters from proposed consultants indicating willingness to serve in order for such participation to be evaluated during the proposal review process. (See § 3403.11(d) or § 3403.12(5), as appropriate).

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

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

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

Firms with prior USDA SBIR grant support should summarize their progress in commercializing the results of that research. Past performance in the commercialization process may be considered in award decisions.

(h) *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.

(1) 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.

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

(3) 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.

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

(5) Title of research project.

(6) 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.

(i) *Cost breakdown on proposal budget.* Photocopy and complete Form CSRS-55 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.) Please note the following in completing the budget:

(1) *Salaries and wages.* Indicate the number and kind of personnel for whom salary support is sought. For key personnel, also indicate the number of work months of involvement to be supported with USDA funds (see blocks labeled "CSRS Funded Work Months"), and explain how the level of compensation was established, e.g., the hourly rate of pay, the monthly rate of pay, or the yearly rate of pay.

(2) *Equipment.* Performing organizations are expected to have appropriate facilities, suitably furnished and equipped. Items of equipment may be requested provided that they are specifically identified and adequately justified, but such requests should normally not exceed 10% of the budget for phase I. When purchasing equipment or a product under the SBIR funding agreement, the awardee should purchase only American-made items whenever possible. Equipment is defined as an article of nonexpendable, tangible personal property having a useful life of more than 2 years and an acquisition cost of \$500 or more per unit. Vesting of title to equipment

purchased with funds provided under an SBIR funding agreement will be determined by USDA based upon whether such transfer would be more cost effective than recovery of the property by the government. Awardees should plan to lease expensive equipment.

(3) *Travel.* The inclusion of travel will be carefully reviewed with respect to need and appropriateness for the research proposed. Foreign travel may not be included in the phase I budget.

(4) *Subcontracting limits.* Subcontracting may not exceed one-third of the research or analytical effort during phase I. In addition, subcontractors must perform their portion of the work in the United States. If subcontracting costs are anticipated, they should be indicated in block I, "All Other Direct Costs," on the budget sheet. A breakdown of subcontractual costs is required. For proposals involving subcontractual arrangements, the applicant must submit an agreement or letter of consent signed by the subcontractor in order for such participation to be evaluated during the proposal review process.

(5) *Fee.* A reasonable fee not to exceed 7% is permitted under this program. All fees are subject to negotiation with USDA. If a fee is requested, the amount should be indicated in block M on the budget sheet.

(6) *Indirect costs.* If available, the current rate negotiated with the cognizant Federal negotiating agency should be used, unless restricted by statute. Indirect costs may not exceed the lesser of the negotiated rate or the rate restricted by statute. If no rate has been negotiated, a reasonable dollar amount in lieu of indirect costs may be requested, which will be subject to approval by USDA. A proposer may elect not to charge indirect costs and, instead, use all grant funds for direct costs. If a negotiated rate is used, the percentage and base should be indicated in the space allotted under item K on the budget sheet. If indirect costs are not charged, the phrase "None requested" should be written in this space.

(7) *Cost-sharing.* Cost-sharing is permitted for proposals under this program; however, cost-sharing is not required nor will it be an evaluation factor in considering the competitive merit of proposals submitted.

(j) *Research involving special considerations.* (1) 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 CSRS-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. This form will not be considered a part of the 25-page limitation for Phase I proposals and the 50-page limitation for Phase II proposals. 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" prior to commencing actual substantive work. It is suggested that proposers contact local universities, colleges, or nonprofit research organizations which have established such reviewing mechanisms to have this service performed.

(2) Guidelines to be applied and observed when conducting such research are:

(i) *Recombinant DNA Molecules*. "Guidelines for Research Involving Recombinant DNA Molecules" issued by the National Institutes of Health, as revised.

(ii) *Human Subjects at Risk*. Regulations issued by the Department of Health and Human Services. (See 7 CFR Part 1c.)

(iii) *Laboratory Animal Care*. Regulations issued by the Department of Agriculture. (See 9 CFR Parts 1, 2, 3, and 4.)

(k) *Proprietary information*. (1) 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" is confined to a separate page or pages, and provided the following legend also appears in the designated area at the bottom of the proposal's cover sheet (Form CSRS-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.

(2) 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.

(3) 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 (k)(1) 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.

(l) *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."

(1) 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.

(2) 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.

(m) *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. Form CSRS-666 ("Organizational Information") and Form CSRS-665 ("Assurance of Compliance with the Department of Agriculture Regulations Under Title VI of the Civil Rights Act of 1964, as amended") are used for this purpose. 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 forms should be submitted if a small business 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) *Cover sheet*. Follow instructions found in § 3403.7(a) of this part.

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

(c) *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.

(d) *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(c) of this part should be followed, tailoring the information requested to the phase II project.

(e) *Cost breakdown on proposal budget*. (1) 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. Form CSRS-55, "Proposal Budget," is to be used for this purpose and may be photocopied as necessary.

(2) *Travel*. Foreign travel may be included as necessary in the phase II budget. Such a request will be reviewed with respect to need and appropriateness for the research proposed and therefore should be adequately justified in the proposal.

(3) *Subcontracting limits*. The instructions found in § 3403.7(i)(4) of

this part apply to phase II proposals except that the subcontracting limit is changed from one-third to one-half of the research or analytical effort.

(f) *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).

(g) *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. It will not count as part of the 50-page limit for a phase II application.

(h) *Documentation of multiple phase II awards.* (1) An applicant that submits a proposal for a funding agreement for phase I and that 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 award. 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.

(2) USDA shall collect and retain the information submitted under paragraph (h)(1) 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 listed in § 3403.11 or § 3403.12 of this part, 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.

§ 3403.11 Phase I evaluation criteria.

USDA plans to select for award those proposals offering the best value to the Nation, with approximately equal consideration given to each of the following criteria except for paragraph (a) of this section which will receive twice the value of any of the other items:

(a) The scientific/technical quality of the phase I research plan and its relevance to the stated objectives, with special emphasis on innovativeness and originality.

(b) Importance of the problem or opportunity and anticipated benefits of the proposed research, if successful.

(c) Adequacy of the phase I objectives to show incremental progress toward proving the feasibility of approach.

(d) Qualifications of the principal investigator(s), other key staff and consultants, and the probable adequacy of available or obtainable instrumentation and facilities.

§ 3403.12 Phase II evaluation criteria.

(a) A phase II proposal may be submitted only by a phase I awardee.

The phase II proposal will be reviewed for overall merit based on the following criteria with each item receiving approximately equal weight except for paragraphs (a) (1) and (2) of this section, which will receive twice the value of any of the other items:

(1) The scientific/technical quality of the proposed research, with special emphasis on innovativeness and originality.

(2) Degree to which phase I objectives were met and feasibility was established.

(3) The technical, economic, and/or social importance of the problem or opportunity and anticipated benefits if Phase II research is successful.

(4) The adequacy of the phase II objectives to meet the problem or opportunity.

(5) The qualifications of the principal investigator(s) and other key personnel to carry out the proposed work.

(6) Reasonableness of the budget requested for the work proposed.

(b) 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.

§ 3403.13 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

§ 3403.14 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 this part. 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).

§ 3403.15 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 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 during the project period.
 - (7) Legal authorities under which the grant is awarded.
 - (8) Approved budget plan for categorizing allocable 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 above.

§ 3403.16 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 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 Department for a final determination.

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

(c) *Changes in project period.* The project period may be extended by the Department to complete or fulfill the purposes of an approved project provided Federal funds remain. The extension shall be conditioned upon prior request by the grantee and approval in writing by the Department. In such cases the extension will not normally exceed 12 months, the phase I award will still be limited to \$55,000, 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 Department prior to instituting such changes if the revision will:

- (1) Involve transfers of amounts budgeted for indirect costs to absorb 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.

§ 3403.17 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 (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;

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 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).

§ 3403.18 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 10th day of
August 1995.

William D. Carlson,

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

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