

§ 3411.11

§ 3411.11 Composition of peer review groups.

(a) Peer review group members and *ad hoc* reviewers will be selected based upon their training and experience in relevant scientific or technical fields, taking into account the following factors:

(1) The level of formal scientific or technical education and other relevant experience of the individual and the extent to which an individual is engaged in relevant research and other relevant activities;

(2) The need to include as peer reviewers experts from various areas of specialization within relevant scientific or technical fields;

(3) The need to include as peer reviewers experts from a variety of organizational types (e.g., universities, industry, private consultant(s)) and geographic locations; and

(4) The need to maintain a balanced composition of peer review groups related to minority and female representation and an equitable age distribution.

(b) [Reserved]

§ 3411.12 Conflicts of interest.

(a) Members of peer review groups covered by this part are subject to relevant provisions contained in title 18 of the United States Code relating to criminal activity, Departmental regulations governing employee responsibilities and conduct (part 0 of this title), and Executive Order 11222, as amended.

(b) Reviewers may not review proposals submitted by institutions or other entities with which they have an affiliation or in which they have an interest. For the purposes of determining whether such a conflict exists, an institution shall be considered as an organization if it possesses a significant degree of academic and administrative autonomy, as specified in the annual program solicitation.

[56 FR 57952, Nov. 14, 1991. Redesignated and amended at 60 FR 63368, 63370, Dec. 8, 1995]

§ 3411.13 Availability of information.

Information regarding the peer review process will be made available to the extent permitted under the Free-

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dom of Information Act (5 U.S.C. 552), the Privacy Act (5 U.S.C. 552a.), and Departmental implementing regulations (part 1 of this title).

§ 3411.14 Proposal review.

(a) All grant applications will be acknowledged. Prior to technical examination, a preliminary review will be made for responsiveness to the program solicitation (e.g., relationship of application to announced program area). Proposals which do not fall within the guidelines as stated in the program solicitation will be eliminated from competition and will be returned to the applicant.

(b) All applications will be carefully reviewed by the Administrator, qualified officers or employees of the Department, the respective peer review group, and *ad hoc* reviewers, as required. Written comments will be solicited from *ad hoc* reviewers when required, and individual written comments and indepth discussions will be provided by peer review group members prior to recommending applications for funding. Applications will be ranked and support levels recommended with the limitation of total available funding for each research program area as announced in the program solicitation.

(c) No awarding official will make a grant based upon an application covered by this part unless the application has been reviewed by a peer review group and/or *ad hoc* reviewers in accordance with the provisions of this part and said reviewers have made recommendations concerning the merit of such application.

(d) Except to the extent otherwise provided by law, such recommendations are advisory only and are not binding on program officers or on the awarding official.

§ 3411.15 Evaluation factors.

Subject to the varying conditions and needs of States, Federally funded agricultural research supported under this program shall be designed to, among other things, accomplish one or more of the following purposes: Continue to satisfy human food and fiber needs; enhance the long-term viability and competitiveness of the food production and agricultural system of the

United States within the global economy; expand economic opportunities in rural America and enhance the quality of life for farmers, rural citizens, and society as a whole; improve the productivity of the American Agricultural system and develop new agricultural crops and new uses for agricultural commodities; develop information and systems to enhance the environment and the natural resource base upon which a sustainable agricultural economy depends; or enhance human health. Therefore, in carrying out its review under §3411.14, the peer review group shall take into account the following factors unless, pursuant to §3411.5(a), different evaluation criteria are specified in the program solicitation:

- (a) Scientific merit of the proposal.
 - (1) Conceptual adequacy of hypothesis;
 - (2) Clarity and delineation of objectives;
 - (3) Adequacy of the description of the undertaking and suitability and feasibility of methodology;
 - (4) Demonstration of feasibility through preliminary data;
 - (5) Probability of success of project; and
 - (6) Novelty, uniqueness and originality.
- (b) Qualifications of proposed project personnel and adequacy of facilities.
 - (1) Training and demonstrated awareness of previous and alternative approaches to the problem identified in the proposal, and performance record and/or potential for future accomplishments;
 - (2) Time allocated for systematic attainment of objectives;
 - (3) Institutional experience and competence in subject area; and
 - (4) Adequacy of available or obtainable support personnel, facilities, and instrumentation.
- (c) Relevance of project to long-range improvements in and sustainability of United States agriculture or to one or more of the research purposes outlined in the first paragraph of this section.
 - (1) Scientific contribution of research in leading to important discoveries or significant breakthroughs in announced program areas; and

(2) Relevance of the research to agricultural, environmental, or social needs.

[56 FR 57952, Nov. 14, 1991. Redesignated at 60 FR 63368, Dec. 8, 1995, as amended at 61 FR 45319, Aug. 29, 1996]

PART 3415—BIOTECHNOLOGY RISK ASSESSMENT RESEARCH GRANTS PROGRAM

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AUTHORITY: 5 U.S.C. 301 and 7 U.S.C. 5921.

SOURCE: 58 FR 65647, Dec. 15, 1993, unless otherwise noted.

Subpart A—General

§ 3415.1 Applicability of regulations.

(a) The regulations of this part apply to research grants awarded under the authority of section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990, (7 U.S.C. 5921). Grants awarded under this section will support biotechnology risk assessment research to help address concerns about the effects of introducing certain biotechnology products into the environment and to help regulators develop policies concerning the introduction of such products. Taking into consideration any determinations made through consultations with such entities as the Animal and Plant Health Inspection Service, the Forest Service, the Environmental Protection Agency,