United States Department of Agriculture
Research, Education, and Economics

ARS CSREES ERS NASS

Manual

Title: Peer Review of ARS Research Project Plans

Number: 500-1

Date: November 2005

Originating Office: Office of Scientific Quality Review, Office of the Administrator, ARS

This Replaces: **500-1, November 22, 2000**

Distribution:

This Manual describes the process employed by the Agricultural Research Service (ARS) to obtain independent and credible scientific peer review of research project plans developed to meet the objectives and aims of its National Programs.

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INTRODUCTION

The ARS Peer Review Process was implemented according to the Agricultural Research Extension, and Education Reform Act of 1998. These peer reviews are important because they provide a forum through which scientific research conducted by the Agency can be improved. In addition, peer reviews provide an opportunity to those outside the Agency to learn what ARS scientists are doing. This is important from two standpoints. First, it increases the potential for collaboration between ARS and non-ARS scientists. Second, and perhaps more importantly peer reviews of research project plans result in a collective evaluation of the Agency, overall.

Some of the public laws pertaining to the development and visibility of ARS' peer review can be found in Appendix 1: Public Laws. These laws are often cited in reference to public accessibility to project plans and peer review results.

AUTHORITY

The Agricultural Research Extension, and Education Reform Act of 1998 (Public Law 105-185, Section 103d)

SEC. 103. RELEVANCE AND MERIT OF AGRICULTURAL RESEARCH, EXTENSION, AND EDUCATION FUNDED BY THE DEPARTMENT.

(d) SCIENTIFIC PEER REVIEW OF AGRICULTURAL RESEARCH-

(1) PEER REVIEW PROCEDURES- The Secretary shall establish procedures that ensure scientific peer review of all research activities conducted by the Department.

(2) Review panel required--As part of the procedures established under paragraph (1), a review panel shall verify, at least once every 5 years, that each research activity of the Department and research conducted under each research program of the Department has scientific merit and relevance.

(3) Mission area.--If the research activity or program to be reviewed is included in the research, educational, and economics mission area of the Department, the review panel shall consider--

(A) the scientific merit and relevance of the activity or research in light of the priorities established pursuant to section 102; and

(B) the national or multistate significance of the activity or research.

(4) Composition of review panel.--

(A) In general.--A review panel shall be composed of individuals with scientific expertise, a majority of who are not employees of the agency whose research is being reviewed.

(B) Scientists from colleges and universities.--To the maximum extent practicable, the Secretary shall use scientists from colleges and universities to serve on the review panels.

(5) Submission of results.--The results of the panel reviews shall be submitted to the Advisory Board.

CHAPTER ONE: RESEACH PROJECT PLANS AS PART OF ARS SCIENTIFIC PROGRAMS

Section 1.1 Introduction and Impact on ARS Scientific Programs

The Agricultural Research Extension, and Education Reform Act of 1998, Public Law 105-185, mandates establishment of procedures for scientific peer review of ARS research projects and verifies that ARS' research has scientific merit and programmatic relevance. Projects are to be reviewed at least once every 5 years. A majority of the reviewers must be non-ARS scientists. Overall results of the reviews are submitted annually to the National Agricultural Research, Extension, Education, and Economics Advisory Board.

ARS uses these peer reviews to verify technical merit and methods proposed, and to ensure scientific relevance meets the expectations established for the mission and program objectives. Prospective peer review affords ARS scientists the opportunity to receive peer input and to make improvements to the project design and technical approaches prior to implementing the research. Peer review also provides ARS scientists insight on how to conduct the highest quality research in support of Agency missions and program objectives.

ARS views scientific peer review as an integral part of its overall scientific program. Congress sets the ARS research agenda, upon which ARS designs research initiatives based on input from customers and stakeholders. The National Program Staff (NPS) establishes specific charges for research activities, outlining the nature of the research to be performed. NPS also designates operating and other resources available for the project and research staff. In response, the research teams develop project plans detailing the work to be performed over the next 5 years. The project plans are then evaluated by a panel of external scientists who focus on three key elements of research planning: (1) **merit and significance**, and **relevance** to the National Program Action Plan; (2) **adequacy** of experimental approaches and procedures; and (3) **probability of success** in accomplishing the project's objectives within 5 years. Sound and credible scientific peer review by expert and independent scientists serves to improve the quality of research ideas, to enhance creative thinking, and to identify alternative approaches that may not have been considered by ARS scientists and staff.

The ARS Peer Review Process places an increased emphasis and importance on <u>prospective</u> planning and design of research projects. *Even if intermediate research results require the research team to modify their activities, the benefits of early, attentive consideration of the objectives and methods of the research serve to improve the quality of the work performed.*

Listed below are numerous additional benefits of the Peer Review Process that enhance the overall planning, coordination, and communication skills of the ARS scientific workforce:

- An increased awareness of the relationships and multi-disciplinary linkages among research activities within a National Program (NP)
- Increased communications and collaboration among National Program Teams and the research scientists planning and performing the research

- An increased emphasis on clearly communicated objectives and approaches in research project plans
- An increased knowledge and appreciation of ARS research activities and capabilities by non-ARS scientists.
- Improved abilities to write competitive grant proposals for extramural funds.

Project plans are part of the ARS process of accountability, planning, and budgeting. The project plan development and review process managed by the OSQR office is only one part of the overall National Program Planning Cycle. The linkage of the project plan to the successful implementation and conduct of a National Program begins with the development and review of project plans. The linkage to yearly updates of progress through the Annual Report of Progress (AD-421s) and project cycle assessments and stakeholder meetings are based on this initial step of developing quality science projects.

Section 1.2 Impact of Peer Review on Annual Report of Progress, and Performance Plan

Project plan development and the resulting peer review action directly impact the Annual Report of Progress and Annual Performance Plan, and may influence Research Position Evaluation System (RPES) evaluation of each scientist. The defined sequence of research described in project plans should simplify development of the Annual Report of Progress when research activities follow the plan. All research cannot be fully predicted, but the major research directions developed in project plans serve as a basic outline for development of the Annual Report of Progress. Participation in the peer review process, including contributing input to the plan (if a member of a scientific team), and reviewing the plan (if in a supervisory position), are now components of a scientist's performance. Performance standards developed in relation to a well-designed project plan will simplify establishment of yearly goals in specific performance elements. These goals may not be exactly as detailed in the project plan but should reflect the flexibility of the project plan to accommodate developments critical to the success of the project. RPES evaluation is based heavily on impact of research conducted by an individual scientist. Project plan development and associated peer review provides an early evaluation of the relevance and potential impact of the work to be conducted and should allow scientists the opportunity to evaluate and perhaps increase the potential for the planned research to have an impact**.**

Section 1.3 Organization of the Office of Scientific Quality Review

The Office of Scientific Quality Review (OSQR) has the primary responsibility of implementing and tracking the project review process under the Associate Administrator for Research Operations. The mission of the OSQR is "to facilitate the planning and management of the peer review of ARS research." A Scientific Quality Review Officer (SQR Officer) is appointed on a part-time basis from the ranks of the senior scientists within ARS to serve in an oversight role of the process. It is also the responsibility of the SQR Officer to certify completed project plans once they have adequately passed peer review. The OSQR office staff also consists of a Peer Review Coordinator and two Program Assistants and one Program Analyst. The primary responsibilities of this staff are to oversee the conduct and logistics of the project reviews and transmit the panel review comments to the project scientists through administrative channels.

Additional duties of the staff include support for the preparation of assessment reports on the OSQR process, synthesis of the peer review process, and presentations on the peer review process to ARS scientists and other agencies and to organize dates, accommodation, reimbursements and honoraria for the peer reviewers.

Section 1.4 How the Peer Review of Research Fits into ARS' Management Approach

Project plans fulfill two important areas in management: 1) **management of ARS National Programs; and 2) management of scientific personnel**. Management of National Programs can be enhanced through coordination and integration of individual project plans into comprehensive goals, objectives, and potential outcomes of each NP. Each individual project is reviewed as part of the National Program to which the individual project is assigned on a majority basis. *This linkage to NP goals is a critical piece of the project plan and identification of specific areas to which the individual project contributes helps show how each project contributes to the respective National Program's mission.* The sections within the project plan that address NP components are critical to the project review process because they help reviewers see the overall scope and impact of the respective NP. The development of the project plan is an important step in the management of NPs because it allows both NPS and the public to see the scope of the research program and the location at which specific research is being conducted. Annual Report of Progress (AD-421s) provides updates of the progress, expected changes, and impact of each project.

ARS has two routes of management: program management, which addresses the national programs and projects, and line management, which deals with personnel and their accomplishments. Project plans bridge these two management lines by providing a foundation for scientific programs while providing a process for tracking progress of both individuals and programs within the Agency. The following table provides insights into the roles and responsibilities of each individual in both program and line management, as they relate to the project plan peer review process.

Individual	Program Role	Line Management Role
National Program Leader (NPL)	Provides oversight of the NP development and coordination among locations and programs. Prepares Program Direction Resource Allocation Memo (PDRAM) in consultation with the AD, CD/ID/LD, and RL, outlining the objectives of research projects. Presents overview of the NP	

Individual	Program Role	Line Management Role
	to the Peer Review Panel. Evaluates progress of NP plans through Annual Report of Progress (AD-421s) toward program goals.	
Area Director (AD)		Provides oversight of project plan development and performance of personnel in the development and execution of project plans through performance standards.
Center, Institute, or Lab Director (CD/ID/LD)	Provides oversight of project plan development and implementation within the laboratory or center. Provides coordination of projects within the laboratory/center toward NP goals. Interfaces with stakeholders in providing information on project and program impacts on customer needs.	Evaluates progress of scientists involved in project plans through performance standards and RPES reviews.
Research Leader (RL)	Provides oversight of project plan development and implementation within the research unit. Coordination of projects within the research unit toward NP goals. Interfaces with stakeholders in providing information on project and program impacts on customer needs.	Evaluates progress of scientists involved in project plans through performance standards and RPES reviews.
Lead Scientist	Is responsible for project plan development and implementation.	

Individual	Program Role	Line Management Role
	Evaluates and documents the progress of the project plan through the five year cycle. Interfaces with stakeholders in providing information on project and program impacts on customer needs. Prepares research papers and summaries of the research findings from the project.	
Scientist	Develops and implements project plans according to guidelines and documents progress and changes for incorporation into the annual report of progress. Interfaces with stakeholders in providing information on project and program impacts on customer needs. Prepares research papers and summaries of the research findings from the project.	

Section 1.5 Verification, Validation and Program Evaluation

ARS conducts a series of review processes designed to ensure relevance and quality of its research and to maintain the highest possible standards for its scientists. This process involves customer input to help keep the research focused on the technical needs of the American food and agricultural system. Approximately 1200 research projects, organized into 22 National Programs, undergo a thorough peer review before new or renewed activities begin. Moreover, all ARS employees, including the scientific workforce, are subject to annual performance reviews. Category 1 scientists undergo a rigorous peer review RPES (Research Personnel Evaluation System) on a three- to five-year cycle. These processes maintain high quality in the ARS scientific workforce.

National Programs focus the work of the Agency on achieving the goals defined in the ARS Strategic Plan. The research priorities for each National Program are established with extensive input from customers, stakeholders, and partners, which is received, in part, through a series of National Program Workshops. A detailed Action Plan is developed for each National Program and is available on the ARS webpage.

Annual Performance Plans and the Annual Report of Progress, required by GPRA (Government Performance and Results Act), focus ARS research on achieving the goals established in the ARS Strategic Plan. The aggregate effect is a strengthened research program and an accountability system that more effectively measures the progress made towards achieving established goals and outcomes.

CHAPTER TWO: ADMINISTRATION OF PEER REVIEW

The ARS Peer Review Process is composed of 5 stages: 1) Identifying Projects to be Reviewed, 2) Prospectus Development, 3) Project Plan Development, 4) Peer Review, and 5) Revision & Response to the Peer Review. After these steps are achieved, the project is certified. This Chapter provides administrative guidance on each stage of the process.

Section 2.1 Identification of Projects to be Reviewed

Projects to be reviewed are identified through a combination of National Program Customer/Stakeholder Workshops and communication among Research Leaders, Area Directors, and National Program Staff (NPS). These discussions identify locations and scientists who can contribute to the National Program (NP). The development of the Action Plan for the NP further identifies potential locations and units contributing to specific components within the NP. Research Units and their scientists who are identified as members of a NP will be provided with a Program Development and Resource Allocation Memo (PDRAM) outlining the project objectives and schedule for the development and review of the prospectus and project plan. The current schedule for review of National Programs is at www.ars.usda.gov/osqr.

At the onset of the NP Review cycle, OSQR provides NPS with a schedule and outline of responsibilities. OSQR then briefs the NP Team on goals for the review session, which may include the following topics:

- Role of OSQR in the project review process
- Collaboration on the allocation of projects among panels
- Coordinating schedules and deadlines during the review session
- NPL role in project review
- Area role in project review
- Understanding the resources available to scientists towards writing their project plan
- Presentations to the panel chairs and panelists
- Interpreting management decisions on projects receiving unacceptable action classification (i.e., “major revision required” or “not feasible”)
- Certification of project plans
- Projects within a NP that may require ad hoc review
- Responsibility of maintaining peer review tracking

Section 2.1.1 Finalization of Projects to be Reviewed

The initial list of projects to be reviewed will be based on all category “D” projects coded to a NP developed from the PDRAM’s transmitted from the NP Teams to the Area Offices. In rare cases, a research team may be granted a postponement of the review of their plan, often on the basis of critical scientific staff vacancies.

Experience has shown that some research projects will be exempt on the basis that they are service projects with less than a five-year term. For example, the USDA Interregional Research Project No. 4 (IR-4) was created in 1963 to address the needs of minor-crop producers through numerous field trials. The plans associated with the field trials have shorter terms and less

complex research approaches than the typical project plans written for peer review. Thus, the IR-4 projects are exempt from the Process.

Research project plans that have already undergone peer review but are subsequently redirected or significantly altered in terms of goals and approaches must develop a new or modified research project plan for ad hoc peer review, if the redirection occurs more than two years prior to the next scheduled peer review. Area Management and the associated NP Team will determine if the plan requires review in its entirety, or whether only the newly modified portions require review.

Some research projects funded by ARS but performed by non-ARS scientists are given equal peer review treatment as that for intramural research projects. Several factors are considered to determine whether non-ARS research projects are excluded from peer review. In some cases, these non-ARS projects should be presented in conjunction with the intramural research project to which it is linked, especially if ARS has assumed responsibility for the quality of the research. All exemptions are granted based on the recommendation of the NPL, with agreement from the appropriate AD. Approval of exemptions is made by the Associate Administrator.

ARS utilizes Specific Cooperative Agreements (SCAs) to conduct cooperative research and enhance the impact of the intramural research program. These projects are linked with base-funded or "D" projects and are cooperative efforts with these projects. For existing SCAs associated with a project plan, note this agreement in the collaboration section of the specific project objective and detail the nature of the collaboration in the collaborator letter.

Section 2.1.2 Postponement of Reviews

Two criteria may allow postponement of peer review of a project plan: 1) vacancies or long-term absences in key scientific leadership positions, and 2) significant unanticipated reorganization, initiation, or redirection of research in a project. *Requests for postponement of peer review of a project plan by the Lead Scientist or Research Leader are handled on a case-by-case basis, and are granted only under exceptional circumstances.* Requests for postponements should be made within 30 days after receipt of the PDRAM. OSQR has developed guidelines for postponing peer review of project plans, and has described them in *Bulletin Number 03-601 "Guidelines for the Postponement of Research Project Plan Peer Reviews."* **Postponements are granted only by the Associate Administrator.** Response to the request for postponement is routed back through the Area Director's office with copies to National Program Staff and OSQR.

Section 2.1.3 Exemption of Projects from the Peer Review Process

Under certain circumstances, a project plan may be exempt from the peer review process. For the exemption to be granted, a request must be made to the Associate Administrator, after approval by the Area Director and the National Program Leader. All requests are handled on a case-by-case basis by Area Management and the National Program Team. Although there are no automatic sanctions, the most common reasons for approving a request is that the project is funded by ARS, but not necessarily led by ARS.

A project plan may also be exempt from peer review if:

1. It is a new project created by combining or splitting projects that recently completed the peer review process as separate or single projects, and the objectives and approaches of the research have not been substantially altered.
2. The project has no scientific activities or staff and is part of a strategy to appropriate funds to other projects. Projects designed for similar budgeting situations--but which do have some scientific activity related to a more comprehensive, problem-solving project--may be peer reviewed as part of the comprehensive project plan.
3. Critical vacancies exist in the scientific staffing of a research project scheduled for peer review. The vacancy must be at such a significant level that existing scientific staff currently assigned to the project is completely devoid of expertise to contribute the components to the project plan germane to the vacant position. Determination that current scientific staff is incapable of making this contribution must be approved by the Area Director, National Program Staff and ultimately, the Associate Administrator.

Section 2.1.4 Significant Changes in a Project Plan Necessitating a New Review

Peer review adds value to the project plan and enhances the credibility of the plan. A new peer review should be considered when significant changes are made to a project plan, especially when it is expected that the results of the plan's research will challenge existing science, technology, or current policy, will be used for setting policy or in other decision making efforts, or will impact recommendations concerning human health and nutrition.

Significant change *is any change to the current project plan's goals or objectives that would introduce the need for expert input that was not provided during the original peer review.* Such changes could involve: a) incorporation of a new research approach that was not presented in the original plan which would require substantial development or adaptation to use, b) addition of one or more objectives that were not inherently described with at least an outlined experimental design in the existing plan, or c) reassignment of objectives from projects that were not previously peer-reviewed. To necessitate a new review, the significant change would have to occur prior to two years before the plan's next scheduled panel review session.

It is the responsibility of each research leader to ensure that their research teams conduct research as outlined in the project plan and to notify NPS, their Center, Institute, or Lab Director, and Area Office of any changes in objectives that may necessitate a new review. Concurrence, and appropriate approvals, should be obtained from all relevant parties before contacting the OSQR to schedule a new review.

While various situations may warrant a new peer review, as determined on a case-by-case basis, some examples of situations that may not require a new peer review are the following:

1) Reorganization of a Research Unit – Additional peer review is not required if the objectives of previously peer-reviewed projects will still be met in the reorganized unit. For example, a reorganization that combines two previously peer-reviewed ARS research projects into a new ARS research project would not require an additional peer review.

Conversely, splitting a previously peer-reviewed ARS research project into two new ARS research projects would not require additional peer review.

2) Additional Base Funding – Additional peer review is not required if an increase in base funds is provided to an existing project to support previously peer-reviewed objectives.

3) Change in Research Methodology – If new approaches or methodologies are proposed to meet project objectives, and these were not addressed in the Contingencies section of the previously peer-reviewed project plan, additional peer review may not be needed. A new peer review is not required if the new approaches or methodology are those accepted as state of the art in the field of expertise, were not available when the plan was put in place, and would not require inordinate development or adaptation to use. Examples would be new analytical methods based on or validated by Association of Official Analytical Chemists (AOAC) or American Society for Testing and Materials (ASTM), new genomic or proteomic techniques, use of commercial data banks, addition of new unit operations to monitor feed and exit streams, and the like.

4) Peer review is generally not needed if peer-reviewed ARS science and technology is applied to test new applications. For example, technology developed to process one commodity may be applied to process another.

5) Peer review is not needed if one-time funds are received from another federal agency to conduct ARS research. In this situation, it is the responsibility of the outside agency to determine the need to conduct peer review, and to administer that peer review.

Section 2.1.5 *Ad Hoc* Reviews Outside the National Program Peer Review Panels

ARS recognizes that research projects are not static within NP Action Plans. There may be modifications or new projects created by changes in mission or programmatic direction, Congressional mandates, redirection or new objectives, new initiatives or funding, and organizational and staffing changes. A new research project plan, or one that has been dramatically changed, may require an *ad hoc* peer review if the panel review session for its NP begins more than two years later. Existing research projects that have been combined into a single project need not be peer reviewed again if the goals and approaches of the research have not been substantially altered in the process.

Ad hoc reviews are handled through the OSQR office. Reviewers are selected from knowledgeable scientists within the discipline and they provide written comments to the OSQR office. There is no formal panel meeting of the reviewers. Comments are transmitted back to the Area Office and Lead Scientist using the same process of comment and revision as for a scheduled panel meeting.

Section 2.2 NPS and Area Office Coordination of Prospectus and Project Plan Preparation

Preparation of a project plan is a multi-step process. *The project team (Lead Scientist and*

research team), Research Leaders, and Center/Institute/Laboratory Director. Directors share the responsibility for the creation of a quality project plan. The foundation for the project plan is the PDRAM outlining the objectives and the linkage to the NP Action Plan. In response to the PDRAM, the project team through the leadership of the Lead Scientist prepares a project prospectus for review by the RL, CD/ID/LD, AD, and NPL. Following the approval of the prospectus the project team completes the preparation of the project plan for review through OSQR. Communication among the project team and with RL, CD/ID/LD, AD, and NPLs is critical during the process. Quality project plans are well-prepared documents that describe the approach, impact, collaborations, and capabilities of the project team to address the objectives of the project.

Tips for success, the Lead Scientist should:

1. Contact the RL, NPL and AD early in the OSQR process to begin discussions about the scope of the proposed research and specific objectives.
2. Continue to communicate with all parties involved throughout the OSQR process.
3. Refer to the editorial guidance available on the OSQR website at http://www.ars.usda.gov/osqr.
4. Seek reviews of the project plan from scientific experts both inside and outside of the Agency prior to sending the plan to the AD.
5. Ensure that the project plan is a "seamless" document when multiple SYs contribute to the writing.
6. Proofread the plan for spelling and grammatical errors.
7. Thoughtfully consider the comments, criticisms, and suggestions received and incorporate as many of them as possible into the finished project plan.

Section 2.3 Peer Review Results Distribution and Response

Section 2.3.1 Distribution of Peer Review Results

OSQR distributes review results to the research team's AD, with copies to the NP Team. The review results are transmitted with a cover memo detailing the panel meeting date and the composite score for the project peer review. A detailed summary of the panel comments are provided to the research team for the following categories: Adequacy of Approach and Procedures; Probability of Successfully Accomplishing the Project's Objectives; Merit and Significance; and Additional Comments or Suggestions. Area Directors, through the Area Program Analyst, forward the review results to the research team through the Center, Institute, or Lab Director, if applicable. Included in this transmission are the instructions and dates for completing and returning the revisions and responses to the peer review comments to the Area Program Analyst office.

Section 2.3.2 Revised Project Plans and Responses

Under the Administrative Procedures Act and the Federal Advisory Committee Act, no Federal agency can request advice from a non-Federal entity without also making a reasonable effort to use the advice and provide a response to that advice. It is for this reason that certifications for the peer review process cannot be granted unless OSQR receives a revised project plan with an accompanying "ARS Response File" that is essentially a point-by-point response to each panel recommendation.

The post-peer review signature page is used only if the project receives a favorable peer review (the score is greater than 3.0) or after a successful re-review. Note that this page contains different statements than the pre-peer review signature page. Signatures are required of the Research Leader; Center, Institute, or Lab Director; and Area Director (or their designee which may often be the Associate or Assistant Area Director). As the highest line of authority in the decision for the conduct of research by a designated research team, the Area Director's signature must be the last signature and must be original.

Statements for the post-review signature page include the expectation that these individuals have read the research team's response to the panel recommendations. Thus, the ARS Response file must accompany the revised project plan throughout the routing process.

Section 2.3.3 Post-Peer Review Signature Page

Post-peer review signature pages must contain the following statements:

Statement for the Research Leader:
This project plan was revised, as appropriate, according to the peer review recommendations and/or other insights developed while considering the peer review recommendations. A response to each peer review recommendation is attached. If recommendations were not adopted, a rationale is provided.

Statement for the Center, Institute, or Lab Director:
This final version of the project plan reflects the best efforts of the research team to consider the recommendations provided by peer reviewers. The responses to the peer review recommendations are satisfactory.

Statement for the Area Director:
The attached plan for the project identified above was created by a team of credible researchers and internally reviewed and recognized by the team's management and National Program Leader to establish the project's relevance and dedication to the Agricultural Research Service's mission and Congressional mandates. It reflects the best efforts of the research team to consider the recommendations provided by peer reviewers. The responses to the peer review recommendations are satisfactory. The plan project has completed a scientific merit peer review in accordance with the Research Title of the 1998 Farm Bill (PL105-185) and was deemed feasible for implementation. Reasonable consideration was given to each recommendation for improvement provided by the peer reviewers.

Section 2.4 Certification Letter

OSQR certifies that the ARS response to the peer review process is complete and that revision to the project plan and response to panel recommendations are in the best interest of the Agency. The certification letter also provides instructions on locating the termination date for the next peer review session on the OSQR website and availability of the public to access information pertaining to the review. Instructions are contained in the certification memo to complete the AD-416/417 as the initial step in the implementation phase of the project plan.

CHAPTER THREE: PROSPECTUS AND PROJECT PLAN DEVELOPMENT AND REVISION

All scientists, especially Lead Scientists, should read Appendix 6: Lead Scientist Preparation for Submitting Project Plans to the ARS Peer Review Process, for specific guidance regarding the development and review of the project plan.

Section 3.1 Purpose of Prospectuses

A prospectus is a planning and communications document that outlines the direction, objectives and approach for research to be conducted over the next five years by each of the projects in a NP. The prospectus allows research conducted in an individual project to be linked to the overall research goals of a NP and to research conducted by other scientists in the same or related NPs. The information needed to develop a prospectus is generated in a three stage process that involves a planning workshop; development of a National Program Action Plan; and interaction among scientists, Area Offices and National Program Leaders.

Each NP conducts a planning workshop to focus the research program by learning the problems and needs of customers, stakeholders and partners. These workshops help ensure that research programs are relevant to constituent concerns. ARS scientists and members of the National Program Staff use information generated at the planning workshop to develop a National Program Action Plan that provides a framework for ARS research over a five-year period. National Program Leaders interact with scientists on individual projects to identify contributions that the project will make to the overall goals of the National Program, to identify overall objectives for the project, and to help develop cooperation among projects addressing common areas of research. The NPLs from the NP Team issue a PDRAM to the Area Office that outlines the specific research objectives to be addressed by the research team. The PDRAM will be used by the scientist in preparation of the prospectus.

The prospectus keeps Research Leaders, Center, Institute, or Lab Directors, and Area Directors informed about the planned research activities of a scientist or group of scientists. National Program Leaders use the prospectus to ensure that the project will be appropriately aligned with the National Program Action Plan. In addition, the prospectus can be used to make sure that all potential collaborative activities among participants in the National Program have been identified and explored. The prospectus is used by OSQR to inform Panel Chairs about the scope of research included in a National Program, and to help Panel Chairs identify the types of expertise that will be needed in the Peer Review Panel.

Section 3.2 Purpose of Project Plans

ARS uses independent, expert peer review of project plans to ensure scientific relevance to its established mission and objectives and to ensure technical merit in terms of scientific methods. Therefore, *the project plan should function as a stand-alone document that should enable the panel to evaluate the merit, feasibility and relevance of the proposed research.* It should frame the research need, objectives, appropriate hypotheses, and expected outcomes for a defined and accomplishable program of research. In addition, and perhaps most importantly, the plan should detail experimental approaches, procedures, contingencies, and collaborations necessary for

accomplishment of the planned research. The clear, concise, and organized communication of the ideas, intentions, and experiments by the research team will demonstrate to the reviewers that the team has the ability to successfully achieve the objectives. Thus, good project plans provide tangible evidence of the quality of science within ARS and the depth of the planning process to conduct the research.

Beyond its role as a tool to evaluate research, a well-conceived project plan is valuable as a tool for strategizing research. As part of the long-term planning process, the roles of the members of the scientific team are clarified and coordinated, and potentially fruitful collaborations are identified and pursued. A critical component of project plans is the identification and development of collaborative efforts with other scientists that can provide an interchange in areas of common interest and a network of colleagues with which to share ideas and concepts. A successful, validated project plan can foster growth in a scientific career, by serving as a road map for high impact research leading to problem solutions and career advancement. Furthermore, a well-developed and executed project plan serves as the foundation for the Annual Report of Progress and performance evaluations.

The project plan is a five-year plan, and serves as a valuable, living document. For that reason, a plan must be adaptable. *A well-developed project's overall goal and objectives ("the mission") generally do not change over five years, but the approaches and experiments (i.e., the strategies and tactics) that are needed to best achieve the objectives may require modification based on the results of the initial research progress and review*. Thus, it is acknowledged that intermediate research results and discoveries may require the reformulation of experimental design and approaches. However, the early thoughtful consideration of the objectives and methods of the research serve to improve the quality of the work.

Characteristics of a good project plan:

Clearly state the problem(s) to solve or question(s) being addressed, will demonstrate that the work proposed is important, and show that new technology or important fundamental knowledge will result.

Demonstrate familiarity with the underlying science at issue, relevant literature and awareness of other work in the field, will show how the studies fit into the bigger picture, will show how the past research accomplishments of the team on this program area serves as a guide for this project, will identify major customers, and make clear connections within ARS and the broader scientific community.

Have related and clearly stated objectives several (but rarely more than 5), and provide a clear conceptual framework for their development, and will present an experimental plan that can be accomplished within 5 years.

Contain a milestone table detailing the milestones, dates, and products of the project. This section enables reviewers to evaluate the significant steps within the project plan. A detailed description of the annual evaluation process to be undertaken to determine and document the progress and potential changes in direction will help the reviewer understand the dynamics of the project team.

Clearly describe what will be done, by whom, and what will result; and will contain clear, concise contingencies to employ if initial approaches do not generate the expected results.

Use illustrations (figures, schemes, etc.) to help explain the plan. In some cases, preliminary data or results may be shown.

Establish the necessary experience and qualifications of the participating scientists, and that required human resources, facilities and equipment are available. Plans and timelines for filling scientific vacancies should be presented.

Document linkages with other scientists (collaborators), and will effectively utilize expertise, databases, etc, that are available in ARS and the larger scientific community.

Be easy to read, well crafted with no typographical errors, and be professional in appearance. (A poorly presented project plan is likely to receive a lower score than otherwise merited).

Section 3.3 Prospectus and Project Plan Formatting Instructions

For the prospectus, create a Word file and name it:
NP# Lead Scientist last name project # P.
Example: 303 Oscar 1234-56789-000-00D P.

For the accompanying Conflicts-of-Interest list(s), create one file to contain the entire team's individual lists, name that file:
NP# Lead Scientist last name project # COI.
Example: 303 Oscar 1234-56789-000-00D COI.

For the project plan, create and name the file:
NP# Lead Scientist last name project # PrePlan.
Example: 303 Oscar 1234-56789-000-00D PrePlan

Both prospectus and plan should be formatted as follows:
8.5x11" letter portrait, single spaced, 1" top, bottom, left and right margins
11-pt Arial or Helvetica font, left justified, no end-of-line hyphens

Header: Lead Scientist last name flushed left, page numbers flushed right, excluding the cover page. Begin page numbering with page 1 for the cover page, but do not show page number on the cover page.
Footer: Version date flushed left, file name flushed right. The version date should reflect the most recent changes. It should be the same or very close to the Research Leader signature date.

For tables (excluding the milestone table), omit all vertical lines; place single horizontal lines under the title, under the column headings, and at the bottom of the table, just above any footnotes. Do not enclose tables with lines or other borders. Avoid creating color graphics, unless necessary to thoroughly describe your plan or demonstrate scientific analyses. If color graphics are included and considered necessary, a note must accompany the plan stating that it must be printed in color. However, do not type on the plan "Please print in color." Do not create attachments.

Submission: Prospectuses are submitted electronically through your Area Office to NPS, who will submit the fully approved version to OSQR. All versions of the project plans should be sent electronically to OSQR as PDF files (preferred) or Word documents. If PDF files are provided, no hard copies are required, except that for the post project plan, a hardcopy of the signature page with the Area Director's original signature must be sent by FedEx or certified mail.

Avoid sending collaboration letters or appendices separately via e-mail. They may be submitted by email if the file size is no more than 10 MB or by postal mail on a Zip Disk or CD if the size exceeds 10 MB.

The prospectus should not exceed 5 pages in length.

The maximum page length for the project plan, for the section from Objectives through Project Management and Evaluation, may vary from 15 to 30 pages depending on the number of SY involved. See the chart below:

SYs on Project	**Maximum Number of Pages**
< 2	15
2 – 3.9	20
4- 6.9	25
≥ 7	30

The plan can have up to two pages of illustrative material (e.g., schemes, figures, flow diagrams) that will not be counted against the page limit. These materials may be used to incorporate figures of data or charts to show the project milestones. These pages are used to provide information to the review team about the project and are effective tools in describing the project plan, preliminary results, or project management.

The first four pages of the project plan do not count against the page limit. Pages of the plan should flow from one section to the next without new page breaks. However, the Cover Page, Signature Page, Table of Contents, Project Summary, Objectives, Literature Cited, Past Accomplishments of Each Investigator, Health, Safety, and Other Issues of Concern Statement, and Appendices should all start on new pages.

The Cover Page must contain the following information:

National Program - The title of the National Program(s) under which the research is conducted

Dates - State the period in which the research project will be peer reviewed. This is provided on the PDRAM.

Old Project Number - The ARS research project number for the expiring project. If projects are being combined, list those that are being combined. If a project is being split, note that the old Research Project is being split during this process.

Research Management Unit - The name of the research management unit.

Location - City and State.

Title - A brief, clear, specific description of the project, understandable to a scientific reader. It should contain no more than 140 total characters. It is preferred that the new project be titled differently from the old project.
Investigator(s) - List all scientists assigned to conduct the research being planned and their percent commitment as decimals to the project. This will include all ARS Category 1 or 4 scientists assigned to the project and possibly non-ARS scientists. Any non-ARS scientist must function in a role equivalent to an ARS Category 1 or 4 scientists. Identify the lead scientist. All scientists not employed by ARS need to be identified as 'non-ARS' scientists. The investigator list should reflect what is proposed for the new project, and need not match the SY listing of the current project in ARIS. Everyone on the list must prepare a Conflicts of Interest list and an accomplishments section in the project plan.
Scientific Staff Years - List total SY commitment of ARS scientific personnel as a decimal, i.e., 2.75.
Planned Duration - List in terms of total months, i.e., 60 months.
Signatures – **For the prospectus and pre-project plan,** submit electronic signatures using /s/ as the standard**.** Original signatures are not required.

Section 3.4 Prospectus Components and Instructions

Cover Page (including signature lines) – See Section 3.3.

Key Words - Provide a list of 6-10 keywords that help identify the project.

Objectives - A clear statement of the specific objectives of the project that are attainable within the time period (not to exceed 5 years) and resources committed to the project. The statement should be complete enough to be used as the basis for scientific understanding of the plan.

Background and Need for Research - List each of the following with a brief description:
-Description of the problem to be solved.
-Relevance to ARS National Program Action Plan.
-Potential benefits expected from attaining objectives.
-Anticipated products of the research.
-Customers of the research and their involvement.

Scientific Background- describe how your project is coordinated with other ARS projects to form a larger effort that addresses relevant aspects of the NP. List projects of a similar nature, even if you are not directly collaborating with them, and describe how you are coordinating your efforts.

Approach and Research Procedures – Within this section for each objective, briefly describe: hypothesis, experimental design, contingencies, and collaborations as separate sections. These sections should provide sufficient detail for NPLs to evaluate the potential contribution of the project to the NP and for the panel chair and OSQR to identify the expertise required for panel members. There may be objectives in which hypotheses are not appropriate and it is acceptable to formulate a non-hypothesis-driven statement. (See Glossary for the details on Hypothesis-driven research and Non-hypothesis-driven research.) Experimental approaches and specific

research procedures should be described in sufficient detail to determine the appropriateness of the methods. Describe approaches and experimental options that will be considered if the initial approach is unsuccessful in the contingency section.

Collaborations – Identify collaborations with scientists outside of this project (ARS and external to ARS) that are necessary to attain the project objectives.

In addition to the prospectus, a conflicts of interest (COI) list for each Category 1 and 4 scientists on the project must be provided as a separate document. Within the document, create a two-column table for each scientist or investigator and begin a new page for each additional scientist or investigator. The first column of the table should contain the individuals' full names (initials are not acceptable) and the second column should describe the nature of the relationship. Conflict of interest relationships include, but are not limited to, the following: (for the last four years) Co-author, Co-researcher, Supervisor or Subordinate. Also any student or post-doctoral relationships within the last eight years must be listed. Other possible conflicts of interest, such as individuals who have a financial stake in the research, should be discussed with OSQR.

An example prospectus and an example COI list can be found on the OSQR website at http://www.ars.usda.gov/osqr.

If there are questions about completing the prospectus, or the Conflicts of Interest List, please contact the Office of Scientific Quality Review at OSQR@ars.usda.gov or call 301-504-3282.

Section 3.5 Project Plan Components and Instructions

Cover Page (page 1) – See Section 3.3 (Appendix 2: Cover page)

Signatures (page 2) - Insert the Signature Page (Section 2.2-2.3). Separate signature pages are required for the Pre-, Post-, and Re-Review of the project plan. (Appendix 3: Signature Pages)

Table of Contents (page 3) - Insert a table of contents. (Appendix 4: Table of Contents).

Project Summary (page 4) - The objectives and research approaches of the project plan should be summarized in 250 words or less. This section should be written to be understood by a general audience.

Objectives - A clear statement of the specific objectives of the project attainable within the project time period (not to exceed 5 years) and with commitment of the human and physical resources that are discussed later in the Approach and Research Procedures section. *The statement should be sufficient to form the basis for scientific understanding of the proposed research.* A statement of the overall goal of the project into which the objectives contribute provides a framework for the objectives within the project.

Need for Research - A statement that summarizes the nature of the problem or opportunity being addressed, its relevance to the appropriate ARS National Program action plan, the anticipated research products, the potential benefits expected from attaining the objective, and the impact of the research on customers and stakeholder needs. In general, *this section is*

relatively short and is one to two pages in length.

Scientific Background – This section should focus on presenting and discussing relevant literature and technology relating to the stated objectives and scientific feasibility of the project plan and provide the rationale for the project objectives. *It should cite only key relevant literature in the field, not be a comprehensive bibliography, should be no more than one third of the project plan* to allow ample space for description of the Approach and Procedures. The literature cited should be sufficient to demonstrate scientific knowledge and understanding of the problem, and activity and degree of advancement in the problem area. Results of your relevant past accomplishments and preliminary new results in the area of proposed research should also be presented and discussed in this section. In fact, presentation of some preliminary results adds greatly to supporting the credibility of the plan. Most peer reviewers will perceive preliminary data as evidence the proposed research is achievable. Avoid repeating information already provided in the "Need for Research" Section, however. This section should include the results of a CSREES-CRIS search ("Current Research Information System") to show how your project is coordinated or associated with other ongoing research projects. Cite the project number, title, location and describe in a few sentences its relationship to your project. Include only the truly relevant and significant projects in this discussion, perhaps five at most. If you are aware of other, non-ARS research projects that are relevant to your project it is helpful to refer to them in this section. Cite the lead investigator(s), institution, and briefly describe the relationship to the research outlined in your project plan. Some of these projects might be mentioned again under "collaborations" in the "Approaches and Procedures" section. It is important to demonstrate that the investigators are aware of and are forthright about acknowledging other groups performing similar research, both within and outside ARS.

Lastly, if instructed by the National Program Leader and Area Director, describe Congressional mandates, if applicable, related to the project. Also, document patent searches if the project deals with product or technology development.

Approach and Research Procedures – For each objective, use three subsections under this heading to elaborate on the following:

Experimental Design - Describe in appropriate detail the scientific and experimental approach that is to be used and the research procedures that will be followed to attain objectives. This section should explicitly state, if applicable, what hypotheses will be tested and how experimental results will be evaluated. (See Hypothesis-driven research and Non-hypothesis-driven research.) *Detail should be sufficient to inform the reviewer of the nature and appropriateness of the planned experiments and the competence of the project team to complete the experiments*. Briefly state the responsibilities of each scientist and Research Associate.

Contingencies - Discuss specific approaches and experimental options that will be undertaken if the initial research plan is unsuccessful in evaluating hypotheses or attaining objectives.

Collaborations - Describe collaborations with scientists outside of this project (ARS and external to ARS) necessary for attaining the objectives and a successful project outcome. Collaborations within the National Program that are directed toward addressing specific national

program goals should be identified in this section and linked to components in the National Program Action Plan. Collaborations should be documented in a letter from the scientist *that specifically details the collaboration*. The letter must discuss what the collaborator will do and what level of commitment is anticipated. Cooperative projects underway through Specific Cooperative Agreements (SCAs) should be described in the collaboration section of project plans and detailed in the accompanying collaboration letter. Information should include specific technologies and resources to be brought to the project. Thoughtfully consider the comments, criticisms, and suggestions received and incorporate as many of them as possible into the finished project plan.

Physical and Human Resources - Describe availability of major physical resources (i.e., facilities, major instrumentation and equipment, etc.) that are necessary to accomplish the research. Estimate the number (FTE) of non-Cat. 1 (or 4) project personnel (postdocs, technicians, students, etc.) who will be available for this project.

Vacancies in the SY team for the project should be addressed in this section with a discussion of the expertise and discipline being filled and the expected contribution of this person to specific objectives within the project plan.

Project Management and Evaluation – Projects composed of a number of investigators should describe the overall project management and evaluation process. *The purpose of this section is to provide the panel with an overview of project management in terms of evaluating progress toward the objectives, changes in approaches, and documentation of these changes.* This section would provide a basis for demonstrating to the panel how the project team functions and makes decisions about changes. The summary of this information during the lifecycle of the project would be linked to the Annual Report of Progress (AD-421). This section should be no longer than ½ page.

Milestones and Expected Outcomes - Describe a series of milestones (points in the project where significant planned accomplishments can be documented) for the life of the project. *These milestones are identified for each objective and hypothesis of the project along with the scientists responsible for each milestone.* Milestones will be linked to the Annual Report of Progress (AD-421) to document the progress each year and the changes in milestones for the next year. This table can be exported from the project plan and maintained by the Lead Scientist for the project. Describe how progress will be documented through products (e.g., scientific papers, databases, germplasm releases, technology transfer, CRADAs). This table ***will not*** count against the page limit for the text or the two additional pages allotted for graphics and table. (Appendix 5: Milestones Table)

Examples:
<u>Hypothesis Statement</u>
Genetic background in elm influences the severity of leaf scorch symptoms.

Intensity of tillage does not affect soil organic matter distribution and carbon flux from the soil surface.

Diet composition in swine does not affect the composition of manure or the pathogen content in manure.

Milestone
Evaluation of GC/MS method to quantify levels of volatile organic compounds in air samples.

Assessment of the validity of a rapid screening process for detection of nematodes in soil samples.

Evaluation of the performance of SWAT model to estimate water quality in corn-soybean watersheds.

Product
Research paper on variation in nitrogen mineralization rates across a combination of soils and manures.

Database that includes meteorological, plant growth, and soil carbon data from multiple crop rotations, soils, and climates

Germplasm release

Technology transfer agreement with a commercial company to market a widget developed from ARS research.

Accomplishments from Prior Project Period - This section summarizes the research accomplishments and impact from ARS Research Projects relevant to this project plan that is current or terminated within the last two years. *The purpose of this section is to provide the reviewers with a description of the accomplishments and impact from the previous efforts that are related to the project plan being reviewed.* The following information must be provided and should not exceed 2 pages. These pages are not included in the project plan page limit.

1. Terminating project number
2. Title
3. Project period (beginning and ending dates)
4. Investigators and FTE (current investigators on AD-416)
5. Project accomplishments and impact
   For each objective in the current or terminated project plan provide the following:
   a. Summary of the most significant accomplishments and their related impact. Cite most significant publications resulting from this research. Mark all publications derived from this research project with asterisk in the Past Accomplishment section for each investigator.
   b. If necessary, provide a synopsis of changes in the objectives and the reasons for the changes.
   c. Describe how the objectives and accomplishments relate to the proposed project plan objectives.

The plan can have up to two pages of illustrative material (e.g., schemes, figures, flow diagrams)

that will not be counted against their page limit.

Literature Cited - Begin this section on a new page. Literature can be listed alphabetically by author or in order of citation in the text. If papers are cited by author(s) and year, they must be listed alphabetically in the Literature Cited section. However, any citation format accepted by a scientific journal that includes all authors, article title, and complete page numbers may be used. Only published or in press papers are listed in this section. Theses and dissertations, state and federal documents intended for professional distribution, electronic databases, and peer-reviewed proceedings of meetings generally are acceptable citations. Meeting abstracts, unpublished materials, and non-peer-reviewed materials may be included in the text, but are not acceptable as citable materials.

Past Accomplishments of Investigator(s) - Begin each investigator's past accomplishments on a new page. In one single-spaced page or less per scientist, provide education and work experience, and describe accomplishments of the investigator(s) of this project over the past 10 years that are significant and pertinent to the proposed research.

Follow each investigator's past accomplishments with a list of not more than 20 of the peer-reviewed publications authored by the investigator. Any citation format accepted by a scientific journal that includes all authors, complete article title, and complete page numbers may be used.

Health, Safety, and Other Issues of Concern Statement - Address the safety concerns for each of the following ten issues. First, state whether the issue is relevant. If yes, identify necessary reviews and/or permits, and give status and ID number either actual or requested.

- Animal Care
- Endangered Species
- National Environmental Policy Act: Research teams should consult their Area Environmental Specialist to make a determination on the potential environmental impact of their research. ARS research projects are typically considered Categorically Excluded under the National Environmental Policy Act's regulations. Project plans would then include the following statement: "On the basis that this federal project is being conducted for the sole purpose of conducting research, this project is categorically excluded in accordance with regulations for the National Environmental Policy Act."
- Human Study Procedure: Research teams under the Human Nutrition National Program should document how they have complied with the legal requirements for using human subjects here.
- Laboratory Hazards
- Occupational Safety & Health
- Recombinant DNA Procedures: The IBC license number must be included in the project plan if there is work with recombinant DNA.
- Homeland Security (http://www.arsnet.usda.gov/ohs/, http://www.arsnet.usda.gov/OHS/biosafety/materials_toxins.htm#I, http://www.arsnet.usda.gov/OHS/biosafety/SelectAgents.doc)
- Intellectual Property Issues (see details in Appendix 7))

- Existing SCAs: Describe an existing SCA in the collaboration section of the specific project objective and in the letter from the cooperator.

Appendices - On a new page, list appendices by page number (if in the main file), or by filename (if additional files are submitted electronically). Letters of collaboration are to be included in the appendix. Scan or paste the collaborators letters into the project plan appendices after the List of Appendices page. If this is not possible, electronically submit additional files as attachments.

Section 3.6 Project Plan Revision and Responses to the Peer Review Panel

Following the panel peer review of each project plan, OSQR sends to the Area Director the review results letter and two documents. One is the panel's written recommendations (with expanding text boxes inserted for the scientist's response). The other is the "Action Class" Rating Worksheet (found in Appendix 8: Action Class Worksheet) that lists each reviewer's score of the project plan (numerical rating from 0 to 8). On this sheet the numerical ratings are averaged and a final action class rating is assigned to the plan by the SQR Officer based on this averaged score.

Action Class Ratings and the Responses Required.

No revision required. No revision is required, but minor changes to the project plan may be made based on comments, if any, made by the panel.

Minor revision required. The project plan is basically feasible as written but requires some revision to increase quality to a higher level.

Moderate revision required. The project plan is basically feasible but requires significant editorial revision or moderate changes or clarifications to the approach and procedures for one or more of the objectives in order to increase quality to a higher level.

Major revision required. Substantial revision to the writing or significant change or clarification in the approach and procedures for one or more objectives is necessary to assess the feasibility of the project plan, but it should be sound and feasible after this significant revision.

Not feasible. The project plan has major flaws or deficiencies, or is so poorly constructed as to render an accurate assessment not possible, and cannot simply be revised to produce a sound project plan. If the project is not terminated (see below), a complete redesign and rewrite are required.

The Area Director forwards the worksheet and peer review recommendations to the Center/Lab Director (if applicable), Research Leader, and Lead Scientist responsible for the project plan, along with an explanatory letter from the SQR Officer. Scientists are required to review this material and carefully consider the guidance provided in the panel recommendations. Lead Scientists and their project team revise the plan to improve its scientific quality and prepare responses to each peer review recommendation as denoted by an "ARS Response" expanding text box. Revisions are highlighted in **bold** text in the plan. There are no page limits for the

revisions, but lengthy additions should be avoided. Revised text should be focused on the comments/recommendations and of appropriate length to address the panel comments. For each recommendation, responses are inserted in the box provided on the peer review form. (Appendix 9: Sample Peer Review Recommendations and ARS Responses) Each response must clearly indicate which components of the recommendation(s) were adopted, should indicate if alternative changes were made, and if applicable, a sound rationale for not accepting a recommendation.

A peer review panel may make any number of recommendations, as there are no specific guidelines for how or what should be written. For instance, if elements of the project plan are deemed incomplete, a panel may ask for more focus in the objectives, more details in the experimental plan, or stronger justification/rationale for a proposed approach. If a panel identifies alternative ways to conduct the science, they may suggest different experimental approaches or may propose that additional collaborators are brought into the project team. In all cases, scientists need to respond fully to the recommendations, and should not avoid, ignore, or circumvent the issue that has been raised. *Though the response may include related scientific points germane to the recommendation, scientists must respond directly to the specific problem identified by the reviewers.*

In some cases, scientists might disagree with a panel recommendation. This is acceptable. While all recommendations must be carefully considered, there is no requirement for all recommendations to be incorporated into the revised project plan. *If a panel suggestion will not be incorporated, scientists must provide a clear, justifiable reason why they believe the revision is not necessary and/or appropriate.* The response should be presented in a polite manner, and convey a respectful difference of opinion. While there are no limitations on the number of recommendations a project team might disagree with, it is anticipated that most peer review recommendations will be justified, and thus scientists should make every effort to add these new ideas to their project plan.

Once the project plan has been revised, and the responses written, Lead Scientists solicit comments and obtain approval of the revised project plan from their Center, Institute, or Lab Director. The revised project plan, and the ARS response form are then forwarded to the Area Director for approval.

The Area Director reviews and approves each revised project plan and forwards the fully approved revised project plan (with Area Director's original signature) and ARS response form to OSQR for processing and distribution to panelists with a copy to the National Program Staff.

If the final action class rating is Not Feasible, then the Area Director of that project is responsible for convening a team of representatives from the Area, Center, Institute, or Lab Director (if applicable), and National Program Staff to determine the best course of action to respond to the peer review. Available outcomes include:

a. *Re-review.* The project is revised and approved (by the Agency) over a 10-week period, using the same steps involved in preparing a project plan prior to a peer review. OSQR sends

the revised project to at least two of the original peer reviewers. The project is peer reviewed within a four-week period.

b. *Termination.* Requests for termination of the project are submitted from the Area Office to the Associate Administrator for Research Operations. These requests should detail why a termination is proposed and the process for developing a new plan to address the objectives. If the termination is approved, objectives that are reassigned from the terminated project to other ARS projects, are peer reviewed according to the receiving project's status in the peer review cycle.

CHAPTER FOUR: COMPONENTS OF THE PEER REVIEW PROCESS

Section 4.1 Requirements for Panel Chairs and Panelists

Peer reviewers sought are individual scientific, technical or industrial experts possessing relevant and extensive knowledge and experience in the field of science pertaining to the projects under review. The expertise of these reviewers allows them to critically evaluate specific scientific research project plans for scientific and technical quality, and, if applicable, technology transfer. Panel chairs and panelists primarily are non-ARS scientists who are independent of the research being planned or performed and who are qualified to serve as an expert reviewer for a particular field of science or technical specialty. Generally, to be considered an expert in a field of science, a peer reviewer must be accomplished in his/her field and be nationally and/or internationally recognized as an authority in the field. On occasion, an ARS scientist may serve on a panel. However, it is generally difficult to find an ARS scientist to serve who does not have a conflict of interest with other ARS scientists whose projects are under review.

Affiliation

While many peer reviewers have past experience with ARS, rarely are ARS scientists appointed as panelists and none are permitted to become panel chair. By law, ARS peer review panels must have a majority of non-ARS members; in practice, ARS scientists may be considered for panel service. Peer reviewers may be members of an academic, industry or government institution, or may be members of other ARS customer or stakeholder groups, provided they meet the above criteria.

Section 4.2 How the Peer Panel is Selected

After finalizing the lists of projects to be reviewed, OSQR begins panel chair selections and the scheduling of individual panel meetings at their headquarters in Beltsville, MD. In National Programs with a large number of projects to be reviewed or in which there is a discreet difference in scientific approaches among projects, the NP team will suggest groups of projects to be reviewed by separate peer panels. This is done so that a reasonable limit (no more than 20) is placed on the number of projects to be reviewed by any particular panel. These groupings ensure projects are consolidated into common scientific fields respective to the particular expertise of a peer review panel.

Nominations for panel chairs are gathered from a wide array of sources, including ARS scientists or administrators, the NP Team, Deputy Administrators, and Area Directors. The SQR Officer may choose to select someone who is not nominated or give preference to a particular candidate after reviewing their credentials or in order to promote diversity among those selected as panel chairs. Once a panel chair is selected, they receive an orientation on the peer review process. During this orientation they are provided the prospectuses of the project plans which will be reviewed. They are also provided names of potential panel members. The chair may or may not use these individuals.

It is the responsibility of the panel chair to select panel members. However, all potential panelists must be approved by OSQR. These approvals are based upon absence of conflicts of

interest and upon an effort to maintain geographic, institutional, ethnic, and gender diversity on the panel. Moreover, most of the panel must be composed of non-ARS scientists, according to Congressional mandate. In addition to panel members, the panel chair may also select individual *ad hoc* reviewers. Such *ad hoc* reviewers will not participate directly in the panel review, but may be used under circumstances where a particular project has a unique component not common to the scientific field of the project or other projects being reviewed. These *ad hoc* reviewers must also be approved by OSQR.

Section 4.3 Responsibilities and Administration

Panel Chair Responsibilities

Panel chairs must be recognized leaders in their field of science. The ARS SQR Officer selects panel chairs based on inputs that include nominations from National Program Leaders, Area Offices, ARS scientists, or independent investigations made by the SQR Officer. After a thorough review of the nominee's background, conflicts of interest, and significant accomplishments, he or she may be retained as a panel chair through a contractual process. Panel chairs are publicly known. Typically, panel chairs work as academic deans, division chiefs, research leaders, and are often leaders within scientific societies. Panel chairs are screened for their experience in managing committees, peer review panels, and other leadership experiences that demonstrate their ability to:

- Facilitate discussions among multidisciplinary experts
- Attract other highly successful experts to serve on their panel
- Manage a review of the array of research topics assigned to their panel
- Maintain good standing in their field.

Within a month of the orientation, panel chairs are to submit their candidate lists to the SQR Officer for approval. SQR Officers provide feedback and approvals based on:

1. *Qualifications and Research Activity*: Panelists are expected to be active in their field. Recent publications, product development, scientific awards, and leadership at major symposia are typical accomplishments of selected panelists. The SQR Officer also confirms that the expertise identified by the panel chair is appropriate for the projects assigned to the panel.
2. *Conflicts of Interest*: For any single project, no more than one panel member can have a conflict of interest with a common project plan. No panel member can have a disproportionate number of conflicts as related to the number of projects assigned to the panel (generally no more than two for large panels with greater than 15 project plans).
3. *Geographic Diversity*: Reviewers may be recruited from wherever appropriate to obtain the necessary expertise, including from outside the United States. Panel chairs are encouraged, however, to consider geographic diversity in recommending potential reviewers from the United States. Exceptions may be made for experts whose research is commonly conducted in a particular geographic region or for experts employed by large academic institutions. (e.g., the University of California, having eight independent campuses.)
4. *Affiliation*: Panels are preferably composed of a combination of academic, government, and industry employees. Other groups include representatives of nonprofit research

organizations and consultants. A panel chair may be asked to make an effort to recruit experts from industry.

5. *Gender, Race, and Ethnicity*: Panel chairs are instructed to strive for inclusion of experts of diverse races, ethnicities, and gender in creation of their candidate lists.

Panel chairs assign primary and secondary reviewers to each project and determine if *ad hoc* reviews are needed to supplement the expertise of the panel. Panel chairs are responsible for setting the agenda of the peer panel, ensuring review quality, enforcing the peer review procedures, moderating panel discussions, and validating their panel's final recommendations. Finally, after review, panel chairs provide statements on the impact they believe their panel on ARS research, including any recommendations not specific to individual project plans, and any comments on the OSQR review process.

Panelist Responsibilities

Panelists lend their expertise and experience to ARS in assessing the scientific and technical quality of research project plans. Panelists, unencumbered by internal or organizational viewpoints and associations with the research itself, are in a unique position to provide constructive feedback to ARS scientists' approaches, methods, procedures, and use of material resources. This type of feedback serves to improve the quality of ARS research by suggesting better approaches and alternatives, or by stimulating creativity by providing new ideas about the science or methods employed. In this capacity, panelists serve as individual advisors to ARS. While their recommendations are not binding upon the Agency, their insights and suggestions are carefully considered to ensure the quality and credibility of the ARS' overall scientific program.

Each reviewer is instructed to clearly identify his/her recommendations, and provide a rationale for each recommendation. The intent of these peer reviews is to improve project plans. Thus, it is reasonable to expect the majority of the peer reviews to contain more recommendations than general comments and compliments, as one might see in the review of a competitive grant. ARS must reasonably consider accepting all peer review recommendations. Recommendations that are not accepted require a justification. (See Appendix 8: Sample Peer Review Recommendations and ARS Response.)

Panel or *ad hoc* peer review recommendations will not result in a redirection of Agency funds from or to an ARS research activity. However, allocated discretionary funding for a specific research project plan may be suspended until the research project plan has been determined by Area Directors and/or the Deputy Administrator of the National Program Staff to meet quality requirements.

Panelists sign and honor a Confidentiality Agreement (Appendix 9) to protect potentially sensitive information included in ARS research project plans. Panelists are anonymous to the researchers responsible for each project plan and are expected to retain their anonymity as a peer reviewer in their discussions with anyone outside the OSQR. The identity of the Panel Chair, however, is made public.

Honoraria for Peer Reviewers
All individuals who serve as a panel peer reviewer for ARS are reimbursed for their travel and lodging expenses according to government travel regulations and procedures. Chairs of panels, who are not employees of the Federal Government, are given an honorarium in recognition of their service. Panel reviewers, who are not employees of the Federal Government, also receive an honorarium.

Conflicts of Interest Guidelines
Conflicts of interest are initially based on a report from members of ARS research teams. Panel members are also given an opportunity to raise attention to a real or perceived conflict of interest with ARS or a particular project plan. Panel chairs and peer reviewers hold a real or potential conflict of interest if he/she possesses an institutional affiliation with the research project laboratory, investigators, or collaborators or have financial stake in the outcome of the research. Furthermore, a conflict of interest exists if the expert has had any of the following relationships with the Lead Scientist or other member of the research team in the past four years:

- Collaboration on research projects
- Co-PI on research grant(s)
- Co-authorship

In addition, a conflict of interest exists if the peer panelist or panel chair has been involved in a graduate student or postdoctoral associate relationship (either being or advising) with a member of the research team in the past eight years.

Peer reviewers with a conflict of interest with regard to a particular plan will excuse themselves from all considerations of that plan. Panel chairs and panel members are not precluded from subsequently entering into agreements or collaboration with any ARS research unit or scientist, but are asked to maintain confidentiality about their role in the peer review process.

Confidentiality of Information
ARS research project plans may include information about the underlying research and existing or anticipated research results that are considered by ARS to be proprietary or confidential. *Reviewers may not copy, quote, discuss, or otherwise use material from the proposal outside the panel review process.* Reviewers must leave all project plans and review materials in the possession of ARS at the conclusion of a panel meeting. They are also required to erase any reviewing materials from their computers, disks, or other electronic storage media. (Appendix 7: Confidentiality Agreement.)

Orientation for Panel Members to the Review Process
Each panelist receives a number of orientations explaining the OSQR peer review process. All OSQR orientations point out to reviewers the similarities the OSQR review has to other types of research project reviews (mainly competitive grants types of reviews). However, these orientations emphasize the nuances of the OSQR review that differ from reviewing competitive grants. The first orientation is a brief description of the process by telephone as each potential panelist, after approval by OSQR, is contacted by the panel chair. A second orientation (Appendix 11: Guidelines for Reviewers) is provided when each panelist is sent their respective peer review packages, mainly containing the project plans to be reviewed and their assignments

as primary or secondary reviewer (all panelists are to read all the projects in their panel unless they have a conflict of interest) and the respective NP's Action Plan. This orientation includes a presentation by the NP Team to introduce the reviewers to the NP Action Plan and the scope of projects being reviewed within a specific panel relative to the NP goals. A third orientation is presented by the SQR Officer in Beltsville prior to the panel convening to review the first project.

Section 4.4 Panel Operations

Operations of a panel meeting consist of four primary components. An overview of the National Program in which the projects being reviewed are assigned is conducted at the onset of the panel meeting. Panel deliberations occur with the primary and secondary reviewers presenting their assessment followed by input from other panel members. Preparation of the panel reports for each project are completed during the panel meeting and signed by the panel chair. The final step in the panel meeting is a debriefing of the panel with the Administrator Staff, appropriate NPLs, and OSQR staff. *Deliberations within the panel meeting are confidential and all materials are left in the panel meeting room for their proper disposal.*

Section 4.5 Peer Review Criteria, Action Classes, and Action Class Matrix

Action Class Matrix

The action class matrix (see Appendix 11: Guidelines for Reviewers) is provided to give reviewers some guidelines for assigning appropriate action classes to project plans. Many projects plans will fit different action classes for different review criteria. In these cases, the reviewer must decide whether strengths or weaknesses in a particular criterion override those of other criteria. For example, a project plan could be rated "not feasible" because of a lack of appropriate personnel and/or facilities, but still be excellent in every other way.

Section 4.6 Release of Reviews

Once the panel chair has validated the panel's recommendations and the SQR Officer has determined that the panel's recommendations are clear and require a response, the SQR Officer writes a memo to the Area Director that discusses the action classification received and a time frame for any required follow-up activities.

Section 4.7 Panel Receipt of the Responses

Panel chairs, primary reviewers, and secondary reviewers receive a copy of the research team's response to each of their recommendations and the final revised project plan. Unless the project plan requires a second review, no further communication occurs between the panel and ARS on the project plan.

Section 4.8 Re-reviews

A re-review is a second peer review of the project plan performed by members of the original panel. Re-reviews are the most commonly chosen corrective action when panels believe a project plan requires major revision or is not feasible. Re-reviews are prompt: the research team is normally allowed only 2 ½ months to revise the plan. Although the goal is to have a re-review result in "No Revision Needed," an Action Class rating of "Moderate Revision" or above is accepted by OSQR as the project having completed the peer review process.

Section 4.9 Panel Reports, Distribution of Scores

Each panel chair is asked to write a statement of the impact their panel has made on the ARS research they reviewed and to generally comment on his/her observations of the ARS Peer Review Process. These "Panel Chair Statements" may include commentary about the panel itself, typical strengths and weaknesses of the research, and suggestions for the Peer Review Process. Panel Chair Statements are compiled into a report from the OSQR, along with background information about the panel, and the distribution of scores for their panel and other panels who reviewed projects in the same National Program. Panel Chair Statements and panel reports are publicly available and open to any ARS employee.

Section 4.10 *Ad Hoc* Reviews

Ad hoc reviews are also solicited outside of a regularly scheduled panel for the evaluation of project plans that are new, have been postponed, or were significantly modified. *Ad hoc* reviewers are subject to the same confidentiality and conflict of interest policies as panel reviewers. As in the panel review process, Lead Scientists are required to formally submit their responses to *ad hoc* reviews to their Area Director. The major differences between an *ad hoc* peer review and a panel review are:

- *Ad hoc* review is not conducted outside a National Program's scheduled review.
- The SQR Officer selects *ad hoc* reviewers from a pool of qualified experts.
- *Ad hoc* reviewers are not generally paid an honorarium to perform the review.
- *Ad hoc* reviewers typically only see a smaller portion of the research for a National Program than that reviewed by peer panelists.

Each project plan reviewed through the *ad hoc* process is receives at least two independent *ad hoc* reviews. *Ad hoc* reviewers perform in-depth reviews on their assigned project plans and provide peer review comments and an Action Class assignment to the OSQR. The SQR Officer assembles the recommendations for each project plan, based on the input from individual reviews. *Ad hoc* review recommendations are compiled by the OSQR and distributed to the appropriate Area Director. Response to the reviews and any administrative action required follows a process similar to a regularly scheduled panel review.

CHAPTER FIVE: ROLES AND RESPONSIBILITIES

Section 5.1 Administrator's Office

The ARS Administrator's office provides executive-level oversight of the ARS Peer Review Process, communicating Agency policy and procedures for peer review to internal and external parties. It stays abreast of program performance and issues, and makes adjustments to the Peer Review Process as necessary. Furthermore, it provides annual updates on the Peer Review Process to the National Agricultural Research, Extension, Education, Economics Advisory Board, and Congressional committees, and represents ARS in matters related to the Peer Review Process. The selection of the Scientific Quality Review Officer is done by the Administrator's office.

The Administrator's Council of senior leaders in ARS also advises the Administrator of emerging issues and policy needs associated with or affected by the Peer Review Process.

Section 5.2 The Office of Scientific Quality Review

The policies for the ARS Peer Review Process are, in part, based on advice from the National Agricultural Research, Extension, Education and Economics Advisory Board to OSQR. As representatives of ARS scientists and National Program teams, the ARS Focus Group on Peer Review advises the Administrator's Office and OSQR personnel to promote the effectiveness and enhance the quality of the ARS Peer Review process.

The OSQR has responsibility for planning and facilitating the scientific and technical peer review of all Agency prospective research project plans. Overall, it manages the Peer Review Process, including policies, processes, and procedures. The OSQR centrally plans and conducts consolidated panel peer review sessions for projects within each National Program and coordinates *ad hoc* reviews of individual plans as necessary. It reports to the ARS Associate Administrator. As an office within ARS, it is provided some autonomy to establish processes and goals for the peer review (It is important that the peer review of ARS project plans, as managed by OSQR, does not involve conflicts of interest with the National Program Staff of ARS administrators. *The chief goal of OSQR is to create an environment in which ARS project plans receive objective and rigorous external peer review.* The OSQR team consists of the Scientific Quality Review Officer, Peer Review Program Coordinator, a Program Analyst, and a Program Assistant, and clerical support as needed.

Scientific Quality Review Officer (SQR Officer)

The SQR Officer is a collateral duty position and provides professional scientific oversight of the Peer Review Process and panel operations. He/she enforces Agency policy and requirements regarding the Peer Review Process. In addition, the SQR Officer evaluates panel results and trends, and reports these to the Administrator's Council on a periodic basis, together with any recommendations which are appropriate to improve and strengthen the peer review process. The SQR Officer also transfers peer review recommendations from peer reviewers to Area Directors, and transmits ARS responses to panel recommendations to peer reviewers.

Peer Review Program Coordinator
The Peer Review Program Coordinator is a permanent member of the OSQR staff and manages the day-to-day operations of the Peer Review Process. He/she is responsible for communicating and enforcing Agency policy and requirements regarding peer review. Management duties of the position include: 1) developing review schedules and providing initial peer review direction to National Program Leaders, Area Offices, and researchers; 2) making logistical arrangements for panel peer reviews and coordinating the flow of information and materials to and from reviewers; 3) creating and maintaining official Agency records concerning peer review throughout the life of the peer-reviewed project (plus an additional two years). In addition, the Peer Review Program Coordinator oversees and supervises the permanent support staff of the OSQR office who perform administrative duties associated with the Peer Review Process, including processing reimbursements for reviewer expenses and external reviewer honoraria.

Section 5.3 Area Director's Office

The Area Director (AD), Associate AD and/or Assistant AD work with the Research Leader (RL) and Center, Institute, or Lab Director in the process of preparing prospectuses and project plans in a manner consistent with performance standards. The Area Director's office also works closely with NPS to ensure and verify that during prospectus development the objectives and approaches are consistent with NP goals. They also work with local line managers to provide direction and instruction to ARS researchers in meeting scientific quality requirements and in addressing the recommendations and suggestions of peer reviewers. Area offices provide input into the peer review process-related policies and procedures and monitor the progress of developing research project plans for various National Programs. The Area Program Analyst tracks and monitors deadlines for all aspects of the OSQR process to ensure timeliness. Review and approval of prospectuses, project plans and responses to peer panel reviews is done in accordance with matrix management guidelines for submission to National Program Staff and the OSQR. Lastly, the AD provides feedback to RLs on their unit's peer review panel scores and ensures that their performance in peer review is reflected in their performance element pertaining to responsibility for OSQR peer reviews.

Area Director's Offices also:

- Identify, create and/or approve members of research teams in collaboration with NPS and RLs
- Train RLs and lead scientists in the OSQR process
- Decides on a corrective action for project plans rated in the major revision or not feasible categories
- Provide final approval of project plans, formatting, and personnel assignments to ARS research projects
- Manage lines of peer review-related communication involving Area institutes, laboratories, and projects
- Provide input on the suggestions for reviewers/chairs, assignment of projects to panels, and scheduling
- Provide comment on the presentation of project plans; checks for a logical flow/organization of the objectives, experimental plan, and evidence supporting the proposed research

- Provide on-going suggestions to OSQR on the peer review process
- Collaborate with NPS in making recommendations, for approval by the Associate Administrator to postpone project review or to add or delete projects from the group of projects being peer reviewed *(Approval for postponement of review is an exception and is granted because of significant limiting factors, such as absence of the key/lead scientist for the project, the unexpected loss/unavailability of essential facilities, or major redirection of the research.)*
- Manage the Area-leval retrospective review of research and provide input to the National Program on the overall programmatic review
- Provide direction on the establishment of replacement ARS research projects after the review process

Section 5.4 National Program Leader/Deputy Administrator

National Program staff, including National Program Leaders and Deputy Administrators, provides programmatic direction to lead scientists through the Area Director. National Program Teams, guided by a designated leader, develop PDRAMs in consultation with the Area Office, Research Leader, and Lead Scientist, outlining the project objectives. NPLs review research prospectuses to verify adherence to the NP Action Plan and programmatic direction and provide input to OSQR in determining scientific discipline requirements for panels. NPLs provide materials and information about a NP to OSQR for reviewer use. They provide an overview of the NP concerning the Program's design, influence of workshops, assignments of and relationships between projects.

National Program Teams also:

- Develop the list of projects to be peer reviewed
- Distribute directions and schedule to initiate peer review sessions
- Facilitate coordination among research teams as appropriate
- Work with Area Directors and Research Leaders in leading research and program direction of each project
- Evaluate the methodology across projects
- Minimize duplication and overlap among projects

Section 5.5 Research Leader, Lead Scientists, and Research Team

The Lead Scientist (LS) works with the Research Leader (RL) in developing a consensus with NPS on each project's direction and scope by documenting the project's relevance to the National Program Action Plan and scientific approach to addressing objectives. LS/RL create the prospectus and research project plan according to programmatic direction developed by NPS, in dialogue with the LS, RL, and Area Director, in accordance with Agency priorities, and Area specific requirements within guidelines established by the OSQR. The LS coordinates input from project scientists and other scientists internal and external to the Agency during development of specific research objectives, methods, contingency plans, and timelines for the project. The LS submits the prospectus and project plan in a timely manner to the RL to ensure adequate review time. The prospectus developed for ARS review is submitted by the RL for approval by the Center, Institute, or Lab Director, Area Director, and National Program Leader within scheduled deadlines set by the Area Office, NPS and OSQR. The project plan is submitted by the SY for

approval by the RL; Center, Institute, or Lab Director; and Area Director with sufficient lead time to allow the LS/RL to make any required changes in a timely manner to meet submission deadlines for final panel peer review. After initial review, the LS/RL review peer panel recommendations and make appropriate modifications to research project plans for submission to the Area Director for review and approval. The RL then submits formal responses to recommendations made by peer panel reviewers to OSQR through the Area Office. *The RL assures that the process of project plan preparation and review, as well as the quality of the projet plan, are tied to individual team scientists' performance evaluation plans.* The RL, with assistance from LS, assures progress on the certified project adheres as closely as possible to timelines and is documented through Annual Report of Progress, publications and other research products, and assures that research progress is addressed in individual scientists' performance evaluation plans.

Section 5.6 ARS Focus Group on Peer Review

Provides advice and counsel to ARS Administrators and OSQR personnel and communicates with ARS scientists to promote the effectiveness and to enhance the quality of the ARS Peer Review Process. Evaluates the ARS Peer Review Process and develops recommendations for the ARS administrator to consider in the improvement and enhancement of the process. Promotes the value and effectiveness of the ARS Peer Review Process and improves the quality of project plans by enhancing communication and education about the ARS Peer Review Process.

OSQR Focus Group specifically:

- Evaluates the feedback from panels and stakeholders to identify potential improvements in the ARS Peer Review process.
- Evaluates the project plan format and requirements relative to agency goals, National Programs, and panel operations.
- Recommends specific approaches that will enhance communication of the value of the ARS Peer Review in a scientist's research and career.
- Evaluates the ARS Peer Review process to assure mechanisms are in place for accountability especially after the ARS Peer Review certification process, for example, during project implementation, interim review, and research follow-through.

LIST OF ACRONYMS AND ABBREVIATIONS

AA	Associate Administrator
AAD	Associate or Assistant Area Director
AC	Administrator's Council
AD	Area Director
ADODR	Authorized Departmental Officer’s Designated Representative
ARS	Agricultural Research Service
ARIS	Agricultural Research Information System
CRIS	Current Research Information System
LS	Lead Scientist
NAL	National Agricultural Library
NPL	National Program Leader
NPS	National Program Staff
ODA	Office of the Deputy Administrator, NPS
OSQR	Office of Scientific Quality Review
PDRAM	Program Direction and Resource Allocation Memo
RL	Research Leader
SCA	Specific Cooperative Agreement
SY	Scientist Year

GLOSSARY

Action Class: Action Classes refer to the degree of revision peer reviewers believe project plans need. The Action Classes correspond to the extent of peer reviewers' recommendations and are meant to give ARS management an overall idea of the quality of project plans.

Administrator's Council: The AC is composed of the Administrator, Associate Administrators, Deputy Administrators in NPS, Area Directors, and the Director, NAL. Senior Advisors include the heads of offices reporting directly to the Administrator.

ARS Resource Management System: A system for central management of resource assets to enhance and control program accountability within ARS.

Authorized Departmental Officer's Designated Representative (ADODR): The ADODR is the ARS person who is responsible for the proper conduct of an extramural research project.

Biohazard: Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or parasite or vector, or biological toxin, or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing: (1) Death, disease, or other biological malfunction in a human, an animal, a plant or another living organism or deterioration of food, water, equipment, supplies, or material of any kind; or; (2) Deleterious alteration of the environment.

Category: An ARS system of administrative designations for groups of positions having generally similar characteristics, primarily for personnel and budgetary tracking purposes. Category has no legal or administrative significance outside of ARS. Some positions may perform duties from more than one category. ARS categories established for professional scientific positions are as follows:

Category 1 (Research Scientist): Permanent positions in which the highest level of work, for a major portion of time, involves personal conduct or conduct and leadership of theoretical and experimental investigations primarily of a basic or applied nature such as: determining the nature, magnitude, and interrelationships of physical, biological, and psychological phenomena and processes; creating or developing principles, criteria, methods, and a body of knowledge generally applicable for use by others. Category 1 positions are SY positions.

Category 2 (Nonpermanent Research/Service Scientist): Professional scientific positions which are established on a nonpermanent basis, are filled through temporary or term appointments, and entail research and/or service science work. Examples are Research Associate, Research Affiliate, Visiting Scientist, and individuals reemployed in ARS after having retired from Category 1 or Category 4 positions.

Category 3 (Support Scientist): Professional scientist positions which function to provide direct support or service to one or more Category 1 or 4 positions. The work of such positions is characterized by responsible involvement in one or more, but not all, phases of research (particularly not the problem selection and definition phases); responsible participation in

analysis and preliminary interpretation of data (but not including responsibility for final interpretation and conclusion which relate the results to the field of research involved). Examples include but are not limited to: (1) conducting literature searches; (2) selecting procedures and conducting experiments; (3) collecting and analyzing data or specimens; or (4) preparing technical reports.

Category 4 (Service Scientist): Permanent positions whose incumbents either primarily or exclusively serve as project or program leaders over or personally perform, work assigned to ARS involving professional scientific services to the public or to other governmental agencies, such as: identification of animals, plants, or insects; diagnosis of diseases; mass production of plants, animals, or insects; collection, introduction, and maintenance of germplasm or specimens; vaccine production; education, extension, or technology transfer activities; or nutrient data and food intake surveys. Category 4 positions are SY positions.

Category 6 (Specialist): "Specialist" positions which perform scientific program management, administration and/or analytical duties and therefore require professional education and training. Examples are: Area Director, Center Director, Agricultural Administrator, and National Research Program Leader.

Current Research Information System (CRIS): An electronic system for the filing and retrieval of information about individual agricultural research projects. All ARS research projects are part of the CRIS and are assigned an ARS research project number. (See also: "*D project*")

D Project or 00D Project: A phrase used to describe the category of ARS research projects that have been funded by Congress or ARS headquarters, whose identification number ends with the characters '00D'. All D projects are panel peer-reviewed unless deemed exempt. ARS Headquarters projects are further classified with '0500' in the first four characters of the ARS research project number and are usually exempt on the basis of the research is short-term or is considered to be done for demonstration purposes. Several other types of research projects exist, such as trusts (00T) and specific cooperative agreements (00S).

Extramural Research: A legal document that enables ARS to obtain research or research related services from organizations or individuals outside ARS (Specific Cooperative Agreement, Contract, Grant)

Hypothesis-driven research: Webster defines a hypothesis as a tentative assumption made in order to draw out and test its logical or empirical consequences. A hypothesis may be a conjecture or an unproved model. It often includes a prediction about what will happen and a possible explanation for why it will happen. A hypothesis is an integral part of the Scientific Method, which has four steps, as follows:

1. Observation and description of a phenomenon or group of phenomena.
2. Formulation of a hypothesis to explain the phenomena.
3. Use of the hypothesis to predict the existence of other phenomena, or to predict quantitatively the results of new observations.

4. Performance of experimental tests of the predictions by several independent experimenters and properly performed experiments.

Questions are asked concerning observations, followed by formulations of hypotheses. Then, predictions are made based on the hypothesis, and appropriately-controlled experiments are performed to test it, providing evidence to support or refute the hypothesis. Hypotheses are tested by doing experiments; thus, hypothesis-driven research is targeted.

National Program Action Plan: A document written as a result of the issues raised by Congress, stakeholders, and researchers (ARS and non-ARS) associated with a particular National Program. The Action Plan addresses 1) rationale and purpose for the program; 2) background; 3) program components; 4) anticipated outcomes/impacts over 5 years; and 5) research objectives by program component.

National Program Overview: A presentation or document given to peer reviewers to discuss the components, objectives, and relationships between projects associated with a particular National Program. The National Program Overview is provided in support of the National Program's Action Plan.

National Program Staff (NPS): The NPS serves the Administrator of ARS in developing and coordinating research plans and strategies on a national basis. The NPS sets National Program directions, establishes priorities, and allocates resources. Considerable interaction with Area Directors, stakeholders, and scientists is required to successfully accomplish the NPS's mission.

Panel Chair: The facilitator and manager of a peer review panel. Panel chairs must meet the same expertise, confidentiality, and freedom of conflicts of interest requirements as peer reviewers. They are often sought as panel chairs because of their obvious recognition as being a leader in their respective field of science, their facilitation skills and broad knowledge of the subject matter and other experts in their field. Panel chairs are responsible for retaining peer reviewers for their panel, becoming knowledgeable of ARS's peer review criteria and other policies, managing the peer review meetings, and validating the final peer review recommendations.

Peer Review: A process by which independent, expert reviewers assess a research project plan for its scientific and technical quality and suitability of approach.

Peer Reviewer: An individual designated by ARS as qualified and capable of independently and critically assessing the scientific and technical quality of a research project plan. Peer reviewers are mainly non-ARS scientists but may be an ARS scientist.

Peer Reviewer Independent: A peer reviewer must be recognized as having expertise in the field under which the review is taking place. The peer reviewer is said to be independent of the project plan if he or she was not involved in the plan being reviewed and has no benefit from the funding of the project. Furthermore, independent peer reviewers must have no conflicts of interest with project plans that they review. Independent peer reviewers ensure that a project plan is impartially reviewed.

Peer Review Recommendation: A document submitted by a peer review panel that contains a critical review of an ARS research project plan. Recommendations contain input from all members, but do not necessarily reflect a consensus of recommendations.

Primary National Program: The National Program in which a ARS Research Project is focused. Projects may be related to other National Programs and so described by the National Program Staff in their National Program Overview.

Primary Reviewer: A peer reviewer assigned to perform a comprehensive and extensive review of a particular research project plan based upon applicable scientific or subject matter expertise. A primary reviewer is responsible for reading and assessing the project plan in-depth, documenting detailed recommendation for improvement if warranted, and when applicable, leading panel discussions about the project plan.

Program Direction and Resource Allocation Memo (PDRAM): A PDRAM is developed by the National Program Staff as a result of development of the National Program Action Plan and addresses the objectives the Area Office is to direct a specific project team to study. These objectives are aligned with the Action Plan and the compilation of the objectives within the Action Plan represents the portfolio of ARS research being conducted in a specific problem area.

Project Plan: A project plan details the research need, objectives, appropriate hypotheses, experimental approaches, contingencies, collaborations necessary for accomplishment of the planned research and the milestones and products expected from the successful completion of the research project.

Prospectus: A prospectus is a planning and communications document that outlines the direction, objectives and approach for research to be conducted over the next five years by each of the projects in a National Program.

Reorganization: The establishment, discontinuance, consolidation, transfer, or realignment of work, functions, areas of responsibility or geographical jurisdiction, and changes in official organizational titles.

Research Position Evaluation System (RPES): The RPES process is the periodic review of CAT 1 scientist for their grade determination. These factors include assignment, research objectives, assigned authority, and accomplishments. These processes are detailed in Manual 431.1.

Research Unit (Also Management Unit): The ARS unit performing the research in the project plan that is subject to peer review. Research Leaders scientifically and administratively manage these units. Typically, a research unit is comprised of 5-10 scientists, plus additional support staff, and several temporary student and postdoctoral employees. Most units are associated with a specific ARS Institute or Center that also provides direction. The program and mission of the unit is often limited. Discipline or program gaps might be filled by collaboration with other units in ARS or with non-ARS scientists.

Secondary Reviewer: A peer reviewer assigned to perform a comprehensive and extensive review of a particular project plan based on applicable scientific or subject matter expertise. A secondary reviewer is responsible for reading and assessing the project plan thoroughly, documenting detailed recommendations for improvement if warranted, and participating actively in panel discussions about the project plan. The secondary reviewer reads and edits the final recommendations written by the primary reviewer. The secondary reviewer may act as the primary reviewer in his or her absence.

Scientist Year (SY): The effort of an ARS research scientist for one year. Fractional efforts in a given project are possible when a scientist is involved in more than one project during the course of a fiscal year. The term is also used in ARS as a synonym for a research scientist.

APPENDICES

APPENDIX 1. Related Authorities

The Administrative Procedures Act

According to provisions of the Administrative Procedures Act, public comment solicited from the general public through the *Federal Register*, or other means, is often required prior to making significant decisions or taking significant actions. Public comment is open to all issues, whereas peer review is limited to where there is only consideration of technical issues. Thus, peer review recommendations are not open to public involvement in that they are provided by a small group of independent, subject-matter experts.

The Freedom of Information Act (FOIA)

External groups may obtain general, non-sensitive peer review data via procedures made in compliance with the ARS Freedom of Information Act (ARS 158.1 FOIA & Privacy Act Procedures; February 23, 1998). These procedures outline the limitations on release of certain types of information, such as names and addresses of peer reviewers, and the right for the OSQR to delegate access to individual research project plans to the Area Directors. A FOIA request is not necessary to obtain a general report from panel chairs, the distribution of scores, or a list of projects reviewed by a panel.

The Federal Advisory Committee Act (FACA)

FACA defines that non-governmental advisor's opinions must be taken individually for formal and established federal advisory committees. However, since the ARS Peer Review Process does not require chartered peer review committees, total action class scores from individual peer reviewers are averaged (vs. consensus-based). The primary reviewer is in charge of putting together comments and recommendations that may involve all panelists. Therefore, the provisions of FACA do not apply for the final recommendations; as validated by a panel chair.

The Paperwork Reduction Act

To maintain a reasonable work load on peer reviewers, it is ARS' policy that research project plans have page limits. Instructions encourage research teams to write concisely and comprehensively to the extent that reviewers can, on average, review a single project plan and document a peer review within 4-6 hours.

Title 44-Public Printing and Documents

Title 44 covers all recordkeeping and documentation rules for Federal agencies. Sec. 3101. "Records management by agency heads; general duties" directs all agencies to develop procedures to properly document agency decisions. The OSQR records the results of all peer reviews as a matter of Agency record. Individual peer review forms remain confidential in OSQR and are not distributed to other offices in ARS. No peer review-related documents are distributed externally; however, Annual Report of Progress about the overall success of the Peer Review Process and participating peer reviewers are available upon request.

APPENDIX 2. Example of a Project Plan Cover Page

Project Plan
NP 108 Food Safety
August-September 2005

Old Project Number
1234-56789-000-00D

Management Research Unit
Food Safety and Technology Laboratory

Location
Beltsville, Maryland

Title
Food Safety Technologies to Avoid Spoilage in Food Systems

Investigators

Fred Flintstone, Lead Scientist	1.0	
Barney Rubble		.50
Henry Slate	1.0	

Scientific Staff Years
2.50

Planned Duration
60 months

APPENDIX 3. Signature Pages

Pre-Peer Review Signature Page

(SIGNATURE AND DATES MUST BE COMPLETE PRIOR TO DISTRIBUTING THIS PROJECT PLAN TO PEER REVIEWERS)

[Lead Scientist, Project Number and Title]

This project plan was found to meet the peer review criteria, to be in compliance with the Project Plan Instructions and Format, and demonstrate how the research team will conduct research in a manner appropriate for this area of research. The funds committed toward this project are sufficient to support the planned research.

_____ _____

Research Leader Date

This project plan was prepared by a qualified research team and demonstrates the research team's best effort towards achieving the assigned research objectives.

_____ _____

Center, Institute or Lab Director Date

This project plan was prepared by a qualified research team and demonstrates the research team's best effort towards achieving the assigned research objectives. All internal review and approval requirements have been met. This project plan is relevant to the Agricultural Research Service's National Program [enter NP # and title] Action Plan and was prepared in accordance with the outlined objectives, experimental approach, and project duration previously agreed to by the National Program Team and Research Team. To validate the plan's readiness for implementation and gain recommendations for improvement, the project plan is now available for peer review.

_____ _____

Area Director Date

These officials have not performed a scientific merit peer review. Their statements do not necessarily require expertise in the scientific subjects associated with this research. The approval to implement this project plan cannot be made without scientific peer review coordinated by the Office of Scientific Quality Review, ARS, USDA.

Post-Peer Review Signature Page

[Lead Scientist, Project Number and Title]

This project plan was revised, as appropriate, according to the peer review recommendations and/or other insights developed while considering the peer review recommendations. A response to each peer review recommendation is attached. If recommendations were not adopted, a rationale is provided.

_____ _____

Research Leader Date

This final version of the project plan reflects the best efforts of the research team to consider the recommendations provided by peer reviewers. The responses to the peer review recommendations are satisfactory.

_____ _____

Center, Institute or Lab Director Date

The attached plan for the project identified above was created by a team of credible researchers and internally reviewed and recognized by the team's management and National Program Leader to establish the project's relevance and dedication to the Agricultural Research Service's mission and Congressional mandates. It reflects the best efforts of the research team to consider the recommendations provided by peer reviewers. The responses to the peer review recommendations are satisfactory. The project plan has completed a scientific merit peer review in accordance with the Research Title of the 1998 Farm Bill (PL105-185) and was deemed feasible for implementation. Reasonable consideration was given to each recommendation for improvement provided by the peer reviewers.

_____ _____

Area Director (original signature required) Date

Re-Review Signature Page

(SIGNATURE AND DATES MUST BE COMPLETE PRIOR TO DISTRIBUTING THIS PROJECT PLAN TO PEER REVIEWERS)

[Lead Scientist, Project Number and Title]

This project plan was revised according to the recommendations made by the panel. It is found to meet the peer review criteria and to be in compliance with the project plan instructions and format, and demonstrate how the research team will conduct research in a manner appropriate for this area of research. The funds committed toward this project are sufficient to support the planned research.

_____ _____

Research Leader Date

This project plan was prepared by a qualified research team and demonstrates the research team's best effort towards achieving the assigned research objectives.

_____ _____

Center, Institute or Lab Director Date

This project plan was prepared by a qualified research team and demonstrates the research team's best effort towards achieving the assigned research objectives. All internal review and approval requirements have been met. This project plan is relevant to the Agricultural Research Service's National Program [enter NP # and title] Action Plan and was prepared in accordance with the outlined objectives, experimental approach, and project duration previously agreed to by the National Program Team and Research Team. To validate the plan's readiness for implementation and gain recommendations for improvement, the project plan is now available for peer review.

_____ _____

Area Director Date

These officials have not performed a scientific merit peer review. Their statements do not necessarily require expertise in the scientific subjects associated with this research. The approval to implement this project plan cannot be made without scientific peer review coordinated by the Office of Scientific Quality Review, ARS, USDA.

APPENDIX 4. Table of Contents

Table of Contents

APPENDIX 5. Milestones Table

Project Title[a]		Project No.[b]			
Objective[c]					
Performance Measure[d]					
Subobjective[e]					
Hypothesis[f]	SY Team[g]	Months[h]	Milestones[i]	Progress/ Changes[j]	Products[k]
		12			
		24			
		36			
		48			
		60			
Hypothesis	SY Team	Months	Milestones	Progress/ Changes	Products
		12			
		24			
		36			
		48			
		60			

The goal of the table is to present a summary of the project in a form that is easily used to link to Annual Report of Progress (421's) and Performance Plans for each scientist. The intent of the table is to be a dynamic representation of the project that captures over the project life cycle the important progress and products derived from the project.

Table can be expanded by copying any section below the project title line.

Explanation of Footnotes

[a] Project title from the project plan

[b] Project number from the ARS-416

[c] Objective from the project plan

[d] List the Performance Measure from the NP Action that the Objective Addresses

[e] Subobjective from project plan (if used, if not this line can be deleted)

[f] A statement of the hypothesis for the objective, if appropriate. Otherwise the non-hypothesis statement

[g] Initials of the project team members contributing expertise to the specific hypothesis and significant collaborators (if a vacancy exists on the project, identify this position within the table)

[h] Milestones for the specific months of the project, be as specific as possible as to the measurable milestones

[i] The Progress/Changes section may completed at the end of each year by the project team as part of the Project Management and Evaluation process and a summary of these are entered into the table and if there is a revised milestone or hypothesis this is entered for the next period of the

project plan. (Note: This is to aid project management. Annual completion of this section is not required as part of the Peer Review Process).

[j] Specific products of the project for each hypothesis line.

APPENDIX 6. Lead Scientist Preparation for Submitting Project Plans to the ARS Peer Review Process

Lead scientists are responsible for writing project plans for their prospective research every five years, in accordance with the peer review schedule designated for their primary national program. You, above all others in ARS, are responsible for creating a plan that has scientific merit and will be judged to require little or no revision by a group of your peers. Your success in writing an excellent plan is especially dependent upon the attention you provide to your experimental design. In addition, a seamless plan for a research team requires much preparation. As Lead Scientist, you are responsible for ensuring that the project plan is not presented as a series of mini-project plans bound together because they are part of a common National Program at your location.

For your convenience, the following checklist is provided to show the required steps along each stage of the process. You should also consult with your Area Office and National Program Leader to determine if they have additional requirements (e.g., attendance at workshops, references to the NP action plan, and additional formatting standards). Feel free to call OSQR at 301-504-3282 or e-mail osqr@ars.usda.gov if you have questions about the review process. You may also contact your Area representative to the ARS Peer Review Focus-Group.

General preparation:

- View the OSQR Video on Project Plan Development. (Your Research Leader should have a copy.)
- If possible, attend a presentation by the OSQR Scientific Review Officer. These presentations are often provided at Area-wide training or meetings and workshops sponsored by the National Program Staff.
- See Manual 500-1, *The ARS Peer Review Process*. Especially read policy sections on: roles & responsibilities, review criteria, action classes and matrix, reviewer information, and steps in the process.
- Inform your research team that the ARS Peer Review Process is about to begin and encourage team members to view the OSQR Video. Consider approach to creating a seamless document between team members.

Preliminary Planning After Receiving the PDRAM:

- Review the prospectus instructions available from www.ars.usda.gov/osqr.
- During discussions with your NPL, determine whether more than one panel will be held for the projects in your National Program. Be sure that you know to which panel (by name or topic) your project has been assigned. Similarly, give the NPL your suggestions for panel chairs.
- Begin sending OSQR nominations for panel and/or ad hoc reviewers using the form at www.ars.usda.gov/osqr. Ask your research team members to do the same.
- Acknowledge deadlines and work to incorporate them into your schedule. A general schedule is posted at http://www.ars.usda.gov/research/docs.htm?docid=1289 and you'll

receive a complete schedule in the transmittal of the PDRAM from the Area Office. Your Area Program Analyst will provide guidance on the specific deadlines. Make your research team members aware of this schedule.

- Begin updating your list of individuals with whom you have a conflict of interest. (See http://www.ars.usda.gov/osqr/COIExample.PDF) Ensure that your team research members complete their COI.
- Begin contacting current and potential collaborators and request a letter documenting their commitment to the prospective research. Your team members will need to do the same. (See http://www.ars.usda.gov/Research/docs.htm?docid=1570)

Prospectus Development:

- Meet with your research team and discuss ideas for prospectus. This may actually require several discussions.
- Prepare your prospectus according to the guidelines at www.ars.usda.gov/osqr/prospectus1page.html and any additional guidelines provided by your NPL or Area Office.
- Give your research team an opportunity to review the prospectus.
- Have your Research Leader review and approve your prospectus and then forward it to the next manager in line.

Project Plan Development:

- As soon as you have finished your prospectus, begin to meet with your research team to consider the project plan. Pay particular attention to the experimental details, the milestones, and contingencies. Keep your RL informed of major issues as they are examined and/or developed. Extra time spent in preparation will result in a better project plan.
- Prepare your project plan according to the guidelines at www.ars.usda.gov/osqr/projectplan.html and any additional guidelines or comments provided by your NPL or Area Office.
- Anticipate having a good draft product done in 8 weeks. Another 8-10 weeks are used to incorporate comments from your Area Office, NP Team and other input you seek. This other input may include colleagues, support scientists or a secretary with good editorial skills, your Area representative to the ARS Peer Review Focus Group, or your Program Analyst.
- Make sure every section of the plan is present as shown in the table of contents. Read the peer review criteria again and judge whether you have met them.
- Have your Research Leader review and sign off on your plan and then forward it to the next line manager as shown on the cover sheet.
- A one-page **informational** update may be sent (one time only) to OSQR until the day before the panel meeting, with Area Director approval. This might apply to new collaborations, publications, or errors you discovered after submitting the plan.
- If your conflict of interest list has changed since your earlier submission, please resubmit the up-to-date version as soon as possible through your Area Office.

Internal/Informal Peer Review Networks:

The most successful project plans are those that have been examined by other scientists either inside or outside of the Agency prior to submission to the Area Director. Review of the project plan by colleagues helps to ensure the plan is clearly written, experiments are adequately described and state of the art approaches and techniques are proposed. One criticism by peer review panel members of project plans written by multiple SYs is that the plans are not "seamless" and appear to be composed of several separate project plans simply "stuck together." Colleagues reading the project plan for the first time usually readily identify this type of deficiency in a project plan. Obtaining reviews by colleagues is especially important when the expertise needed to carry out some of the proposed research is not currently available in a project due to a temporary vacancy or absence.

Project Plan Revision and Response to the Review:

- Upon receiving the peer review results, meet with your research team and develop reasonable and professional responses to the peer review recommendations. Consult with your RL to ensure that they are in agreement with you and your research team's approach. Note: If your project plan receives a 'major revision' or 'not feasible' action class rating, you will need to consult first with management and NPS to determine the next steps for correcting the unfavorable aspects of the plan.
- You and your research team will develop a final revised plan.
- Have your Research Leader review and sign off on your plan and then forward it to the next manager in line as shown on the cover sheet. Anticipate collaboration with your Research Leader, Area Office, and fellow scientists on the responses and revised plan.
- Upon receiving a certification from OSQR, the program analysts will coordinate the creation of your new ARS Research Project that is established for the period through the next panel review session.

APPENDIX 7. Intellectual Property

ARS Research Projects
and
Intellectual Property Issues

Introduction
In developing and executing research projects in ARS, it is critical to understand the role of intellectual property and its impact on our ability to perform research and to transfer the technology to our customers.

In planning and conducting research, there are several key manifestations of intellectual property (IP) that may impact the research process and the ultimate use of the resulting technologies, including:

confidentiality of information,
proprietary nature of materials, processes and/or research tools, and intellectual property issues associated with collaborations.

Definitions

Intellectual Property: "… applies to any product of the human intellect … whether or not the subject matter is protectable ... ." These include "invention, discovery, technology, creation, development, or other form of expression of an idea." (excerpts from *Technology Transfer Desk Reference, Federal Laboratory Consortium, 2003)*

Technology Transfer: the process by which research results are adopted and put into practice

Developing the Research Plan
It is important to recognize and identify potential IP issues in developing the research plan in order to avoid potential conflicts in using the results of the research or difficulties in ultimately transferring the technology to our targeted customers. If materials or methods/processes are used that are proprietary or protected by patents or other means, it may limit our ability to transfer the technology to our end users and/or it may increase the cost for customers to use our technology because of costs associated with licensing non-ARS background technology. For guidance on identification or management of IP issues, contact your Patent Advisors and Technology Transfer Coordinators in the ARS Office of Technology Transfer.

Materials and Experimental Procedures: In developing a research plan and in selection of experimental methods, the materials and/or methods proposed for the research approach should be reviewed to identify any potential IP associated with them and, if so, to identify the owners of the technology. Technologies to be used that are patented or proprietary should be clearly identified, including ownership and, if necessary, Material Transfer Agreements should be initiated for use of proprietary materials. Consideration

should be given to the impacts of using protected technologies on the outcomes of the research and, if appropriate, alternatives should be identified.

Scientific Background and Literature Review: In conducting a literature review for the proposed project, it is useful to check the citations of the publications for references to patents that may be relevant to the materials or procedures of the proposed research approach. If appropriate to the field of research, a patent search should be performed in order to identify any potential IP issues that may be associated with the use of proprietary information or materials. Remember that publication of research results in journals does not preclude the existence of associated patents, even if they are not referenced in the publication.

Collaborations: Collaborative efforts may include, but are not limited to, development of the research plan, cooperative research activities and/or transfer of materials to or from ARS. In order to preserve any potential IP rights, Confidentiality Agreements should be used when developing the project with collaborators or sharing new or unpublished ideas or data. Use of Cooperator's confidential information in the research project may limit our ability to publish or transfer the results of the research freely; such issues should be discussed in advance and appropriate Confidentiality Agreements or Research Agreements put in place prior to initiation of the research. In addition, if materials will be transferred to or from ARS, a Material Transfer Agreement should be used if these are patented or proprietary materials. If there is a potential for IP to result from the project, cooperative research agreements (e.g.: Memorandum of Understanding, Trust Agreement, Specific Cooperative Agreement, or Cooperative Research and Development Agreement) should be developed to define how intellectual property issues associated with the collaboration will be managed.

Transferring the Technology

Anticipated Products and Customers of the Research:
As a result of the Federal Technology Act of 1986, technology transfer is the responsibility of each ARS scientist. Because ARS is a publicly-funded federal institution, the transfer of ARS technology to our customers is the primary consideration in determining whether or not to protect any inventions that result from our research. Examples of technology transfer include demonstrations, presentations, publications, utility or plant patents, plant variety protection certificates and biological material inventions. ARS protects intellectual property only if it enhances or is necessary for successful technology transfer. Consult with your ARS Patent Advisors and Technology Transfer Coordinators for evaluation of potential IP in order to determine the most appropriate mechanisms for transfer of new ARS technologies.

In developing a research plan and identifying customers of the research, there should be an evaluation of the potential outcomes and products of the research. Who will the ultimate users be? How will the technology be transferred? Will further development or protection of the research results be needed in order to transfer the technology? Are there regulatory actions or approvals needed before end products can be made available? If so, appropriate steps should be taken during the research process to prevent premature disclosure of confidential information

and to protect potential IP rights (Confidentiality Agreements, Material Transfer Agreements, Cooperative Research Agreements). Avoiding premature disclosure is critical because, in many instances, there may be substantial oversees markets for U.S. companies developing products from ARS technologies. Any enabling oral or printed disclosure of an invention eliminates patent options in foreign countries unless an application has already been filed in the U.S. Webpage publication of meeting abstracts, field days, and open house poster sessions can potentially constitute a disclosure. Scientists should consult with their ARS Patent Advisor prior to submitting such materials.

Conclusions

In order to maximize our ability to perform research and to facilitate technology transfer, it is important to be aware of current and emerging technologies and to identify protected intellectual property issues associated with them. Likewise, it is critical to evaluate our research results for potential IP and to work with the Office of Technology Transfer to select the optimal vehicles for transfer of new technologies to our customers.

For further assistance:

Patents, identifying background IP, how to do a patent search, patentability issues: ARS Patent Advisors

Confidentiality Agreements, Material Transfer Agreements, Research Agreements: ARS Technology Transfer Coordinators

APPENDIX 8. Action Class Worksheet

ACTION CLASS RATING WORKSHEET

United States Department of Agriculture
Agricultural Research Service
Office of Scientific Quality Review

National Program:

Review Dates:

Project Plan Title:

Lead Scientist:

Scientific Quality Review Officers: The Officer whose signature appears below agrees to treat the contents of this Plan as confidential and that no basis for a conflict of interest has been found. Final determination of conflicts of interest, which are outlined in the Peer Review Guidelines for ARS Panel Reviewers, resides with the OSQR.

SEE GUIDELINES FOR REVIEWING ARS RESEARCH PROJECT PLANS

Individual quality ratings translate into the following numerical values:

Reviewer	Quality Rating	Numerical Value
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
Total # of Reviewers:		Total Rating:
Average Rating:		#DIV/0!

EVALUATION

No Revision Required (≥ 7.0)
Minor Revision Required (5.1 to 6.9)
Moderate Revision Required (3.1 to 5.0)
Major Revision Required (1.1 to 3.0)
Not Feasible (<1.1)

Per project plan, individual panelist quality ratings will be tallied, divided by the total number of panelists (panel members, plus panel chair, excluding ad hoc reviewers), and rounded to the nearest tenth to arrive at a final project score. Final project ratings are shown above.

No Revision Required = 8 points No revision is required, but minor changes to the project plan may be made.

Minor Revision Required = 6 points The project plan is basically feasible as written but requires some revision to increase quality to a higher level.

Moderate Revision Required = 4 points The project plan is basically feasible as written but requires moderate revision in the Approach and Procedures of one or more objectives, perhaps involving changes to the experimental approaches, in order to increase the quality to a higher level. The project plan may also need some rewriting for greater clarity.

Major Revision Required = 2 points Substantial revision in the Approach and Procedures of one or more objectives is necessary, but the project plan should be sound and feasible after significant revision.

Not Feasible = 0 points The project plan has major flaws or deficiencies, and cannot be simply revised to produce a sound project. If the project is not terminated, a complete redesign and rewrite are required.

Jerry L. Hatfield /s/

JERRY L. HATFIELD, Scientific Quality Review Officer Date

APPENDIX 9. Sample of Peer Review Recommendations and ARS Response

Project Title: **Development of Gentle Intervention Processes to Enhance the Safety of Heat Sensitive Foods**

Lead Scientist: **ARS Scientist** National Program: **108 Food Safety-Postharvest**

Reviewer Number: **NNCK1120**

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1. Adequacy of Approach and Procedures: Are the hypotheses and/or plan of work well conceived? Are the experiments, analytical methods, and approaches and procedures appropriate and sufficient to accomplish the objectives? How could the approach or research procedures be improved?

Comments:
1. The hypothesis that… condensing steam will inactivate bacteria on the surface of solid foods without causing thermal damage if the interfering air and water layers on the surface are removed by vacuum and the condensed steam is removed to evaporatively cool the surface… is scientifically sound and workable. Indeed, the group has developed and tested the technology with a pilot plant prototype and chicken pieces, which indicated a 2 log reduction of LM in initial studies. Further refinement will involve retrofitting the prototype to treat the whole carcass (surface, visceral cavity) and development of a field VSV pasteurization system. Additional studies will focus on ready-to-eat meats, specifically hot dogs (and the known LM hazard) and catfish, with both aspects under appropriate CRADAs. The former is a high priority research need for food safety regulatory agencies, and the contingency inactivation studies "in-package" (within plastic) should probably be elevated to practice in the proposal. The portion of the proposal indicating the development of models and process simulations, towards determining the mechanism of VSV inactivation, is appropriate, but of lower priority in the overall project schema. Any modeling aspect should be focused on process delivery and eventual development and validation of performance standards to support food safety.

2. The controversial theory that "pasteurization" of heat-sensitive foods is accomplished by applied voltage or magnetic field and, perhaps, can be demonstrated with the incumbents' "uniquely modified RF heater" is the overall working hypothesis for this objective. This entire objective is very high risk, but the payoff is potentially high. The proposal articulates a clear, stepwise protocol. The modified RF "heater" appears to be designed to offset the often-stated criticism towards the non-thermal theories that precise measurements of the time-"temperature" history and its spatial variations are lacking.

Recommendations:

1. Objective 1 - The proposal needs to incorporate a more specific explanation of the steps needed to determine the effectiveness of the VSV treatment. Will naturally occurring pathogen populations be known or established?

ARS Response: We added more detail to the plan of work (see pp 12-13). Specifically, we will use Null hypothesis to determine statistically significant differences between the treated and control, within 1 day, across 3 days, over weeks and seasons. Each company will have their own specific tests to run to determine effectiveness. We will test for *Campylobacter* and generic *E. coli* at Athens. One company has expressed an interest in looking at *Salmonella*. At that plant, they will test for it. It is the objective to develop the process for commercial adoption. We expect individual companies will do more specific tests and share the data. In all cases in which it is feasible, we will try to establish the pathogens present.

2. Objective 1 – Although the primary focus of the research may be on reducing microbial populations on the surface of solid foods, the evaluation of the process should incorporate measurements of the process impact on product quality; color, texture, etc.

ARS Response: We agree, but that is best left to the companies to do. They are the 'product specialists' and are much better equipped to do those studies. They have the equipment, experience and personnel to do them. We added text to indicate that industry will do these tests as part of our collaborative arrangements (see p. 13). The research on this objective is at the developmental stage. We need industry to cooperate in testing at processing plants. We will supply the equipment and expertise on the VSV intervention processor. We will do the microbiology evaluation although industry will undoubtedly do their own microbiology evaluation as well. Industry is best equipped to evaluate the consumer acceptance of the product. We are in a better position to do basic research into the mechanism and model the process.

3. Objective 1 – The portion of the proposal on models and simulation of the bacterial "destruction" process needs to be developed with much more specific information on the approach to be used and the outcomes to be achieved. The models should focus on process delivery and eventual development and validation of performance standards to support food safety.

ARS Response: We agree. This research objective belongs to a high level vacancy, as yet unfilled. However, we added a detailed research plan based on our conception (see pp 18-19). It is a difficult research assignment and we hope to hire a highly qualified engineer to do it.

4. Objective 2 – The hypothesis of the research should be reversed to prove that a non-thermal influence on inactivation of microbial cells does exist.

ARS Response: We concur and changed the order as suggested (see p. 19).

5. Objective 2 - The portion of the research on the non-thermal influence of electromagnetic energy on microbial inactivation will require a more detailed experimental design than presented in the proposal. Since the influence can be expected to be small, and a well designed statistical study is needed.

ARS Response: We expanded the text to give the details of the planned experiments (see pp. 21-22). We are performing an engineering study to develop a process based on a nonthermal effect. The first step is to prove such an effect exists and is significant. If it is small it might be of

scientific interest but is unlikely to form the basis of a new process. The effect must be large enough to justify developing a process. Therefore, we will look for a non-thermal effect within the framework of a steady state process.

6. Objective 2 - A portion of the research has a focus on mechanisms for inactivation of microbial cells due to electromagnetic energy. These investigations should be expanded to include all forms of electrical energy.

ARS Response: This phase of the research is meant to support the process development through a better understanding of the basic principles involved. There are insufficient funds to look at all forms of electrical energy. We must be selective and choose to investigate the form we consider has the greatest potential for commercialization.

APPENDIX 10. Confidentiality Agreement

OSQR Confidentiality Agreement

	For Review of ARS Research Project Plans by the National Program Panel:
	For Review of a Specific ARS Research Project Plan:

THIS AGREEMENT is by and between the US. Department of Agriculture, Agricultural Research Service (hereinafter ARS), and _____ (hereinafter Reviewer).
(Name of Reviewer)

WHEREAS, in order for Reviewer to assess the scientific merit of ARS Research Project Plan(s), (hereinafter project plan(s)), ARS may have included detailed information in the project plan(s) about the underlying research and existing and anticipated research results that is considered by ARS to be proprietary or confidential information (hereinafter Confidential Information); and

THEREFORE, Reviewer agrees to maintain in complete confidence and secrecy the Confidential Information contained in the project plan(s), will not disclose directly or indirectly the Confidential Information to others, and will not use or make use of the Confidential Information, except in connection with said reviews.

For purposes of this Agreement, such Confidential Information shall not include:

1. Information already known to Reviewer;
2. Information which Reviewer receives from a third party who has not obtained such information directly or indirectly from ARS;
3. Information that has become public knowledge through no actions of Reviewer; or
4. Information received after the disclosure from a third party having the right to the information and who does not impose a confidentiality obligation on Reviewer.

This Confidentiality Agreement shall remain in effect for five years from the Effective Date.

Signatures:

Peer Reviewer: _____ Date _____

ARS Representative: _____ Date _____

Please fax this form to OSQR at 301-504-1251 as soon as possible. Then mail the original to the address below.

Public Burden Statement: According to the Paperwork Reduction Act of 1995, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB number. The valid OMB control number for this information collection is 0518-0028. The time required to complete this information collection is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

APPENDIX 11. Guidelines for Peer Reviewers

PEER REVIEW GUIDELINES FOR

ARS PANEL REVIEWERS

United States Department of Agriculture

Agricultural Research Service
Office of Scientific Quality Review

United States Department of Agriculture

Research, Education, and Economics
Agricultural Research Service

Dear Panelist:

Thank you for agreeing to serve as a peer review panelist for the Office of Scientific Quality Review (OSQR). This Office has been charged with managing the peer review process of all ARS research projects. The ARS Peer Review Process has the same fundamental requisites of any rigorous and anonymous peer review process. There are, however, a number of other important differences. The purpose of these reviews and their impact may differ from other review panels on which you have served.

ARS project plans are written for funded intramural projects. Each of these projects was created in response to a congressional mandate and/or through National Program Workshops. The collective input results in Action Plans for each ARS National Program. A National Program is composed of coordinated research projects that address the various goals in its Action Plan. Each project addresses one or more of the Action Plan's stated objectives.

ARS project plans are not evaluated in the same manner as a proposal submitted for a competitive grant. In fact, document for review is a "prospective research project plan;" not a 'proposal'. We seek your opinion of the overall quality of research plans, especially the approaches and procedures, probability of success and its impact or significance. Your input provides scientists an opportunity to incorporate technical improvements to their research methods and assures that the best possible science is brought to bear on important agricultural concerns.

Research project plans outline prospective work over a five-year period. Scientists are, therefore, asked to provide research contingencies and a plan for project management. ARS projects may have somewhat diverse objectives, involve issues of more than one National Program, and may include several cooperating investigators with varying types of scientific expertise.

If this is your first experience of our peer review process, you are strongly urged to read these guidelines. Please contact the OSQR Staff should you need any assistance during this review. We hope that you find this experience of personal benefit.

Sincerely,

The OSQR Team

Orientation

Your panel will receive a brief introduction from the OSQR Team on the first morning of your meeting. The National Program (NP) Leader will have provided an overview of the NP Action Plan and the components at an earlier briefing just after you received the project plans. These briefings and information are provided to help you understand the content of these projects and the expected results. Once you've read these guidelines and completed your reviews, you may still have questions. We welcome them and will make every effort to answer them.

Confidentiality

ARS project plans may include detailed information about underlying research strategies and existing or anticipated research results. This type of information is considered by ARS to be proprietary or confidential nature. *For this reason, do not copy, quote, or otherwise use material gained during the Peer Review Process.* If you believe that a colleague can make a substantial contribution to the review, consult with the OSQR before disclosing any information. **When you complete the review, destroy all copies of the plan and associated materials.**

Anonymity

Panel chairs are publicly known. Their statements on this particular panel's experience are also distributed to the public upon request. All other members of your panel are anonymous. *Final reviews from your panel are held in the strictest confidentiality between the OSQR, the subject research team, and their immediate managers.* All other documentation from your panel will be used and stored only by OSQR or destroyed.

Conflicts of Interest

By now you've had an opportunity to discern any conflicts of interest you may have by reviewing the list of projects assigned to your panel. Nevertheless, it is possible that you may discover an unexpected conflict after reading the entire coversheet of a plan. *Do not review any ARS project plan if you have an institutional or consulting affiliation with the submitting institution, investigators, or collaborators, or will gain some immediate financial benefit from the project.* Also, please decline the review if, during the **past four years**, you have been a research collaborator or co-author of a submitting applicant **or during the past eight years** you have been a thesis or postdoctoral advisor; worked as a graduate student, or postdoctoral associate. If you are uncertain about potential conflicts, please contact the OSQR office.

Debriefing

Before you leave, we'll hold a debriefing with your panel to gather input on the Review Process, comprehensive comments about the nature of the plans, and other comments. Depending on their availability, National Program Leaders and high-level ARS and USDA managers may attend your debriefing. Each of these individuals will honor your anonymity. The Panel Chair will use most of your substantive comments in their Panel Chair statement. We'll also use your comments and suggestions in writing our own report about the review session.

After the review, please leave all peer review-related documents and electronic media with OSQR.

Background on the Format of ARS Project Plans

ARS investigators are given instructions for writing their project plans that encourage adequate details for reviewers to judge whether the peer review criteria have been met and concise writing to avoid an unreasonable burden on reviewers to complete their task. The following information is provided so you, as a reviewer, recognize the level of guidance given to scientists to prepare their project plans. For more complete information, please visit our website at: http://www.ars.usda.gov/osqr.

Page Limits

The page limits on project plans correspond with the number of scientific years assigned to the project, as indicated on the coversheet. For a given number of scientific years, project plans should not exceed:

<2 Scientific Years = 15 pages
2-3.9 Scientific Years = 20 pages
4-6.9 Scientific Years = 25 pages
≥7 Scientific Years = 30 pages

from the "Objectives' through 'Milestones & Expected Outcomes' sections.

Cover Page

The cover page includes:
National Program - Title of the National Program under which the research is conducted. This same National Program has submitted an Action Plan for your use.

ARS Research Project Number- ARS uses this number for tracking the funds, personnel, objectives and accomplishments of every research project.

Research Management Unit & *Location* – Helps identify the specific lab and its geographic location.

Title - Provide a clear indication of what the project is about.

Investigator(s) - Lists all scientists assigned to conduct the research being planned and their percent commitment to the project. This includes all ARS Category 1 or 4 scientists assigned to the project and possibly non-ARS scientists under an equivalent status. Everyone on the list must also turn in a conflicts of interest list to OSQR and have an accomplishments section in the plan.

Scientific Staff Years – Shown as a decimal percentage for the time an individual spends on the subject project.

Planned Duration – Shown in number of months. Most panel-reviewed project plans are written for a 5-year period.

Signatures

The Signature Page provides an individual statement for all managers to sign their agreement to. Note that these statements do not indicate that the project plan has been previously peer reviewed prior to your receipt of it.

Table of Contents

All project plans should have a table of contents to show what the plan contains. Each of the sections described here should be listed.

Project Summary

The objectives and research approaches of the project plan are summarized in 250 words or less.

Objectives

Clear statements are given about the specific objectives of the project that are attainable within the specified duration and with the

physical resources committed to the project as discussed in the 'Approach and Research Procedures' section. The statement should be complete enough to be used as the basis for scientific review.

Need for Research
This is a statement that described the project's relevance to the ARS National Program Action Plan. The following points are also made:
· Description of the problem to be solved. Relevance to ARS National Program Action Plan.
· Potential benefits expected from attaining objectives.
· Anticipated products of the research.
· Customers of the research and their involvement.

Scientific Background
The "Scientific Background" section should focus on presenting relevant literature and technology related to the stated objectives and scientific feasibility of the project plan. The literature cited should be sufficient to allow you to conclude the investigators have current knowledge and understanding of the field of study. It should not, however, be an exhaustive review.
The following information is also provided:
· Results of past projects or other preliminary results of the investigators relevant to the subject project plan.
· CSREES-CRIS search ("Current Research Information System"). Supplemental information is included to show how the project is coordinated with related research projects. Some of these projects might be mentioned again under 'Collaborations'.
· Congressional mandates (if applicable)
· Patent searches (if applicable)

Approach and Research Procedures
Each of the following sections is provided for each objective and subobjective:

Experimental Design – This section details the scientific and experimental approach that is to be used and the research procedures that will be followed to attain objectives. This section should discuss, if applicable, what hypotheses will be tested; how they will be tested; and how experimental results will be evaluated.

Contingencies – Contingency plans discuss the approaches and experimental options that will be considered if the initial research plan is either unsuccessful, proceeds faster than expected, or if new opportunities arise.

Collaborations – Collaborations with scientists outside of this project (ARS and external to ARS) that are necessary to attaining the objectives are described here. Letters from collaborators are in the appendix and discuss who the collaborators are, their role in the research, and their level of commitment anticipated.

Physical and Human Resources – This section describes the availability of major physical resources (i.e., facilities, major instrumentation and equipment, etc.) that are necessary to accomplish the research. A description of the entire research team is also provided.

Project Management and Evaluation
ARS project plans may include a number of different research disciplines and a broad set of objectives. The project team will describe their approach to project management and assessment of progress toward these objectives.

Milestones and Expected Outcomes
Significant events in the project are listed here. A timeline estimating when these milestones can be reasonably met, showing which scientists will be responsible for each milestone or step in the process is constructed in a logical manner. Scientists

also describe how progress will be documented and evaluated (i.e., products of the research.

Accomplishments from Prior Project Period
This section summarizes the research accomplishments and impact from ARS research projects relevant to this project plan that is current or terminated within the last two years. The purpose of this section is to provide the reviewers with a description of the accomplishments and impact from the previous efforts that are related to the project plan being reviewed.

Literature Cited
Any citation format accepted by a scientific journal that includes all authors, article title, and complete page numbers may be used. Only material or papers that are published or in press should be provided in this section. Theses and dissertations, state and federal documents intended for professional distribution, and peer-reviewed proceedings of meetings generally are acceptable citations.

Past Accomplishments of Investigator(s)
In one page or less, scientists provide education, experience, and accomplishments over the past ten years that are significant and pertinent to the proposed research. Each investigator also lists their 20 most relevant peer-reviewed publications

Health, Safety, and Other Issues of Concern Statement
Safety and health requirements under ten sets of laws are set on all ARS projects. If a requirement is not relevant, the plan will explain this as the case. The ten requirements are:

- Animal Care
- Endangered Species
- National Environmental Policy Act
- Human Study Procedure
- Laboratory Hazards
- Occupational Safety & Health
- Recombinant DNA Procedures
- Homeland Security
- Intellectual Property
- Existing SCAs

Appendix
On a new page, appendices are listed by page number. Letters of collaboration are included here, as well as any other supplementary materials essential to the plan.

Review Criteria

The peer review of ARS project plans is essentially a two-step process. The first is evaluation of the quality of the plan; second reviewers provide advice on how the plan might be improved. Project plans are assessed for quality using three broad criteria: 1) adequacy of approach and procedures, 2) probability of success, and 3) merit and significance. The ARS sets these review criteria; however, peer reviewers are encouraged to make additional recommendations.

Adequacy of Approach and Procedures
Assess the scientific quality of the proposed research. Questions to be answered are:

- Are the hypotheses and/or plan of work well conceived?
- Are the experiments, analytical methods, and approaches and procedures current, appropriate, and sufficient to accomplish the objectives?
- How could the approach or research procedures be improved?

Probability of Successfully Accomplishing the Project Objectives
Consider the feasibility of the project. Your panel will determine:

- The probability of success in light of the investigator or project team's training, research experience, preliminary data if available, and past accomplishments
- Whether the objectives are both feasible and realistic within the stated timeframe and with the resources proposed
- Whether the investigators have adequate knowledge of the literature as it relates to the proposed research.

Merit and Significance
Do the problems to be solved or addressed fit within the National Program Action Plan to which the project plan is assigned. Aspects that should be addressed are:

- Will the successful completion of the project enhance knowledge of a scientifically important problem?
- Will the project lead to the development of new knowledge and technology?
- Are you aware of any other data/studies relevant to this research effort?
- If applied research, of what value is the research to its customers?

Our primary interest is in your evaluation of the technical and scientific quality of the research proposed for solving the problem or answering the hypothesis that is being addressed. If you are critical of the approach taken in a project plan or skeptical of the feasibility of a project, your recommendations for improvement are invaluable.

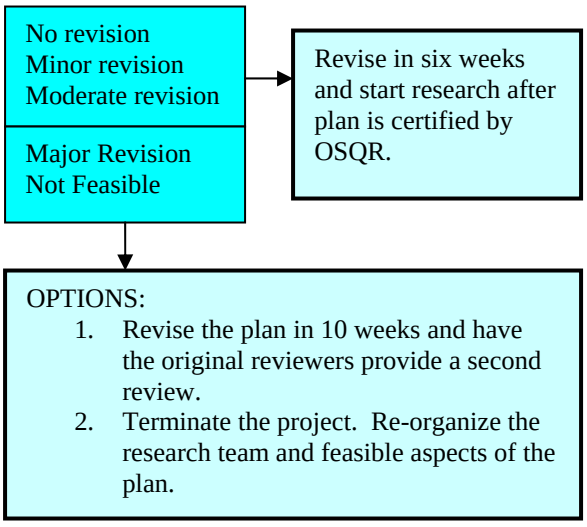
Action Classes

After your panel has completed a discussion, each panelist makes an individual judgment to assign the plan to an 'action class', based on the level of modification needed to raise the plan to the highest quality. OSQR will convert the action classification into a numerical score, average the group of action classes submitted, and assign a final action to the project plan. Each reviewer provides a rating. By Law, the panel may not report a consensus score.

The "Action Classes" are defined as:
1. No revision required. No revision is required, but minor changes to the project plan may be made.
2. Minor revision required. The project plan is basically feasible as written but requires some revision to increase quality to a higher level.
3. Moderate revision required. The project plan is basically feasible as written but requires moderate revision to one or more objectives, perhaps involving changes to the experimental approaches, in order to increase quality to a higher level. The project plan may also need some rewriting for greater clarity.
4. Major revision required. Substantial revision to one or more objectives is necessary, but the project plan should be sound and feasible after significant revision.
5. Not feasible. The project plan, as presented, has major flaws or deficiencies, and cannot be simply revised to produce a sound project. If the project is not terminated, a complete redesign and rewrite are required.

ARS managers may take one of two corrective steps on project plans that receive a 'major revision' or 'not feasible' action class. (See Diagram 1.) The most common step is to ask you, the panelists, to take a second look at the plan about 2-3 months after your meeting.

Diagram 1. Agency steps in response to the cumulative action assigned to each project.



The following matrix is provided to give you some guidelines for assigning appropriate Action Classes to project plans. Many projects plans will fit different Action Classes for different review criteria. In these cases, you must decide whether strengths or weaknesses in a particular criterion override those of other criteria. For example, a project plan could be rated "not feasible" because of a lack of appropriate personnel and/or facilities, but still be excellent in every other way.

The Federal Advisory Committee Act defines the operating requirements for formal Federal advisory committees, and prohibits any advisory panel from making consensus-based recommendations --unless certain requirements are met. ARS requests that the primary reviewer write the final recommendations based on the salient points made in your discussions.

Table 1. The ARS Action Class Matrix.

Action Class	Approach and Procedures	Probability of Success	Merit & Significance
No Revision Required	The project plan is well conceived and clearly articulated.	The research team has the necessary training and experience to accomplish the stated goals.	Outcomes are important to the national interest and closely fit the National Program Action Plan.
	The project directly addresses the stated research goals.	The approach is reasonable with resources available and necessary equipment and facilities are in place.	The project will lead to new knowledge and technology, or will produce results of value to customers.
	The procedures and analytical methods are appropriate and sufficient to accomplish the objectives.	The research team is completely aware of the relevant current literature in the area.	Similar research is not being conducted elsewhere.
Minor Revision Required	The project plan is generally well conceived and all of the approaches are sound. The project plan is basically feasible.	The research team has the training and experience to accomplish the stated goals.	Outcomes are important to the national interest and closely fit the National Program Action Plan.
	The project addresses the stated research goals.	The objectives are generally reasonable with resources available and essential equipment and facilities are available.	The project will lead to new knowledge and technology, or will produce results of value to customers.
	Some minor changes to one or more experimental approaches are suggested, and may involve modifications or alterations to specified procedures or analytical methods.	The research team is aware of current literature in the area.	Similar research is not being conducted elsewhere.
Moderate Revision Required	The project plan is generally sound, but perhaps not clearly articulated.	The research team has most of the training and experience necessary but some areas could be strengthened. One or more of the approaches needs some modification in order to be reasonable with resources available.	Outcomes are important to the national interest and fit the National Program Action Plan.

Moderate Revision Required (cont')	The approaches may need some modification to better fit the stated goals.	Most of the necessary equipment and essential facilities are in place but some aspects could be strengthened.	The project has potential to lead to new knowledge and technology, or to produce results of value to customers.
	Moderate revision to one or more objectives may be required, and may involve changes in experimental approaches or analytical methods.	The research team is aware of most of the current literature in the area.	Similar research may be conducted at other locations suggesting some modification to the present project plan.
Major Revision Required	The approach to one or more of the objectives may not directly address the stated goals.	The research team may lack some important aspects of training or expertise.	One or more of the outcomes may not significantly impact the National Program Action Plan.
	Major revision to the plan for one or more objectives may be necessary because of inappropriate hypotheses or inadequate experimental approaches.	Several approaches are not in line with the resources available. Critical equipment, facilities or experimental tools are not yet in place or available to the research team. The research team is not aware of significant current literature in the area.	The project plan as written is not likely to lead to new knowledge or new technology.
			Similar research is being conducted at other locations such that undesirable duplication of effort is apparent.
Not Feasible	The approach and procedures for one or more of the objectives have major flaws that may involve inappropriate hypotheses or completely inadequate experimental approaches.	The research team has substantive deficiencies in essential expertise or required facilities.	One or more of the outcomes may not significantly impact the National Program Action Plan.
	The procedures are unrelated to the stated goals.	The research team is completely unaware of current activity and literature in the area.	As written, the project plan will not lead to new knowledge or technology.

Documenting Your Peer Review

We anticipate that it will take a few hours to read, interpret, and comment on each project plan you are assigned as either a primary or secondary reviewer. Since each plan is about 35 pages-long, anticipate the time you need to prepare your review. The deadline to submit your review is the Thursday prior to your meeting. OSQR will compile your panel's preliminary reviews and distribute them to you. (Depending on the circumstances, your panel's reviews might be delivered to your hotel upon arrival.) You will also need to become familiar with the relevant National Program Action Plan (http://www.nps.ars.usda.gov).

Use the *Panelist Review of ARS Research Project Plan* forms for your comments. (Provided to you via e-mail.) Recognize that this is your preliminary peer review and is intended to prepare you for your panel discussion. These preliminary reviews are filed by OSQR, but are not given to anyone else in the Agency.

Take a look at the example of a peer review on the following page. Note the following tips for writing your own peer review:

- Clearly differentiate between substantive and minor criticisms.
- Provide suggestions for correction of problems that your panel considered substantive.
- Number your recommendations and always provide a rationale for each one.
- Write your preliminary review as if it were the final review, it cuts time in writing the final and eases its readability by others on your panel.
- When citing other research, provide adequate documentation. OSQR can assist you if needed.
- Address what the plan needs and use 3rd person statements. Avoid direct commentary that might be misconstrued as an attack on the individual scientists.
- If you discover that a portion of the plan requires reviewer expertise not represented on your panel, please immediately discuss your concern with your panel chair. He or she may consider getting an *ad hoc* reviewer's input at anytime prior to your panel's discussion.

Some Recommendation Guides:

Do: This project needs _____ equipment because….
Don't: The Panel is not sure whether the project has sufficient funds to purchase _____...
(Funding is not part of this review)

Do: This project would benefit from the expertise of Dr. _____ at the_____ ARS location. We suggest a collaboration between…..
Don't: Dr. _____ should be reassigned to _____ARS location…
(OSQR reviews do not assess such agency issues)

Do: The project is relevant to the National Program Action Plan….
Don't: The National Program Action Plan should/should not include _____ goals…..
(The Action Plan is established through a different process that may include Congressional mandate. It is not reviewed by OSQR panels)

Again, we understand that you have other important endeavors. We truly appreciate the time and effort you make available for this review.

Thank you.

An example of a well-written set of recommendations:

Adequacy of Approach and Procedures: Are the hypotheses and/or plan of work well conceived? Are the experiments, analytical methods, and approaches and procedures appropriate and sufficient to accomplish the objectives? How could the approach or research procedures be improved?

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1. The hypothesis that… condensing steam will inactivate bacteria on the surface of solid foods without causing thermal damage if the interfering air and water layers on the surface are removed by vacuum and the condensed steam is removed to evaporatively cool the surface… is scientifically sound and workable. Indeed, the group has developed and tested the technology with a pilot plant prototype and chicken pieces, which indicated a 2 log reduction of LM in initial studies. Further refinement will involve retrofitting the prototype to treat the whole carcass (surface, visceral cavity) and development of a field VSV pasteurization system. Additional studies will focus on ready-to-eat meats, specifically hot dogs (and the known LM hazard) and catfish, with both aspects under appropriate CRADAs. The former is a high priority research need for food safety regulatory agencies, and the contingency inactivation studies "in-package" (within plastic) should probably be elevated to practice in the proposal.

The portion of the proposal indicating the development of models and process simulations, towards determining the mechanism of VSV inactivation, is appropriate, but of lower priority in the overall project schema. Any modeling aspect should be focused on process delivery and eventual development and validation of performance standards to support food safety.

2. The controversial theory that "pasteurization" of heat-sensitive foods is accomplished by applied voltage or magnetic field and, perhaps, can be demonstrated with the incumbents' "uniquely modified RF heater" is the overall working hypothesis for this objective. This entire objective is very high risk, but the payoff is potentially high. The proposal articulates a clear, stepwise protocol. The modified RF "heater" appears to be designed to offset the often-stated criticism towards the non-thermal theories that precise measurements of the time-"temperature" history and its spatial variations are lacking.

Recommendations:

I. Objective 1- The proposal needs to incorporate a more specific explanation of the steps needed to determine the effectiveness of the VSV treatment. Will naturally occurring pathogen populations be known or established?

II. Objective 1– Although the primary focus of the research may be on reducing microbial populations on the surface of solid foods, the evaluation of the process should incorporate measurements of the process impact on product quality; color, texture, etc.

III. Objective 1– The portion of the proposal on models and simulation of the bacterial "destruction" process needs to be developed with much more specific information on the approach to be used and the outcomes to be achieved. The models should focus on process delivery and eventual development and validation of performance standards to support food safety.

Frequently Asked Questions

1. How much time should I expect to spend on the reviews?
Most reviewers spend 4-6 hours on each of their in-depth reviews. We encourage you to start your reviews early.

2. Can I recommend an ad hoc reviewer?
Yes, please discuss your ideas with your panel chair. Your panel chair will contact us and we'll solicit the ad hoc reviewer for you. We recommend giving ad hoc reviewers at least one month to submit their input to you. Ad hoc reviewers submit only written reviews. They do not attend the panel meeting.

3. Can we score the projects by objective vs. assigning one score to the entire plan?
No, the projects are designed to operate as one entity. Since you may have a different judgment on each objective, you should recommend ways to improve individual objectives and experimental designs in your review. The Action Class Matrix on page 9 gives you some guidelines for assigning a single score to a multi-objective plan.

4. If a project plan is scientifically sound, but is poorly written, should I nevertheless consider it a good plan? When scoring the project, how much weight is put on poor presentation?
Each project plan you review should demonstrate a high likelihood of success without requiring that you make inferences or assumptions. If the plan inadequately presents the information you need to apply the review criteria, we ask that you address the inadequacy in your peer review. Depending on the type of presentation flaw, you'll need to judge which action class is most appropriate. For example, a plan that lacks a logical flow from one experiment to another may still score better than a plan that lacks detail in the contingency and milestone sections. Our goal is a plan that is both scientifically sound and well-presented.

5. Can I call or visit with the research teams to discuss their project plans?
No, all the information you need to complete your review should be enclosed in the plan. If you have specific questions contact the OSQR Coordinator or Scientific Officer.

6. Can I establish collaboration with the scientists associated with these plans?
Yes, but we ask that you not reveal your involvement with the peer review in your discussions with them.

7. Once I get a response to my panel's recommendations from the research team, can I respond back?
No, unless your panel's average action class score resulted in a 'major revision required' or 'not feasible', the response from the ARS research team officially completes the peer review process. If the project received a 'major revision required' or 'not feasible' score, ARS will likely ask you to provide a second (final) review of the project.

8. ***Once the panel has finished is my job as a reviewer over?***
Not necessarily. If any plans in your panel received a 'major revision' or 'not feasible' and it is determined by management these plans should be re-submitted for review after revision, you may be

asked to review the revised plan. If you are contacted and agree to perform the re-review, this would be an ad hoc review (not panel). The re-review would occur approximately three months after the panel convened.

9. ***As a primary reviewer, can I complete the "Panel Recommendations" form after I return home from the panel?***

No. All “Panel Recommendations Forms" must be completed before the reviewer departs from the panel. Only under unusual circumstances will there be exceptions. The reason OSQR wants those forms completed before the panel disbands is so that all discussions, any differences of opinion by panelists, and initialing by the Panel Chair can be completed. OSQR notifies the scientists the results of the panel within a day or two after the panel is completed.