United States Department of Agriculture
Research, Education, and Economics
Agricultural Research Service

Handbook

Peer Review of Research Project Plans

ARS
Office of Scientific
Quality Review

This handbook provides guidance to ARS scientists in the preparation of a research Project Plan for Peer Review through the ARS Office of Scientific Quality Review.

August 2008

PREFACE

This Handbook replaces the "OSQR Manual" (500-1: Peer Review of ARS Research Project Plans). Appendix 13 herein replaces Bulletin No. 07-601: Postponement Guidelines. It is issued by the Office of Scientific Quality Review (OSQR) and is available from their web site (www.ars.usda.gov/osqr) in PDF format. Printed copies will be sent upon request. The text is formatted so as to facilitate printing in a two-sided format.

Inquiries regarding this Handbook should be directed to the Office of Scientific Quality Review.

Office of Scientific Quality Review
August 2008

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RESEACH PROJECT PLANS AS PART OF ARS SCIENTIFIC PROGRAMS

The ARS Peer Review Process is an essential part of the 5-year ARS research program cycle (Figure). Review was mandated by the Agricultural Research Extension, and Education Reform Act of 1998 (Appendix 1), which requires successful completion of peer review as a prerequisite to actual performance of the work. This handbook is intended to provide guidance as ARS researchers prepare project plans. *As such, researchers are strongly urged to read it through before developing a project plan.*

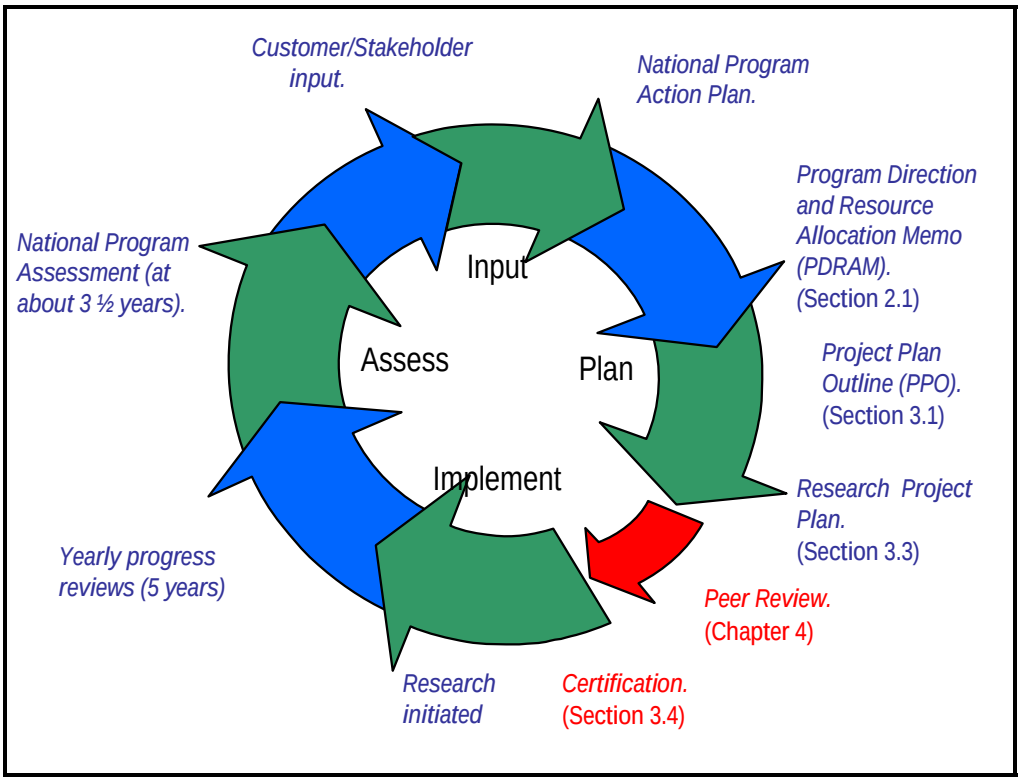

Figure. The 5-year ARS Program Cycle showing how project plans emerge following development of the National Program Action Plan (which may include Congressional mandates), peer review and certification, progress and monitoring of the work, and retrospective assessment of the National Program in preparation for a new program cycle.

While this outlines a general format for plans (Figure 2), the most important aspects of a highly rated plan are clarity, logical presentation, and ease of understanding. Project size and/or number of objectives and sub-objectives may make departure from the prescribed format necessary to achieve a clear presentation. *Researchers are, above all, to provide plans that are well-prepared, appropriately documented, logically presented, and carefully and thoroughly edited.*

The ultimate responsibility for quality in a project plan rests with the project team. The Office of Scientific Quality Review provides information on project plan development at scheduled online researcher briefings, through its web site (www.ars.usda.gov/osqr), at various ARS researcher gatherings, and through this handbook.

Outline of a "Typical"
Project Plan

Title and Investigator(s)	**1 page**	**(p. 11, App. 2)**
Signature Page	**1 page**	**(p. 11, App. 3)**
Table of Contents	**1 page**	**(p. 11)**
Project summary (250 words)	**½ page**	**(p. 11)**
Objectives	**1-3 pages**	**(p. 11, App. 4)**
Need for research	**1-2 pages**	**(p. 11)**
Scientific Background	**5-7 pages**	**(p. 12)**
Related Research & CRIS search	**1-2 pages**	**(p. 12)**
Approach & Procedures	**6-16 pages**	**(p. 12, App. 5)**
Physical and Human Resources	**½-1 page**	**(p. 12)**
Project Management & Evaluation	**½ page**	**(p. 12)**
Milestone Table	**as needed**	**(p. 13, App. 6)**
Prior Period Accomplishments	**2-3 pages**	**(p. 14)**
Literature Cited	**as needed**	**(p. 14)**
Past Accomplishments of Project Team	1-2 pages each	(p. 14)
Issues of Concern statements	as needed	(p. 15)
Specific Cooperative Agreements	as needed	(p. 15)
Appendices (letters plus other material)	as needed	(p. 15)

The bolded portions are sent to reviewers both as printed documents and as part of the complete electronic file as submitted to OSQR. To conserve paper, reviewers do not receive printed versions of the non-bold sections but they are included in their full electronic versions.

Figure 2. Basic organization of a "typical" Project Plan document showing the elements needed. Section references in parentheses indicate where further detail may be found in this handbook. While it is expected that most plans will follow this format, some changes may be made (typically in organization of background and approach sections to facilitate ease of understanding in large, diverse plans). Be aware, however, that radical departure from the format can complicate the task for reviewers seeking this information and lead to a lower score.

Success in Peer Review is a cooperative effort among many within the Agency. The National Program Staff (NPS), in cooperation with the Area Office, Research Leaders (RLs), and individual researchers, establishes objectives, outlining the research to be performed in accordance with Congressional mandates and customer and stakeholder input. As plans are developed the recommendations, informal review, and guidance of RLs, the Area Office, and others is important to development of a clear, well-prepared plan. Research teams, in response to the NPS-issued objectives, develop research plans detailing the work to be performed over 5 years. These plans are evaluated by a panel of external scientists who focus on three key elements of research planning:

(1) **Adequacy** of experimental approaches and procedures;
(2) **Probability of success** in accomplishing the project's objectives; and
(3) **Merit and significance** of the research proposed.

1.1 Office of Scientific Quality Review

The Office of Scientific Quality Review is responsible for implementing and tracking the project review process under the Associate Administrator for Research Operations. A Scientific Quality

Review Officer is appointed from the ranks of senior ARS scientists to serve a 2-year term in an oversight role of the peer review process and to certify completed project plans.

1.2 Peer Review and ARS Management

ARS' matrix management means that responsibilities for research development and management are shared between NPS and the Areas:

> Program Management (NPS), addresses the direction of national programs. National Program Leaders (NPLs) are responsible for developing the National Program Action Plan, determining national research priorities, and for allocating resources.
>
> Line Management (Areas), addresses issues of research staff, physical, and human resources. Areas have oversight responsibility for quality, implementation, and performance with regard to research project plans.

While, on the surface, these may appear to be compartmentalized responsibilities, the essence of matrix management is the cooperation from NPS through Areas to research teams and researchers to produce a clear, concise, and aggressive research program which addresses the most urgent and important needs for agriculture. A successfully reviewed project plan represents the effort of all (National Program Leaders, Area Directors, Center or Institute Directors, Research Leaders, Lead Scientists, and scientists) to produce a clear and effective research plan.

2
ADMINISTRATION OF PEER REVIEW

The ARS Peer Review Process can be seen in four stages:

1) Identifying Projects to be Reviewed;
2) Project Plan Development;
3) Peer Review; and
4) Response to the Peer Review.

If these steps are successfully achieved, the project is certified. This Chapter provides administrative guidance for this process.

2.1 Identifying Projects to be Reviewed

Projects for review are identified by National Program Leaders (NPLs) with input from scientists, Research Leaders (RLs), and Area Directors (AD). These discussions identify locations and scientists who can contribute to the National Program. A National Program Action Plan includes locations contributing to specific components within a program. The Program Direction and Resource Allocation Memo (PDRAM) outlines specific project objectives and sets a schedule for the development and review of the project plan. The initial list of projects to be reviewed typically (but not necessarily exclusively) will be based on category "D" projects coded to a National Program. In rare cases, a research team may be granted a postponement of the review of their plan, often on the basis of critical vacancies in scientific staff. Some short-term (less than 5 years) or service-based projects may be exempted from review. The current schedule for review of National Programs is at www.ars.usda.gov/osqr.

2.1.1 Postponing Reviews

Two criteria may allow postponement from peer review:

1) Vacancies or long-term absences in key scientific leadership positions; and
2) Significant reorganization, initiation, or redirection of a project.

Requests for postponement of peer review of a project plan are granted only under exceptional circumstances. The Lead Scientist or Research Leader (RL) typically initiates a request, which should, in general, be prior to receipt of the PDRAM (Appendix 13).

2.1.2 Exempting Projects from Peer Review

Under certain circumstances, a project may be exempt from the peer review process. These are handled on a case-by-case basis by Area Management and the relevant NPL. Decisions are subject to review by the Associate Administrator for Research Operations.

2.1.3 Significant Change Necessitating New Review

Changes to the objectives or approach in a project plan may necessitate new (*ad hoc*) review of the altered portions of a plan.

Significant change is any alteration 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) A new research approach that was not in the original plan;
b) Addition of one or more newly-created objectives to the plan; or

c) Inclusion of not previously reviewed objectives from other projects.

It is the RL's responsibility to ensure that research is conducted as originally outlined. Changes which impact the plan as noted above should be discussed with the Center, Institute, or Laboratory Director, Area Office, and National Program Staff (NPS) and may necessitate a new PDRAM and review.

2.1.4 *Ad Hoc* Reviews

ARS recognizes that research agendas are dynamic. 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 significantly changed, may require an *ad hoc* review if the relevant panel review session is more than 2 years away (See 2.1.3).

Ad hoc reviewers are knowledgeable scientists within the discipline who, typically, provide written comments. 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. Where similar plans are scheduled for *ad hoc* review, the Office of Scientific Quality Review (OSQR) may assemble an *ad hoc* panel to perform the review. *Ad hoc* panels generally are convened through a web-based meeting tool, but may also be assembled for an in-person meeting. Such panels provide responses in a manner similar to regularly scheduled review panels.

2.2 Project Plan Development

Preparing the project plan is a multi-step process. The project team (Lead Scientist and research team), RL, and Center/Institute/Laboratory Director share the responsibility for the creation of a quality project plan. The foundation for the project plan is the PDRAM which provides some background and justification for the new project, sets objectives, and allocates resources related to overall funding and personnel.

In response to the PDRAM, the project team through the leadership of the Lead Scientist prepares a Project Plan Outline (PPO) which is approved by the RL, Center/Institute/Laboratory Director, AD, and NPL. This ensures agreement on the overall research design and approach, and serves as the basic outline that can be used to develop the more detailed final project plan. Communication among the project team and with RL, Center/Institute/Laboratory Director, Area Director, and NPL is critical to this process. *Quality project plans are well-prepared documents that describe the approach, impact, collaborations, and capabilities of the team to address the stated objectives.* Instructions for preparing the PPO are supplied by NPS with the PDRAM (Appendix 12).

Competitive or Non-Competitive Review?
Review of ARS Project Plans is not competitive. The panels do not award research grants among several potential research groups. Rather, the review is an examination of the scientific quality of a prospective plan. Budget and other resource-related evaluations are not considered.

However, reviewers typically have experience in competitive panels for USDA or other agencies. Thus, they carry with them a sense of quality based on the highly competitive plans seen elsewhere. That understanding can significantly influence their notions of an acceptable research plan.

Further, it is not unusual or unexpected for panelists to gauge their understanding of plan quality and Action Class scores against the other plans they review in the panel. In this light, several strong plans in a panel can "raise the bar" for what is expected to achieve a high score.

In short, this review is not competitive, but researchers are strongly urged to treat it as if it were!

2.3 Peer Review Outcomes

Peer review by OSQR-appointed panel or *ad hoc* reviewers results in both quantitative and qualitative evaluations. Quantitative response is in the form of Action Class Scores (see section 3.4.1 for description of Action Classes) provided by each reviewer. (The overall action class for a plan is the average of all individual scores.) Qualitative review is in the form of a consensus narrative detailing specific review comments and recommendations. OSQR distributes review results to the research team's AD, with copies to the National Program team. These are forwarded to the research team through the line management. Also included are instructions for revising and responding to reviewers' comments.

2.4 Revision and Response to Peer Review

The Administrative Procedures Act and the Federal Advisory Committee Act, require ARS to make a reasonable effort to use the advice received from peer reviewers and to provide response to that advice. It is for this reason that a revised project plan, regardless of the Action Class Score received, be accompanied by a point-by-point response to identified panel recommendations.

2.5 Certification

The Scientific Quality Review Officer, on behalf of ARS, certifies that the response to the peer review process is complete and that revisions to the project plan are satisfactory. Instructions are contained in the certification memo to submit the AD-416/417 as the initial step in the implementation of the project.

3
PROJECT PLAN DEVELOPMENT AND REVISION

This chapter outlines the steps to preparing a project plan. An excellent plan persuades reviewers of the importance of a particular body of research, the wisdom and creativeness of the proposed approach, and the expertise of the project team.

There are two steps to preparing a project plan (See 2.2). First is development of the Project Plan Outline (PPO), lists the objectives and an overview of the intended approach and procedures. This serves as the basic outline to be used in the second step of developing a full, detailed project plan.

3.1 Project Plan Outline

The PPO is required by the National Program Staff (NPS) to ensure there is agreement among the research team and NPS on objectives, approach, and procedures. Guidelines for preparation of the PPO are supplied by NPS (Appendix 12).

> **The PPO is ONLY an outline.** *Review panels expect to see considerably greater detail in project plans.* The descriptions in a PPO are sufficient ONLY to provide a general overview for the National Program Leader. Be sure that your plan presents a clear, detailed set of approaches similar in detail to the methods section of a scientific paper.

3.2 Conflict of Interest List

A Conflict of Interest (COI) List for each Category 1 and 4 scientist (i.e., all listed on the project cover page) on the project must be provided as a separate document. For each, provide a list containing the names of those with conflicts and the nature of that conflict. Conflict of interest relationships include: co-author; collaborator; supervisor or subordinate within 4 years; student or post-doctoral relationships within 8 years; or a potentially direct financial benefit from the research. If in doubt, contact the Office of Scientific Quality Review (OSQR).

An example COI List can be found on the OSQR Web site at www.ars.usda.gov/osqr. While a tabular listing is requested, it is not essential to conform to this style. OSQR will accept copies of similar conflicts forms for other programs, such as those required by the National Research Initiative, providing that they are developed using criteria no less than those stated here. In general, COI Lists are due shortly after receipt of the Program Direction and Resource Allocation Memo (PDRAM). See the Schedule of Peer Reviews at the above web site for the precise date for your National Program.

3.3 Project Plans

The project plan is a stand-alone document that enables reviewers to evaluate the merit, feasibility, and relevance of the proposed research. It should frame the research need, objectives, hypotheses (or non-hypothesis research goals), and expected outcomes for a defined program of research. The plan details experimental approaches, procedures, contingencies, and collaborations necessary for accomplishing the proposed research. Clear, concise, and organized communication demonstrates to reviewers the team's ability to achieve their objectives. Thus, well-written project plans provide tangible evidence of the quality of science within ARS.

Plans are, typically, for 5 years, and are intended to be dynamic. Thus, as research proceeds, the intended plan may need to be altered. Intermediate research results and discoveries may require the reformulation of hypotheses, experimental designs, or milestones. Where these changes are deemed significant, review of new portions of the plan may be needed (See Section 2.1.3).

3.3.1 Project Plan Formatting

While the size and scope of a plan may dictate a particular organization to provide ease of understanding, the basic formats below aid in tracking and managing plans in the peer review process.

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

Text Headers should contain Lead Scientist last name flushed left, page numbers flushed right, please do not show a page number on the cover page.

Footer should contain a version date flushed left and file name flushed right. The version date should reflect the most recent changes.

Page Limits The page length for the project plan, including the sections from Objectives through Approach and Procedures (but not including Literature Cited), varies from 15 to 30 pages depending on the number of scientists (SYs) as follows:

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

I don't have enough pages!
Many tell us that they simply do not have enough room to adequately explain their plan. In fact, a majority of project plans use fewer pages than they are allotted. Further, reviewers frequently tell us that we could reduce the page limits further.

The key to success is not length, but a clearly set out, logical, narrative that provides a concise and authoritative understanding of the basis for the work and the path to success. Achieving this requires careful editing, thoughtful writing, and frank critical review by colleagues (before reviewers see it).

The essential questions, knowledge gaps, methods, and anticipated results should be clearly understood from the summary information in the opening pages of your plan (before the Background or Approach and Procedures sections). Panels understand that there are page restrictions and, typically, are led to ask for more information because the opening portions of the plan are unclear.

Extra Pages
Two to four additional pages of tables, figures, diagrams, etc. may be included. The Milestone Table is not included in the page limit. For plans with many SYs and objectives, it may be necessary to alter the overall format to achieve a clear, readable result (as, for example, moving background sections to precede the approach for the objectives where they are relevant).

3.3.2 Project Plan Submission

Project plans are submitted electronically through the Area Office. Plans should be sent to the Area Office as Word files. That office will convert the plan to PDF format for transmission to OSQR. The exception is the signature page for the *post* project plan. For this, once the plan is ready for certification, a printed copy with the original signature of the Area Director is required.

3.3.3 Project Plan Components and Instructions

This section provides guidance on the elements in a project plan, along with an order for their presentation. While all of this information is needed, each plan is unique and researchers are reminded that the principal aim is to present a logical, easily readable, document. *Do not treat these as "boxes" on a government form*. Similarly, assigning responsibility for writing of sections or subsections to colleagues and assembling the parts without careful editing for consistency of message can lead to a poor review outcome.

Cover Page – See Appendix 2 for an example.

Signatures – Separate signature pages are required for Pre-Review, Post-Review, and Re-Review of the project plans (Appendix 3). *Please note the statements that accompany signatures which imply signatory responsibility for the content of the project plan.*

Table of Contents – Include the major headings in your plan, as suggested in this section. The order may be altered to suit the scope and size of your plan; and to enhance clarity.

Project Summary – Like the abstract of a paper this should be summarize the project in about 250 words (10 to 12 sentences). The text should aim at a general audience and provide a clear description of the overall goals, essential questions/knowledge gaps, general approach, and expected outcomes or benefits of the research. It is crucial that the reader gain a clear, but brief, knowledge of your project here to enable them to better understand the context for the greater detail provided later in the document.

Objectives – The objectives should be as in the PDRAM or the subsequently-approved PPO. Accompanying this should be one to three paragraphs illustrating the linkages and general bases for this set of objectives to be part of this plan. This provides a framework for the objectives and a clear context that will guide the reviewer. A figure to illustrate the relationships among objectives, overall goals or outcomes, and staff can be most valuable and is strongly encouraged (Appendix 4). Such a figure or diagram can be useful in refining the prior Project Summary section.

Need for Research – This short section (1-2 pages) summarizes the nature of the problem to be addressed, its relevance to the National Program Action Plan, the anticipated products, the potential benefits, the customers/recipients of the research, and, where appropriate, their involvement. Rather than detailing these as individual subsections, including the information in a single narrative will provide a clear picture while conserving pages. Build upon, rather than repeat, the project summary.

Scientific Background – Do not repeat information from the previous sections. The "Scientific Background" section should focus on presenting the relevant (key) literature and identifying the

gaps in knowledge the research addresses. This is, primarily, a discussion of the gaps in knowledge that the research is intended to address. The literature cited should be sufficient to allow reviewers to conclude the investigators have *current* knowledge and understanding of the field of study, not a comprehensive review. This should be no more than 1/3 of your allowed pages in length.

Results of past projects or other preliminary results of the investigators relevant to the current project plan may also be presented. *If applicable, try to show how your project relates to other ongoing research within and outside ARS.* It is not necessary to cite every ARS Research Project: only those relevant. Some of these projects might be discussed under collaborations in the Approach and Procedures section. It is important that peer reviewers see that investigators are aware of others performing similar research.

What is "Appropriate" Detail?
The level of detail in a Project Plan is a balance between what is needed to understand the plan and the space available. There is no set formula or guide. Very clear, well-written, and sound hypotheses, goals, and general procedures go a long way towards assuring reviewers that the plan is sound. *r.*

Lack of clarity may have a negative influence, however. A panel may request more detail because the overall flow and logic is not clear. As scientists, their solution to a lack of understanding is, often (and understandably), to seek more data.

Lastly, some panels have said that although a plan is clear, it needs more detail for them to feel that they have fully discharged their review responsibilities. In such cases they may ask many questions but provide a somewhat higher (Moderate or Minor) score thus acknowledging that they think the basic core is sound. This, of course, assumes that the plan is at or near its page limit…thin plans that are far shorter than their page limits generally fare poorly in review.

So, in general, plans should be clear, well written, and easy to comprehend. Reviewers are aware of the challenges of space constraints.

Related Research – This very important section shows the relationship of the research to other efforts within and outside USDA. Do not repeat detail that may be in the prior section. This includes the CRIS search. If not included in the scientific background you may make this a separate section. The purpose is to show linkages and relation to other, related and similar, work. This is particularly important where there are related or analogous ARS projects. As well, if there are significant efforts outside of ARS, demonstrating your knowledge and/or cooperation with them can be important to note here or elsewhere (For example, as a collaborator in the Approach and Procedures section). See http://cris.csrees.usda.gov for information on doing a search for related USDA research.

Approach and Research Procedures – For each objective, elaborate on the following:
Experimental Design – Describe in appropriate detail the experimental design and the related procedures. State, if applicable, the question (hypothesis) that will be tested and how experimental results will be evaluated (Appendix 5). *Detail should be sufficient to inform the reviewer of the nature and appropriateness of the planned experiments and the competence of the project team.*

Contingencies – Discuss specific approaches and experimental options that will be undertaken if the research plan proceeds faster or slower than anticipated, or if early plans prove impractical or unsuccessful. (See Box: Contingencies).

Collaborations – Describe collaborations with other scientists to accomplish portions of this research. These should include collaborations with scientists within and outside ARS. Collaborations should be documented by a letter from the scientist that specifically details the collabora-

tion, how they will contribute to the project, and the level of commitment anticipated. A letter assures reviewers that the collaboration is in place.

Physical and Human Resources – Describe the major physical resources (i.e., facilities, major instrumentation and equipment, etc.) that are available to accomplish the research. Show the number (FTE) of project personnel (e.g., post-docs, technicians, graduate students) available for this project. While these may note be listed elsewhere this is important for demonstrating that there are sufficient persons to accomplish the proposed work.

Vacancies in the research team should be addressed in this section with a discussion of the anticipated expertise and discipline and the expected contributions of this person to the project.

Contingencies

In a memo to Area researchers on developing a project plan Dr. Steve Shafer, former Midwest Area Director, gave the following useful guidance about contingencies.

> This is a frequently misunderstood section, and frankly, I think it has evolved since we started doing these project plans…This is definitely not a place to describe work you would do if you get new funding, either appropriated or grants. This project plan should describe what you will do over the next five years with the specific funds currently appropriated by Congress for the work. Contingencies should describe what will drive your choices of direction as you get results. Another way to think about this might be: What would make us decide to modify our [objectives or] sub-objectives?
>
> A very good approach to Contingencies is to link the section *explicitly* with Milestones that you specify in the Milestone table that comes later in the Plan…If you create good Milestones that serve as decision points along the way, then Contingencies are the decisions that come *as a result of* achieving those Milestones. For example, a good milestone may be completion of a particular experiment that provides important data in the general progress of the plan. You may not know exactly how that experiment is going to turn out (that's why they call it "research", right?), but getting those data is a key event. Once you have that data set, you know whether to choose one course of action and sequence of next experiments, or some other course of action. Approached this way, contingencies are the options you will choose among when a milestone is achieved. This is a very effective way to address both Milestones and Contingencies and shows the reviewers additional depth to your thinking.

To this we would add that Contingencies may also be options you might consider should work proceed differently (faster or slower) than you expect. They are not what you would do should a hurricane destroy your laboratory (although we all know that can happen!).

Project Management and Evaluation – It is particularly important for projects with several researchers to describe the overall management and evaluation plan. This section provides a basis for demonstrating how the project team functions and makes decisions.

Milestones Table – (Does not count against page limit) This illustrates intended progress through the project plan. Reviewers look here to understand the path of the project. Milestones are points where significant accomplishments can be documented. (See Box: What is a Milestone?) These are identified for each objective or subobjective and hypothesis. The table also describes how progress will be documented through products (e.g., scientific papers, databases, germplasm releases, technology transfer, CRADAs). (Appendix 6)

What is a Milestone?
In ancient Rome the Emperor Augustus placed a gilded pillar at the center of the Forum, the *Millarium Aureum*. This marked the starting point for a system of roads, all of which led to Rome. The roads were marked every mile (mille – Latin for 1,000 – the distance a Roman Legion covered in 1,000 paces) with a stone *millarium* or milestone. The milestones had several purposes. By them travelers knew that they were on a Roman road, had a standardized sense of the distance between two points, and these markers showed them just where in their travels they were in relation to the Eternal City.

A research milestone is the measure that tells you, as a researcher, that your work is progressing. It is not a goal or a research accomplishment, nor is it a specific action (such as the purchase of a piece of equipment). Rather, it is how you can tell that things are being accomplished. It can be in terms of numbers of samples processed, specific experiments begun or completed, or any other measure you might use.

Milestones are measures of progress (to the Romans, distance), thus, it may be that you, as a research scientist, do not always estimate them accurately at the outset. Hence, as you arrive at one it may be necessary to revise future milestones to more accurately capture and track your work. Thus, the milestone table of OSQR Research Plans is intended to be dynamic and allows for the adjustment of milestones into the future to meet the realities of research while enabling you, as the researcher to assess your progress. (Having said that, the Agency does not want its scientists casually changing prior project milestones to match what was actually achieved during a given year. That would defeat the purpose of having milestones. See your Area for guidance on when and how to appropriately revise project milestones.)

In summary, when you construct your research milestones, think in terms of those steps along the path (indicators of progress) rather than the goal at the end of your journey.

As the work proceeds, milestones may need to be adjusted. Researchers should consult with the Area Office about the appropriate mechanism for this. OSQR does not monitor changes to milestones after certification (See Section 3.3).

Accomplishments from Prior Project Period – (Does not count against page limit). This section summarizes the research accomplishments from research by this team, relevant to this project plan, and which has terminated within the last 2 years. The purpose of this section is to provide the reviewers greater detail on prior work (which may have been briefly described in the background). The following information should be included:

Terminating project number, title, and project period; Investigators; and Project accomplishments and impact; including: Summary of the most significant accomplishments and their related impact, including publications; and Description of how the objectives and accomplishments relate to the current plan.

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 and year, they must be listed alphabetically here. Any citation format accepted by a peer-reviewed scientific journal that includes all authors, article title, and complete page numbers may be used.

Past Accomplishments of Investigator(s) – Begin each investigator's past accomplishments on a new page. In one single-spaced page or less for each, 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 this with a list of not more than 20 of their major publications. These should be formatted as in your Literature Cited.

Issues of Concern Statement – Address these, as appropriate to the plan. For those issues that are not applicable, list the title and note as "not applicable." Where appropriate, identify the necessary reviews and/or permits, and give status and ID number or note that such have been requested.

- Animal Care
- Endangered Species
- National Environmental Policy Act: Research teams should consult their Area Environmental Specialist regarding the potential environmental impact of their research. ARS research projects are typically considered Categorically Excluded under the National Environmental Policy Act regulations. Project plans could then include the following statement: "On the basis that this Federal project is undertaken for the sole purpose of conducting research, this project is categorically excluded, in accordance with the National Environmental Policy Act (NEPA)."
- Human Study Procedure: Where appropriate (as, for example, plans in the Human Nutrition National Program) should document their compliance with regulations and policies regarding the use of human subjects.
- Laboratory Hazards
- Occupational Safety and Health
- Recombinant DNA Procedures: The IBC license number must be included in the project plan if there is work with recombinant DNA.
- Homeland Security: See the following web sites:
  http://www.arsnet.usda.gov/ohs/
  http://www.arsnet.usda.gov/OHS/biosafety/materials_toxins.htmI
  http://www.arsnet.usda.gov/OHS/biosafety/SelectAgents.doc)
- Intellectual Property Issues (see details in Appendix 8)

Existing Specific Cooperative Agreements (SCAs) – An SCA related to the proposed Project Plan should be described in the Approach and Procedures section under the appropriate objective. The collaboration associated with the SCA should be documented either by a letter or an appended copy of the SCA.

Appendices – On a new page, list appendices by page number. Letters of collaboration are to be included in the appendix. Include scans of collaborator letters at the end of the project plan appendices.

3.4 Response to the Peer Review

Following review, OSQR sends results to the Area Director. Two documents accompany this. First, are the panel's consensus recommendations (with expanding text boxes inserted for the scientist's response). Second, is the "Action Class" Rating Worksheet (See Appendix 9: Action Class Worksheet) that lists each reviewer's score and the overall rating of the project plan. Responses are required wherever an "ARS Response" text box has been inserted by OSQR. When revising a project plan be aware that there are *NO PAGE LIMITS* for the revised plan.

3.4.1 Action Class Rating

The possible Action Class Ratings and the level of response are as follows:

No Revision Required. An excellent plan: no revision is required, but minor changes to the project plan might be considered.

Minor Revision Required. The project plan is very good, and requires only minor clarification or revision to increase quality to a higher level.

Moderate Revision Required. The project plan requires changes or clarification revision to the work on one or more objectives, perhaps involving alteration of the experimental approaches, in order to increase quality to a higher level. The project plan may also need some rewriting for greater clarity.

Major Revision Required. There are significant flaws in the experimental design and/or approach or a lack of clarity which hampers understanding. Significant revision, rewriting and re-review are essential.

Not feasible. The plan is not feasible as proposed. Deficiencies may exist in approach, experimental design, presentation, or expertise that make the plan, as presented, unlikely to succeed, poorly conceived, or impossible to assess.

3.4.2 How to Respond

Panel Recommendations will contain expandable text boxes labeled "ARS Response" for answering the queries and recommendations of the panel. Responses are needed ONLY where a response box is present. In most cases, scientists review and respond to the guidance provided. (See Appendix 10: Sample Peer Review Recommendations and ARS Responses) When comments involve recommendations or questions about project objectives, NPLs share responsibility for formulating the response.

There are no page limits for the revisions, but content and clarity are preferable to volume. Revised text should focus on the comments/recommendations and be of appropriate length. Responses must clearly indicate which components of the recommendation(s) were adopted, indicate if alternative changes were made, and if applicable, the rationale for not accepting a recommendation. A suitable response includes commentary or answer to the stated issue and notation (i.e., page number) where any changes based on this issue appear in the text. In the body of the plan revisions should be highlighted in **bold**.

While all recommendations must be carefully considered, there is no requirement that all be incorporated. It is entirely acceptable to disagree with a panel recommendation. *However, if a suggestion is not taken, appropriate justification is needed.* The response should be professional and convey a respectful difference of opinion.

Once the project plan has been revised, Lead Scientists obtain approval from their RL, and Center, Institute, or Laboratory Director. The revised project plan, and the ARS response form are then forwarded to the Area Director for approval. The plan and responses are then forwarded to OSQR with copies to NPS.

3.4.3 Post-Peer Review Signature Page

The post-peer review signature page is used once the project is ready for certification. Signatures are required of the RL; Center, Institute, or Laboratory Director; and Area Director (or their designee). 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. See Appendix 3 for statements that must appear on this signature page.

3.4.4 Action Classes and Actions

The initial review of a project plan is analogous to the review of a paper by a peer-reviewed journal. Following review, panels may deem the plan sufficient (No Revision) as presented or provide guidance to the Scientific Quality Review Officer (SQRO) for specific issues (Minor or Moderate Revision scores). Alternately, a panel will reevaluate the plan following response and (perhaps extensive) revision by the research team (Major Revision or Not Feasible scores).

No, Minor, or Moderate Revision Scores

Plans receiving an Action Class rating of "No Revision", "Minor Revision", or "Moderate Revision" follow the above (Section 3.4.2) procedure and, once complete, are approved and certified by the Scientific Quality Review Officer.

Major Revision Scores

If the Action Class after initial review is "Major Revision," the plan must be revised and submitted for re-review by the dates indicated in the notification of the review outcome. Response is as noted in section 3.4.2 above. Any change to the plan objectives must be coordinated between the Area and NPS and may necessitate issuance of a revised PDRAM. Revised plans will be re-reviewed by the panel and provided a second Action Class score and consensus review comments.

Not Feasible Scores

For Action Class scores of "Not Feasible", the Area Director, Center, Institute, or Laboratory Director, RL (if applicable), Lead Scientist, and NPS collaborate to determine the appropriate course of action. It is presumed that, in general, these plans will be revised (Section 3.4.2), but final decision is at the discretion of NPS and the Area. Revised plans will be re-reviewed.

Panel Re-Review

Re-review is conducted by the original panel who are asked to assess if the revised plan adequately addresses concerns stated in the original review. Panels may not raise new issues that were not stated in their first review unless introduced in the revision. Re-review meetings typically are held 2 to 3 weeks after the due date for revised plans. Panels are discharged at the conclusion of a Re-review meeting and are not available for further meetings or review.

4
COMPONENTS OF PEER REVIEW

4.1 Panel Chairs and Panelists

Peer reviewers are scientific, technical, or industrial experts possessing relevant and extensive knowledge and experience. Participants are from outside of ARS and are free of conflicts of interest with regard to projects they review. On rare occasions, ARS scientists may serve as *ad hoc* reviewers or panelists.

4.2 How Panels Are Selected

The Office of Scientific Quality Review (OSQR) is responsible for selecting panel chairs, guiding panelist selection, and scheduling reviews. Panels are assigned groups of projects based upon input from the National Program Leaders (NPLs). Final decision on panels is the responsibility of OSQR.

Nominations for chairs are gathered from a wide array of sources, including ARS scientists or administrators, the National Program Staff, Deputy Administrators, and Area Directors. The Scientific Quality Review Officer (SQRO) selects the panel chair and may invite persons not otherwise suggested. Issues of expertise, geographic breadth, and gender or ethnic diversity are considered. Panel chairs receive an orientation on the peer review process, and background on the National Program.

4.3 Responsibilities and Administration

The efforts of panel chairs and panelists are essential to a successful peer review. Thus, significant effort is taken to assure that highly qualified individuals are invited to chair panels and to serve as panel reviewers.

4.3.1 Panel Chairs

Panel chairs select their panels, assign review responsibilities, and facilitate discussions. Candidate panelists are examined by OSQR for conflicts of interest (using a variety of resources, including the Conflict of Interest Lists provided by Lead Scientists). A final proposed list of panelists must be approved by the SQRO. The Officer's approval considers: qualifications and research activity; conflicts of interest; geographic diversity of the panel; affiliation; and gender, race, and ethnic balance.

Panel chairs are charged with ensuring review quality, enforcing procedures, moderating panel discussions, and validating their panel's final recommendations. After review, the chair provides a statement summarizing the review. The identity of the panel chair is part of the OSQR public record.

4.3.2 Panelists

Panelists assess the scientific and technical quality of research project plans. While their recommendations are not binding upon the Agency, their insights and suggestions are carefully considered, ensuring the quality and credibility of ARS' overall scientific program. All panelists sign a Confidentiality Agreement (Appendix 11) to protect potentially sensitive information included in ARS research project plans. The identity of panelists is not part of the OSQR public record.

4.3.3 Panelist Preparation

Preparing panelists is an important part of the peer review. Essential to their work is a clear understanding of the unique nature of this particular review. This includes differentiation of this ARS review from competitive reviews, its similarity to manuscript review, the nature and origin of plan objectives, and the role of stakeholders, Congress, and others in setting research directions.

Conflicts of Interest

Peer reviewers who have a conflict of interest with a particular plan are excused from all considerations of that plan. Final decision on conflicts rests with the SQRO in accordance with the following guidelines. Panelists may not have a direct institutional affiliation with the research team or have direct financial interest in the outcome of the research. In addition, conflicts include the following relationship with a member of the research team in the preceding 4 years: research collaboration (including sharing of research grant responsibility), or co-authorship. A direct student or postdoctoral relationship (including advising) with a member of the research team within the preceding 8 years is also considered a conflict of interest.

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 must agree to not copy, quote, discuss, or otherwise use material from the proposal outside the panel review process.* (Appendix 11)

Reviewer Training

Panelists receive both written and detailed web-based training on the OSQR peer review process. This includes an overview of the process and its unique aspects. A presentation by NPLs introduces reviewers to the relevant National Program Action Plan and the scope of projects being reviewed.

4.4 Release of Information

Deliberations of the panel are confidential. Recommendations represent the consensus views of the whole panel, are completed during the meeting, and validated by the panel chair before delivery to OSQR. The Officer assures that recommendations are clear, complete, and reflective of the Action Class Score. Panel Recommendations and the Action Class are then transmitted to NPS and Areas along with guidance on the timing and appropriate actions for response (See Section 3.4).

4.5 Re-Reviews

A re-review is a second peer review of the project plan performed by the original panel (see Section 3.4). Re-reviews are the expected corrective action when plans receive "Major Revision" or "Not Feasible" Action Class. *No other avenue to reconsider a score exists.* The research team is typically provided ten weeks to revise the plan for re-review by the panel. Dates for receipt of revised plans are firm and cannot be extended. If not officially postponed, plans not received in sufficient time to enable review by the panel will be deemed to have failed Re-review.

4.6 Panel Reports, Distribution of Scores

Each panel chair provides a statement summarizing the activities of their panel, general observations, and any recommendations for ARS with regard to the review process or the National Pro-

gram. Statements become part of a report that includes demographic information about the panel and the distribution of scores. These reports are available to ARS employees upon request.

4.7 *Ad Hoc* Reviews

Ad hoc reviews are solicited outside of a regularly scheduled panel for the evaluation of project plans that are new, have been postponed, or have been 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 through their Area Director (See Section 3.4).

5
ROLES AND RESPONSIBILITIES

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. Updates on the Peer Review Process are provided to the National Agricultural Research, Extension, Education, Economics Advisory Board, the Office of Management and Budget, and others, as requested. The Administrator's Office represents ARS and appoints the Scientific Quality Review Officer (SQRO).

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

5.2 The Office of Scientific Quality Review

The goal of the Office of Scientific Quality Review (OSQR) is to create an environment in which ARS project plans receive objective, fair, and rigorous external peer review. OSQR manages the Peer Review Process, including policies, processes, and procedures, and has autonomy to establish processes and goals for the peer review. OSQR personnel report to the Associate Administrator for Research Operations and maintain strict independence, both from the National Program Staff (NPS) and the Areas.

5.2.1 Scientific Quality Review Officer

The SQRO is a collateral duty position to provide professional oversight of Peer Review and panel operations. The SQRO enforces Agency policy and requirements, evaluates panel results, and transfers peer review recommendations.

5.2.1 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. The Coordinator is responsible for communicating and enforcing Agency policy and requirements; oversees and supervises OSQR staff; performs analyses of review results; and collaborates with the SQRO on issues of communication, training, policy, and procedure.

5.3 Area Director's Office

The Area Director (AD), Associate AD and/or Assistant AD work with the Research Leader (RL) and the Center, Institute, or Laboratory Director in assuring timely completion of the project plan. The Area Office also works with NPS to ensure that the Project Plan Outline (PPO) objectives and approaches are consistent with the National Program goals. They also work through line managers to provide direction and instruction in addressing the recommendations and suggestions of peer reviewers. The Area Program Analyst (PA) is the point of control on proper execution of peer review policies and practices and tracks and monitors deadlines to ensure timeliness. Area Offices set and administer internal review procedures and practices to assure that plans are complete and that they meet high standards of technical merit and written clarity. While changes to objectives require concurrence of the National Program Leader (NPL), alterations to milestones are approved by the Area Office.

5.4 National Program Leader/Deputy Administrator

NPS, including National Program Leaders and Deputy Administrators, provide programmatic direction to lead scientists through line management. National Program Teams develop Program Direction and Resource Allocation Memos (PDRAMs) in consultation with the Area Office, RL, and Lead Scientist. National Program Teams review planned research to verify adherence to the Action Plan and programmatic direction. They provide recommendations to OSQR for panels, and provide materials and information about the National Program to panelists. Any changes to project objectives must be approved by the relevant NPL.

5.5 Research Leader, Lead Scientists, and Research Team

The Lead Scientist works with the 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. The Lead Scientist/RL create the PPO and research project plan according to programmatic direction from NPS. The Lead Scientist submits the project plan in a timely manner to ensure adequate opportunity for internal review. After initial panel review, the Lead Scientist/RL review recommendations and make appropriate modifications, submitting them to the Area Director for review and approval.

5.6 ARS Focus Group on Peer Review

The ARS Focus Group on Peer Review provides a valuable conduit for communication between OSQR and ARS scientists to promote the effectiveness and enhance the quality of the ARS Peer Review Process. A representative from each Area, NPS, and the Area PAs serve on this group. They bring forward and discuss a variety of concerns related to project plans and peer review on behalf of their Area colleagues. Where appropriate they make recommendations on how to address issues. Thus they comprise an important and valuable mechanism for airing peer review related issues. The chair of the Focus Group is appointed by the Associate Administrator for Research Operations from among their membership.

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
DA	Deputy Administrator
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
PA	Program Analyst
PDRAM	Program Direction and Resource Allocation Memo
PPO	Project Plan Outline
RL	Research Leader
SCA	Specific Cooperative Agreement
SQRO	Scientific Quality Review Officer
SY	Scientist Year (may also refer to an individual as a "Lead SY")

GLOSSARY

Action Class: Action Classes refer to the degree of revision peer reviewers believe project plans require. These provide an overall assessment of the quality of project plans.

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

Agricultural Research Information System (ARIS): An electronic system for the filing and retrieval of information about individual agricultural research projects. All ARS research projects are part of the ARIS and are assigned an ARS research project number (often incorrectly referred to as a "CRIS number"). See also: "*Research project.*"

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 ARS individual responsible for the proper conduct of an extramural research project.

Biohazard: Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), parasite, vector, biological toxin, infectious substance, or naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing: (1) Death, disease, or other biological malfunction in another living organism or deterioration of food, water, equipment, supplies, or material; 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; and 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 af-

ter 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); and 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 Program Leader (NPL).

Extramural Research: Research or research-related services from organizations or individuals outside ARS (e.g., through Specific Cooperative Agreement, contract, or grant).

National Program: The National Program in which an ARS Research Project has its greatest focus. Projects also may be related to other National Programs on a contributory basis.

National Program Action Plan: A document which addresses: 1) Rationale and purpose for a National Program; 2) The National Program's background; 3) National Program components; 4) Anticipated products and/or potential benefits over 5 years; and 5) Research objectives by program component. The document incorporates issues raised by Congress, stakeholders, and researchers (ARS and non-ARS) associated with a particular National Program.

National Program Code: The National Program in which an ARS Research Project has its greatest focus. Projects also may be related to other National Programs.

National Program Leader (NPL): See National Program Staff.

National Program Staff (NPS): More properly, this is the Office of National Programs (ONP). This staff serves the Administrator of ARS in developing and coordinating research plans and strategies on a national basis. The ONP, through its National Program Leaders (NPLs) sets National Program directions, establishes priorities, and allocates resources, in consultation with Area Directors, stakeholders, and scientists.

Office of National Programs (ONP): See National Program Staff.

Panel Chair: The OSQR-appointed facilitator and manager of a peer review panel. See Chapter 4 for description of the Chair's selection and responsibilities.

Peer Review: A process by which independent reviewers assess a research project plan for its scientific and technical quality and suitability of approach in an area of their expertise.

Peer Reviewer: An individual designated as qualified and capable of independently and critically assessing the scientific and technical quality of a research project plan, and who is free of real or perceived conflicts of interest (See Chapter 4).

Panel Recommendation: A document from a peer review panel that contains a critical review of an ARS research project plan. Its recommendations contain input from all members and reflect the consensus recommendations and comments of the panel.

Primary Reviewer: The lead peer reviewer assigned to perform a comprehensive and extensive review of a particular research project plan based upon applicable scientific or subject matter expertise, and to lead panel discussions about the project plan.

Program Analyst: The control point and coordinators in Areas and at NPS for the timely and orderly implementation, management, and evaluation of research monitoring activities relative to the peer review process.

Program Direction and Resource Allocation Memo (PDRAM): A document developed by the National Program Staff in consultation with researchers, Research Leaders, Center/Laboratory/Institute Directors and the Areas Office which allocates resources and identifies objectives within the National Program Action Plan that the Area Office directs to a specific project.

Project Plan: A document detailing 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, and developed according to guidelines set forth herein.

Project Plan Outline (PPO): A planning and communications document that develops the direction, objectives, and approach for research to be conducted in the project. This assures concurrence of researchers and NPLs on the approach and procedures before a full plan is prepared. Instructions for preparing a PPO are provided by NPS when a PDRAM is issued.

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 Category 1 scientists. The factors considered include assignment, research objectives, assigned authority, and accomplishments. This process is detailed in Manual 431.1,

www.afm.ars.usda.gov/rpes/index.html.

Research Project: A phrase used to describe the category of ARS research projects that have been funded through ARS headquarters, and for which the project identification number ends with the character 'D'. All D projects are 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 because the research is short-term or is considered to be for demonstration purposes. Several other types of research projects exist, such as trusts (-00T) and specific cooperative agreements (-01S).

Research Unit (also Management Unit): The ARS unit where the research under consideration is performed.

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 provides additional in-depth analysis and may act as the primary reviewer in the absence of the primary reviewer.

Scientist Year (SY): The effort of an ARS research scientist for 1 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 as a synonym for a research scientist.

APPENDICES

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APPENDIX 1
Authorities for Peer Review

The 1998 Farm Bill

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.

Related Authorities

A number of other public laws relate to the activities of peer review and government advisory committees, in general. The following highlights the most relevant of these and how they impact the peer review process.

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 the consideration of technical issues. Thus, peer review recommendations are not open to public involvement because they are from 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)
The Federal Advisory Committee Act (FACA) requires non-governmental advisor's opinions to be taken individually for formal and established federal advisory committees. However, since the ARS Peer Review Process does not require chartered peer review committees, individual action class scores from peer reviewers are averaged. The primary reviewer composes comments and recommendations that represent the panel's consensus. The provisions of FACA do not apply for these final recommendations.

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.

Title 44-Public Printing and Documents
Title 44 covers all record keeping 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 Office of Scientific Quality Review (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. No peer review-related documents are distributed externally; however, an Annual Report of Progress about the overall success of the Peer Review Process is available upon request.

APPENDIX 2
Example of a Project Plan Cover Page

Project Plan
NP 108 Food Safety
August-September 2005

Old ARS Research 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
Henry Slate	1.0

Non-ARS Investigators

Barney Rubble	.50 (Non-ARS)

Scientific Staff Years
2.50

Planned Duration
60 months

APPPENDIX 3
Signature Pages

[Pre-Peer Review Signature Page]

Lead Scientist, Project Number and Title

This project plan demonstrates clearly 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 by the Office of Scientific Quality Review, ARS, USDA.

For labs that have a 3-tier organization structure (vs. the 4-tier organization that is implied on the signature page), you may combine the first and second signature block. If your lab uses a different title for the Research Leader or Center Director, you may edit the title lines accordingly.

[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 externally 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

For labs that have a 3-tier organization structure (vs. the 4-tier organization that is implied on the signature page), you may combine the first and second signature block. If your lab uses a different title for the Research Leader or Center Director, you may edit the title lines accordingly.

[Re-Review Signature Page]

Lead Scientist, Project Number and Title

This project plan was revised according to the recommendations made by the panel, and demonstrates how the team will conduct the 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

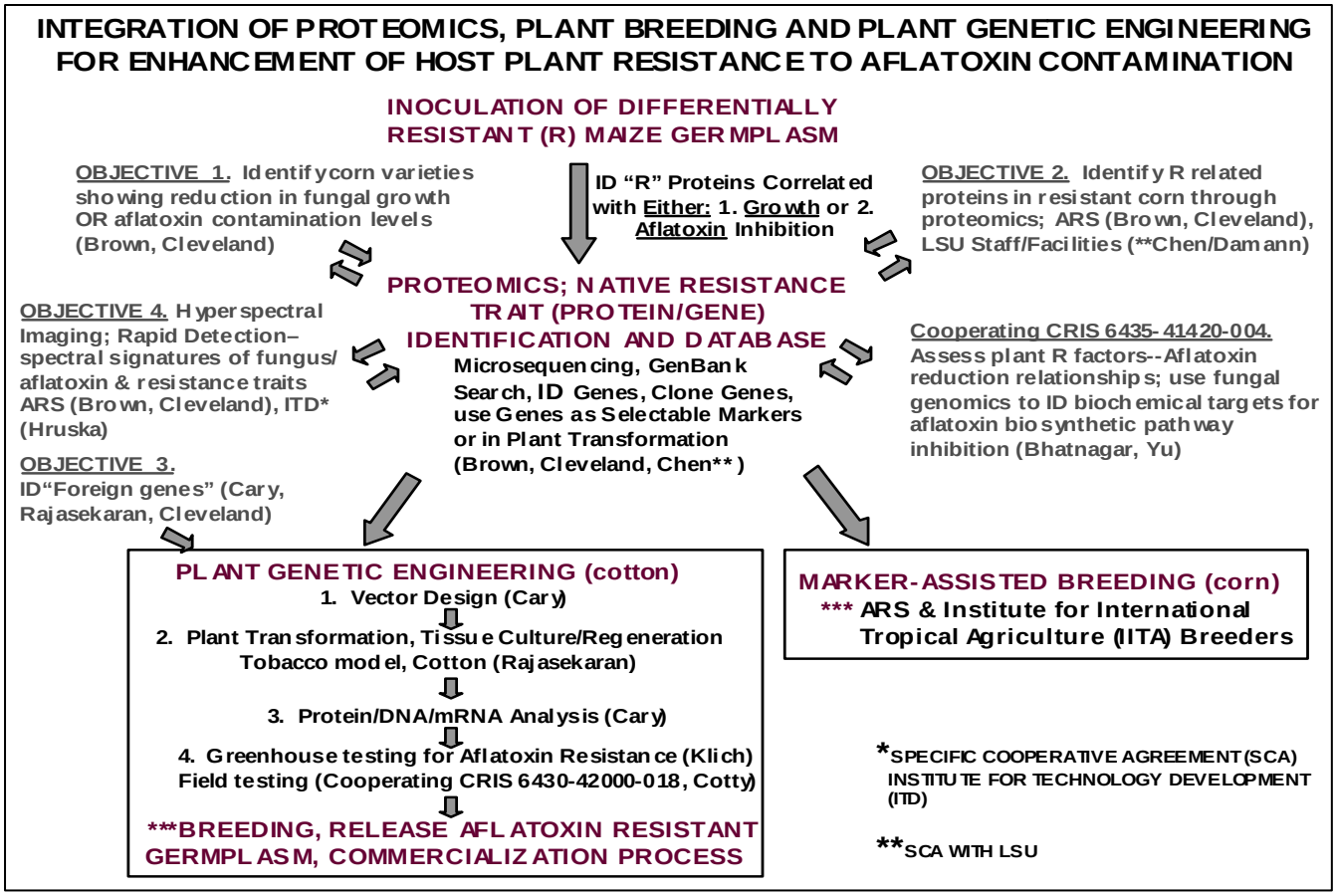
These officials have not performed a scientific merit peer review. Their statements do not necessarily require expertise in the scientific subjects associated with this research. The approval to implement this project plan cannot be made without scientific peer review by the Office of Scientific Quality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

For labs that have a 3-tier organization structure (vs. the 4-tier organization that is implied on the signature page), you may combine the first and second signature block. If your lab uses a different title for the Research Leader or Center Director, you may edit the title lines accordingly.

APPENDIX 4
Sample Project Flow Diagram

Sample Flow Chart
A Useful addition to Objectives or Approach and Procedures
(Sample used by permission of authors)

The flow chart below describes interrelationships of research approaches, objectives, procedures, and personnel within this project and between ARS projects.



How a chart helps:
1. Shows who is working on each objective (but be sure you haven't said that a 0.1SY researcher is responsible for a large part of the work!).
2. Illustrates how the whole project team relates (include vacant positions and back up your need for a person with the expertise to do this in the text of your plan).
3. Demonstrates a "path to success" (more than saying who will do what, it shows how each contributes to the "flow" of the research).
4. Helps to integrate the objectives showing how they relate to one another. Where there are subobjectives be sure that it is clear how they fit.
Producing such a diagram takes time, and care to be sure that your narrative confirms and expands upon this. If you say one thing here and something else in your narrative then this can hurt instead of help!

APPENDIX 5
Hypothesis and Non Hypothesis Research

Most scientific research is hypothesis-driven. That is, it seeks to address a specific, measurable, and answerable question, which may be intermediate to its ultimate objective, but essential to attaining the same. A well constructed hypothesis has several characteristics: it is clear, testable, falsifiable, and serves as the basis for constructing a clear set of experiments that will allow either its acceptance or rejection. One of the most frequent comments OSQR receives from reviewers is that plans contain hypotheses that do not meet these standards. There are several potential areas of difficulty (thanks to Dr. Steve Shafer, Midwest Area Director):

Too Complex: Hypothesis statements that contain words like "and" and "or" are essentially "compound hypotheses. This makes testing difficult if not impossible because while part may be true the other may not be so.

Imprecise: Hypotheses should be definite statements for which the answer can be confirmed or rejected. Use of "may", "might", "could" make the statement equivocal and render it impossible to reject the hypothesis (it may be true even if your result says it's not!).

Misdirected to Researcher: The hypothesis is a test that tells you something about what you are researching. It does not address your capabilities. Example: "Discovering the mechanism behind X will enable us to better detect the pathogen." This tests the ability of the researchers to take information and use it. It is a result of successful hypothesis driven research. Rather the hypothesis should focus on the experimental system.

Statements of the Obvious: "Disease results from expression of genes for virulence in the genes for susceptibility in the host." Actually this also is too complex (see the "and"?). Instead the hypothesis should focus on a particular expression of a particular gene or set of genes.

Global Statements: "Quantifying X will provide significant increases in income for industry." This is utterly untestable in 5-year plan and is really a potential outcome, not a hypothesis.

Some ARS research is not hypothesis-driven. This work may include model development, plant breeding, database development, high throughput genomics, service work, and engineering. Even where research is not guided by a hypothesis, there should be a clearly articulated goal to assure the reviewer that the work has a clear direction and is not a "random walk." For example, plant exploration is not, typically, hypothesis-driven, but the work should have a clearly stated set of goals that will guide it over the research period.

There is a wealth of Internet resources on how to prepare clear, testable hypotheses. In addition many areas have statisticians available who can work with project teams to construct hypotheses and, help you assess whether your research might not be better focused by adding them. In general, we have found that reviewers find equal fault with plans that omit hypotheses where they are appropriate and with those that artificially "squeeze" in one of the above examples.

APPENDIX 6
Milestone Table Format

The goal of the Milestone Table is to present a summary of the project in a form that enables reviewers to readily see the plan of work and the intended path to achieving identified project goals. In addition, it can be used to link to Annual Report of Progress (421's) and Performance Plans. The table is a dynamic representation of the project that captures the important progress and products derived over the project lifecycle. In this way it can become a useful tool for project management after the OSQR peer review. The table may be expanded by copying any relevant sections

The form below is for a Milestone Table. This and a sample completed table are available on the OSQR website www.ars.usda.gov/osqr. Note that boxes in the table available at the OSQR website expand to allow for additional text. We suggest using a narrow font such as Arial Narrow to better utilize space.

Project Title[a]				**Project No.[b]**	
National Program[c]					
Objective[d]					
Subobjective[e]					
NP Action Plan Component[f]					
NP Action Plan Problem Statement[g]					
Hypothesis[h]	**SY Team[i]**	**Months**	**Milestones[j]**	**Progress/ Changes[k]**	**Products[l]**
		12			
		24			
		36			
		48			
		60			
Hypothesis	**SY Team**	**Months**	**Milestones**	**Progress/ Changes**	**Products**
		12			
		24			
		36			
		48			
		60			

Footnotes

[a] Project Title from the project plan.

[b] Project Number from the ARS-416.

[c] Number and name of the primary National Program.

[d] Objective from the project plan.

[e] Sub-objective from project plan (*if used, if not this line can be deleted*).

[f] Component(s) from the National Program Action Plan that can be used to identify the component being addressed for each objective or sub-objective.

[g] Problem Statement(s) from the National Program Action Plan that can be used to identify the problem being addressed for each objective or sub-objective.

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

[i]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).

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

[k]The Progress/Changes section may be 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. When there is a revised milestone or hypothesis this is entered for the next period of the project plan. Consult your Area Office for guidance on altering milestones.

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

APPENDIX 7.
Project Plan Checklist

Lead scientists are responsible for writing project plans for their prospective research in accordance with the peer review schedule designated for their primary national program. They must create a plan that displays scientific merit, creativity, and excellence. Success in writing a plan depends on attention to production of a clear, understandable, and logical flow through the written document. The project plan should be a seamless and clear presentation of the work to be undertaken.

Well-crafted project plans cannot be prepared overnight. They must be clear, thoughtful narratives that convey the objectives and experimental plans for the work in a way that showcases the unique expertise of the project team. Preparation of plans is a team effort that requires care and attention equal to that needed to write peer-reviewed manuscripts or competitive research proposals.

The following checklist is intended as a guide in the development of a project plan. Additional information may be found at www.ars.usda.gov/osqr.

General preparation:

- Read this Manual.
- Attend Web-based training provided by the Office of Scientific Quality Review (OSQR) for your National Program. You will receive information about this shortly after receipt of your Program Direction and Resource Allocation Memo (PDRAM).
- See the OSQR Web site (www.ars.usda.gov/osqr) for additional resources.

Preliminary Planning After Receiving the PDRAM:

- Prepare the Project Plan Outline (PPO) with instructions and due date provided by the National Program Staff (NPS).
- Note deadlines and allow sufficient time for thorough internal review and revision.
- Update Conflict of Interest lists.
- Confirm collaborations with current or potential collaborators. The body of your plan (in Approach and Procedures) will need to show how these fit into the work and a letter confirming their role and commitment will need to be appended to the final plan. Where appropriate a Memorandum of Understanding or Specific Cooperation Agreement may be provided in place of a letter to document the collaboration.

Project Plan Development:

This process should begin with discussion about the PDRAM, but no later than after its receipt. It is important that the plan present a clear path through the research that documents the contributions of the team and collaborators. The Project Plan Outline (PPO) is intended to be an essential first step in the preparation of a plan. A well-prepared PPO captures the overall direction and approach for a plan and serves as an outline for the Project Plan. Once the PPO is approved, it can then be used to prepare the final Project Plan. As you do this, please keep the following issues in mind.

- Prepare the project plan, building upon and adding detail ("fleshing out") to what is outlined in the PPO.
- Send your draft plan to colleagues for informal review. Plan to have a draft plan several weeks early to allow time for review by colleagues, associates, and line management; and to provide sufficient opportunity for revision.
- Provide plan to line management in sufficient time for their review and sign-off. Areas will provide deadlines for accomplishing this and to allow for revisions that may be requested.
- ***Thoroughly proofread*** plans. The most frequent problems with low-scoring plans relates to lack of clarity, poor, or awkward writing. Allow time to assure that your plan presents a clear and readily understood path.

Internal/Informal Peer Review Networks:
Examine your plan for clarity of presentation and seek review by others to assure that it is a clear, easily understood, presentation. The most successful project plans are those that have been examined by others, both inside and outside the Agency prior to submission.

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. Panel members often cite project plans written by multiple scientists as lacking a "seamless" approach. If necessary, you may alter the general format of the plan (without eliminating requested information) to produce a more readable draft. In particular, plans with several objectives or sub-objectives may be better served by an organization that brings together the background and approach for groups of related portions so that reviewers are not required to find disparate pieces spread throughout your plan.

Project Plan Revision and Response to the Review:
Upon receiving the peer review results, meet with the research team and develop reasonable and professional responses to recommendations. Note: If the project plan receives a 'major revision' or 'not feasible' action class rating, consult first with management and NPS to determine the next steps.

- Develop a final revised plan in accordance with instructions (see Chapter 3).
    - Address each area where an "ARS Response Box" is found in the Panel Review Comments received from OSQR.
    - Make appropriate changes to your project plan in **Bold**.
- If revision includes changes to the plan objectives, contact NPS as a new PDRAM may be required.
- Secure line management approval of your revised plan.
- Upon receiving a certification from OSQR, the program analyst will coordinate the creation of the new ARS Research Project (AD-416/417).

APPENDIX 8.
Intellectual Property

In developing and executing research projects in ARS, it is critical to understand the role of intellectual property (IP) and its impact on research performance and technology transfer.

In planning and conducting research IP may impact the work and the ultimate use of resulting technologies. These include confidentiality of information; the 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 Project Plan
It is important to recognize and identify potential IP issues in developing the project plan to avoid potential conflicts in using the results of the research or difficulties in ultimately transferring the technology. If materials or methods/processes used are proprietary or protected by patents or other means, it may limit the ability to transfer the technology to end users and/or it may increase the cost for customers. For guidance on identification or management of IP issues, contact Patent Advisors and Technology Transfer Coordinators in the ARS Office of Technology Transfer.

> *Materials and Experimental Procedures:* In developing a project 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 issues, 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. 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 to identify any potential IP issues that may be associated with the use of proprietary information or materials. 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. 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 the ability to publish or transfer the results of the research. 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. 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 management of associated intellectual property issues.

Transferring the Technology

Anticipated Products and Customers of the Research:

The Federal Technology Act of 1986 assigns each ARS scientist the responsibility for technology transfer. Because ARS is a publicly-funded Federal institution, the transfer of ARS technology to customers is the primary consideration in determining whether or not to protect any inventions that result from ARS 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 ARS Patent Advisors and Technology Transfer Coordinators for evaluation of potential IP to determine the most appropriate mechanisms for transfer of new ARS technologies.

In developing a project plan and identifying customers of the research, there should be an evaluation of the potential outcomes and products of the research which identifies the ultimate users; how technology will be transferred; if further development or protection will be needed to transfer the technology; if there are regulatory actions or approvals needed, and if so, appropriate steps to be taken 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 there may be substantial overseas 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 United States. Web page publication of meeting abstracts, field days, and open house poster sessions can potentially constitute a disclosure. Scientists should consult with their ARS Patent Advisor in advance.

For further assistance

To maximize the 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 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 information and assistance see:

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 9:
Action Class Rating Worksheet

ACTION CLASS RATING WORKSHEET

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

Project Plan Title:

National Program:

Review Dates:

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:

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

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

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.

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)

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.

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.

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.

Scientific Quality Review Officer *Date*

APPENDIX 10.
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**

---

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 con-

trol, 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).

APPENDIX 11.
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 12.
NPS Guidelines: Project Plan Outlines

Development of National Program 5-Year Project Plans
PDRAMs and PPOs

A National Program (NP) is a set of research projects directed toward common goals to solve agricultural problems of high priority. The role of the National Program Staff (NPS) is to maintain relevancy of research programs, and the role of line management is to ensure the quality of the research activities that make up those programs.

- The National Program Team, with stakeholder/customer/scientist input, identifies high priority problems and develops an Action Plan integrating scientific and stakeholder needs into a program research strategy for the 5-year cycle.

  The Action Plan establishes the basis of the necessary dialogue between NPS and scientists and between Deputy Administrators (DAs) and Area Directors (ADs) that defines research approaches to solve problems that are relevant to the needs of U.S. agriculture.
- The DA and NP Team discuss relevant portions of the Action Plan with each AD and Center Director (CD)/Research Leader (RL)/Lead Scientist (LS), as appropriate, to identify the capacity, capabilities, and resources available, as well as the potential contributions of each project to solve problems addressed by the Action Plan, resulting in a resource strategy for research projects.

  The dialogue enables ADs and RLs to communicate any concerns with proposed research re: available resources -- monetary, facility, or staff. The Resource Strategy for research projects defines the most effective use of available resources and is compiled by component in the Resources section of the Action Plan. This dialogue is essential for developing the Program Direction Resource Allocation Memo (PDRAM).

PDRAM

The PDRAM outlines the project's objectives and linkages to the National Program Action Plan.

- The National Program Leader (NPL), through the DA, forwards the PDRAM identifying new project objectives to the AD with a copy to the Office of Scientific Review (OSQR), who in turn, transmits an implementation letter to the relevant LS, usually including the PDRAM.

  While objectives must be explicit, they should allow sufficient latitude for the creativity and insight of the SY(s) in the development of the project plan.
- Within 2 weeks of receiving the PDRAM, the LS submits to OSQR, through the RL/CD/AD, the Conflict of Interest Statement (COI) for each investigator assigned to the project.

  Submission of the COI meets the functional needs of OSQR.

Project Plan Outline (PPO)

The PPO functions as the outline for developing the Project Plan and assures that there is concurrence between the researcher and NP Team on the approaches, goals, and outcomes of the planned work. The PPO eliminates the need for a project prospectus.

- Within nine weeks of receiving the PDRAM, the Lead Scientist submits a PPO to the NP Team, through the RL/CD/AD, for concurrence. The PPO format (10 pages maximum, not including cover page) includes the following elements:
  - **Cover Page** - Please include the following information:
    - *National Program* under which the research is to be conducted.
    - *Dates* for the peer review period as noted on the PDRAM.
    - *Old Project/Bridging Project Number(s)* and note if resources from the old project are being split.
    - *Name of Research Management Unit.*
    - *Location,* city and state.
    - *Title* (not to exceed 140 characters).
    - *Investigators*, List all scientists assigned to conduct the research being planned and their percent commitment to the project, shown in decimal format (e.g., 0.50, 1.00). (This will include all ARS Category 1 or 4 scientists assigned to the project and possibly non-ARS 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 have an accomplishments section in the back of the plan.)
    - *Scientific Staff Years,* list as decimal. (Total does not include scientists not employed by the ARS.)
    - *Planned Duration,* list in terms of total months.
    - *Signatures* of RL or CD, and AD.
    - *NPL Signature Block,* NPL approval of the PPO is required prior to the preparation of the Project Plan. **Any NPS approved substantive changes in objectives must be immediately communicated to OSQR.**
  - **Objectives -** List the objectives as stated in the PDRAM and any sub-objectives that will be part of the project plan. Latitude is given for creation of sub-objectives not specified in the PDRAM.
  - **Approach and Research Procedures -** For each objective, elaborate on the following:
    - *Experimental Design* – Describe in appropriate detail, as you would for a standard grant proposal, the experimental design and the related procedures. State, if applicable, the question (hypothesis) that will be tested and how experimental results will be evaluated. (See Hypothesis-driven research and Non-hypothesis-driven research, pg. 4) Detail should be sufficient to inform the National Program Leader of the nature and appropriateness of the planned experiments and the competence of the project team.
    - *Contingencies* – Discuss specific approaches and experimental options that will be undertaken if the research plan proceeds faster or slower than anticipated, or if early plans prove impractical or unsuccessful. Contingencies should describe what will drive your choices of direction as you get results. Another way to think about this might be: What would make

us decide to modify the objectives or sub-objectives? (See OSQR manual for additional information.)

- *Collaborations* – Describe collaborations with other scientists to accomplish portions of this research. These should include collaborations with scientists within and outside ARS. In the Project Plan all collaborations will need to be documented by a letter from the scientist that specifically details the collaboration, how they will contribute to the project, and the level of commitment anticipated.

If appropriate, sets for the above subsections may be used for each major sub-objective.

- **Potential Benefits Expected from Attaining Objectives (Outcomes)** State how anticipated research results will advance a field of science; lead to economic, environmental, and/or health benefits for consumers; or enable the formulation of policies and regulations in support of U.S. agriculture by Action and Regulatory agencies.
- **Anticipated Products of the Research -** Describe what ARS has promised to do or produce.

The PPO is an outline of a portion of the Project Plan and should provide a basis for continued discussion between LS/RL and NPS that should improve experimental design and logical flow. As such, it will ensure consistency between the Project Plan and the PDRAM. The table below highlights the sections of the Project Plan Outline that could be used to develop the more expansive project plan.

PPO	Project Plan
Cover Page with Signatures	**Cover Page with Signatures**
	Table of Contents
	Project Summary
Objectives/ Sub-objectives	**Objectives/Sub-objectives**
Potential Benefits Expected from Attaining Objectives **Anticipated Products of the Research**	**Need for Research** *(should include the following information, although not necessarily as discreet sections)* • Description of 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
Approach and Research Procedures **Statement of Issue to be addressed (hypothesis or non-hypothesis research)** • **Experimental Design** • **Contingencies** • **Collaborations**	**Approach and Research Procedures** *(expanded from PPO to provide additional detail sufficient for reviewers)* • **Experimental Design** • **Contingencies** • **Collaborations**
	Physical and Human Resources
	Project Management and Evaluation
	Milestones

PPO	Project Plan
	Accomplishments from Prior Project Period
	Literature Cited
	Past Accomplishments of Investigator(s)
	Issues of Concern Statement
	Appendix

NOTE: A hypothesis must be testable and falsifiable. There are research projects that may have no hypothesis. Many non-hypothesis-driven research projects can be characterized as descriptive, explorative, or discovery research. Such projects involve the study of a biological system or an aspect of a system about which we do not know enough to formulate hypotheses. The general approach is to gather large volumes of information about the particular system or biological function, then analyze the data to discover linkages or other significant characteristics that will provide insight into the mechanism and function of the system.

Examples of research that may not have hypotheses include:

- Systems research
- Model development
- High throughput genomics and other "-omics" research and global gene expression research – this type of non-hypothesis-driven research is often called data-driven research.
- Methods development for analyte detection -- excluded is comparing new methods to currently available methods.
- Product development, although some hypotheses may be tested while conducting the research. This research is goal- or customer-oriented.
- Service projects – taxonomy, IR-4, germplasm repository.

Revised 07/31/2008

APPENDIX 13.
Postponement Guidelines

This replaces Bulletin No. 07-601:
Guidelines for the Postponement of Research Project Plan Peer Reviews

Postponement of peer review will be approved only under special circumstances where potential options have been exhausted. Once a panel has been appointed for review of a set of project plans removal or postponement of plans undermines the credibility and integrity of the Agency and its peer review process. Cooperation at all program and administrative levels is needed to ensure that deadlines are met and that plans are reviewed on time. Before considering postponement, the Lead Scientist and Research Leader, Center/Institute/ Laboratory Director are expected to make every effort to complete the plan as scheduled.

While requests for postponement are not frequently approved, there are criteria that may support such a request:

1. Key Scientific Leadership Vacancies and Long-Term Absences. Departure or absences of key staff or new appropriations providing for new projects may result in critical leadership vacancies. Departure or absences of staff or new appropriations may result in projects with critical vacancies in leadership and/or scientific expertise. Where vacancies or absences are anticipated, it is expected that options to enable completion of the project plan will be diligently considered. Note that the absence of a single scientist, other than the Lead Scientist, from a multiple-scientist project is generally not sufficient to warrant postponement of review.

2. Significant Reorganization or Redirection of Research. Reorganization or redirection of research projects should be done in sufficient time to allow development of project plans on the assigned National Program schedule (see *Schedule of Peer Reviews* at www.ars.usda.gov/osqr). Postponement will be considered when unanticipated appropriations or actions that result in initiation, reorganization, or redirection of research are received.

It is anticipated that careful consideration of all options will result in very few requests for postponement. Consultation with the Area Director and appropriate National Program Leader and Deputy Administrator must occur before requesting postponement. Requests for approval of a postponement originate with the Lead Scientist or Research Leader and addressed to the Associate Administrator, Research Management and Operations. (See the memo template below.) It is important that the request for a postponement be made before an OSQR Review Panel has been selected and it is expected that requests generally would not be made after receipt of a PDRAM by the Area Director.

The memo to the Associate Administrator contains the following information:

1. Project Number
2. Title of the Project

3. National Program
4. Management Unit
5. Name of the Lead Scientist
6. Name of the Research Leader, Center/Institute/Laboratory Director (if applicable), Area Director, National Program Leader, and Deputy Administrator, who the memo goes "through" for concurrence.
7. Investigators assigned to the project and percent time contribution by each.
8. Specific reason(s) for the requested postponement.
9. Efforts made to complete the project plan write-up, and why they were unsuccessful.
10. Time period of the requested postponement and proposed date when the plan will be ready for review.

Requests for postponement are routed electronically through the Research Leader, the appropriate Center/Institute/Laboratory Director, Area Director, and the appropriate National Program Leader and Deputy Administrator, with a copy to the relevant Area and National Program Analyst. *In addition, a copy of the request is sent to OSQR at the time it is initially sent from the Area to the National Program Leader.* If the Deputy Administrator recommends approval of the postponement, the request then is forwarded by OSQR to the Associate Administrator, Research Management and Operations; who will approve or disapprove the request. Postponement requests should not be sent directly to the Associate Administrator, Research Management and Operations.

The Associate Administrator's decision is sent by email to the Area Director with a copy to the National Program Leader, Deputy Administrator, and OSQR. The relevant Area and NPS Program Analysts are informed of the decision by OSQR.

Until a request for postponement is approved, plans are due as originally scheduled.

1) Responsibilities

All involved, line management and National Program Staff, are to make every effort to ensure that research projects are submitted in a timely manner for peer review.

1. Associate Administrator for Research Management and Operations, where applicable, through the OSQR, assures ARS is in compliance with P.L. 104-185; Section 103(d). Considers reasons why project has not met schedule along with recommendations for the postponement, makes, and communicates a final decision of approval or disapproval, and expected date of submission of the project for review to the Area Director, Deputy Administrator, National Program Leader, and OSQR.

2. Office of Scientific Quality Review administers and provides guidance on the ARS Peer Review Process. Tracks progress and status of postponement requests and transmits those recommended for approval by Deputy Administrators to the Associate Administrator for Research Operations and Management.

3. Area Directors discuss, review rationale for the project not meeting the schedule, and approve or disapprove requests for the postponement. Consider input on the rationale for

postponements from the Lead Scientists, Research Leader, Center/Institute/ Laboratory Director and National Program Team.

4. National Program Leaders and Deputy Administrators discuss, review rationale for the projects not meeting the schedule, and approve or disapprove requests for the postponement of peer review.

5. Research Leaders review and approve or disapprove requests for the postponement of peer reviews. Research Leaders may also initiate requests for postponements.

6. Lead Scientists (or individuals acting in their capacity) request postponement of the peer review after all alternatives and options to submit the project in a timely manner have been exhausted.

7. Program Analyst tracks requests through ARIS Peer Review Tracking System.

Template – Memo Requesting Postponement Approval

Note: The Office of Scientific Quality Review (OSQR) should receive a copy of the initial request and, if recommended for approval, the complete request for transmittal to and approval or disapproval by the Associate Administrator, Research Management and Operations.

[Date]

SUBJECT: Request for Approval of Postponement of Project *[number] [Title]* from NP *[number]* Peer Review Session

TO: Antoinette A. Betschart
Associate Administrator
Research Management and Operations

THROUGH: _____
Deputy Administrator, Division

_____
National Program Leader

_____
Area Director, Area

_____
Center/Institute/Laboratory Director, Unit Name

_____
Research Leader, Management Unit

FROM: _____
Lead Scientist, Management Unit

We request that the project [title] be postponed from the peer review scheduled for *[month, year]* by the Office of Scientific Quality Review *[peer/ad hoc/re-review]* panel as part of the review of NP *[number]* project plans.

Reason for Request: *Provide a clear description of the circumstances that preclude review, and options considered for completion of the plan.*

Lead Scientist: *Lead SY*

Investigators: *List investigators with percent time, as shown on the project cover sheet*

Time period of the requested postponement and anticipated date of submission: *[month, year]*
cc:
OSQR
Area PA
NPS PA

From OSQR: If postponement is approved, OSQR anticipates this plan would be in the following review: *[date]*