PEER REVIEW GUIDELINES FOR

ARS PANEL REVIEWS



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



United States Department of Agriculture

Research, Education, and Economics Agricultural Research Service

Dear Panelist:

Thank you for agreeing to serve as a peer review panelist for the Office of Scientific Quality Review (OSQR). This Office has been charged with managing a new peer review process of all ARS research projects. The ARS Peer Review Process has the same fundamental requisites of any rigorous and anonymous peer review process. There are a number of other important points to convey before you begin your review.

ARS project plans are written for funded intramural projects. Each of these projects was created in response to a congressional mandate and/or concerns of our stakeholders conveyed at our National Program Workshops. The collective input from such workshops results in Action Plans for each ARS National Program. As such, a National Program is composed of a number of research projects that are coordinated to address the various goals in its Action Plan.

ARS project plans are not to be evaluated in quite the same manner as a proposal submitted for a competitive grant. In fact, we refer to the research document for review as a prospective research project plan; not a 'proposal'. We seek your opinion of the overall quality of each Plan, especially the approaches and procedures. This is very important to the Agency as it provides scientists an opportunity to incorporate technical improvements to their research methods.

ARS research project plans outline prospective work over a five-year period. Thus, scientists are asked to provide research contingencies. This is somewhat a departure from the two to three-years of research outlined in typical competitive grant proposals. Further, ARS projects may have somewhat diverse objectives, involve issues of more than one National Program, and may include several cooperating investigators with varying types of scientific expertise.

We hope this experience is also beneficial for you. Since this may be the first experience you have had participating in one of our peer reviews, we strongly urge you to read these guidelines. As you read, feel free to contact us at any time for assistance.

Sincerely,

The OSQR Team

Orientation

Your panel will receive a brief introduction from the OSQR Team on the first morning of your meeting. The National Program Leader will also speak on the coordination of the projects in the subject National Program. Once you've read these guidelines and completed your reviews, you may still have questions about the format of the project plans, how our scientists collaborate with other ARS scientists and others outside the Agency. We welcome your questions and intend to make every effort to give you the information you need.

Confidentiality

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

Anonymity

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

Conflicts of Interest

By now you've had an opportunity to discern any conflicts of interest you may have by merely reviewing the list of projects assigned to your panel. Nevertheless, it is possible that you may discover unexpected conflict after reading the entire coversheet of a plan. Do not review any ARS project plan if you have an institutional or consulting affiliation with the submitting institution, investigators, or collaborators, or will gain some immediate financial benefit from the project. Also, please decline the review if, during the past four years, any of the following relationships are applicable with respect to the submitting applicants and collaborators: collaboration on research projects; co-authorship; and during the past eight years for thesis or postdoctoral advisorship; work as graduate students or postdoctoral associate. If you are uncertain about potential conflicts, please contact the OSQR for advice on your decision.

Debriefing

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

Please leave all peer review-related documents and electronic media in the shredder box.

Background on the Format of ARS Project Plans

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

Page Limits

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

<2 Scientific Years = 15 pages</p>

2-3.9 Scientific Years = 20 pages

4-6.9 Scientific Years = 25 pages

>7 Scientific Years = 30 pages

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

Cover Page

The cover page includes:

National Program - The title of and the percent coded to the National Program(s) under which the research is conducted. This same National Program has submitted an Action Plan for your use.

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

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

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

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

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

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

Table of Contents

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

Signatures

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

Project Summary

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

Objectives

Clear statements are given about the specific objectives of the project, that are attainable within the specified duration and with the physical resources committed to the project as discussed in the 'Approach and Research Procedures' section. The statement should be complete enough to be used as the basis for scientific review.

Need for Research

This is a statement that described the project's relevance to the ARS National Program Action Plan. The following points are also made:

- · Description of the problem to be solved.
- · Potential benefits expected from attaining objectives.
- · Anticipated products of the research.
- · Customers of the research and their involvement.

Scientific Background

The "Scientific Background" section should focus on presenting relevant literature and technology related to the stated objectives and scientific feasibility of the project plan. The literature cited should be sufficient to allow you to conclude the investigators have current knowledge and understanding of the field of study.

The following information is also provided:

- · Results of past projects or other preliminary results of the investigators relevant to the subject project plan.
- · CSREES-CRIS search ("Current Research Information System").

Supplemental information is included to show how the project is coordinated with related research projects. Some of these projects might be mentioned again under 'Collaborations'.

- · Congressional mandates (if applicable)
- · Patent searches (if applicable)

Approach and Research Procedures

Each of the following sections are provided for each objective and subobjective:

Experimental Design – This section details the scientific and experimental approach that

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

Contingencies – Contingency plans discuss the approaches and experimental options that will be considered if the initial research plan is unsuccessful in evaluating hypotheses or attaining objectives.

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

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

Milestones and Expected Outcomes

The significant events in the project are listed here. A time-line estimating when these milestones can be reasonably met, showing which scientists will be responsible for each milestone or step in the process, is constructed in a logical manner. Scientists also describe how progress will be documented and evaluated (i.e., products of the research).

Literature Cited

Any citation format accepted by a scientific journal that includes all authors, article title, and complete page numbers may be used. Only material or papers that are published or

in press should be provided in this section. Theses and dissertations, state and federal documents intended for professional distribution, and peer-reviewed proceedings of meetings generally are acceptable citations.

Past Accomplishments of Investigator(s)

In one page or less, scientists provide education, experience, and accomplishments over the past 10 years that are significant and pertinent to the proposed research. Each investigator also lists their peer-reviewed publications from the past 5 years and all publications that are clearly relevant to the area of this research from the past 10 years.

Health, Safety, and Other Issues of Concern Statement

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

- · Animal Care
- · Endangered Species
- · National Environmental Policy Act
- · Human Study Procedure
- · Laboratory Hazards
- · Occupational Safety & Health
- · Recombinant DNA Procedures

Appendix

Letters of collaboration are included here, as well as any other supplementary materials that are essential to the plan.

Review Criteria

The peer review of ARS project plans is essentially a two-step process. The first step involves evaluation of the quality of the plan; the second step involves providing advice on how to improve the plan if needed. Project plans are assessed for quality according to three broad criteria: adequacy of approach and procedures, probability of success, and merit and significance. The ARS sets the review criteria; however, peer reviewers encouraged make additional to recommendations for consideration. Specific questions regarding each of the three criteria that should be addressed are discussed below

Criterion 1: Adequacy of Approach and Procedures

This evaluation criterion measures the scientific quality of the proposed research. Questions to be answered are:

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

Criterion 2: Probability of Successfully Accomplishing the Project Objectives
The feasibility of the project is evaluated by this criterion. Your panel will determine:

- The probability of success in light of the investigator or project team's training, research experience, preliminary data if available, and past accomplishments
- ❖ Whether the objectives are both feasible and realistic within the

- stated timeframe and with the resources proposed
- ❖ Whether the investigators have adequate knowledge of the literature as it relates to the proposed research.

Criterion 3: Merit and Significance

For this criterion, ARS is primarily interested in whether the problems to be solved or addressed fit within the National Program Action Plan to which the project plan is assigned. The National Program Action Plan has been developed with input from stakeholders, congressional mandates, customers, and ARS and non-ARS scientists. Other aspects of these criteria that should be addressed are:

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

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

Action Classes

After your panel has completed a discussion, each panelist makes an individual judgment to assign the plan to an 'action class', based on the level of modification needed to raise the plan to the highest quality. OSQR will convert the action classification into a numerical score, average the group of action classes submitted, and assign a final action to the project plan.

The "Action Classes" are defined as:

- 1. No revision required. No revision is required, but minor changes to the project plan may be made.
- 2. Minor revision required. The project plan is basically feasible as written but requires some revision to increase quality to a higher level
- 3. Moderate revision required. The project plan is basically feasible as written but requires moderate revision to one or more objectives, perhaps involving changes to the experimental approaches, in order to increase quality to a higher level. The project plan may also need some rewriting for greater clarity.
- 4. Major revision required. Substantial revision to one or more objectives is necessary, but the project plan should be sound and feasible after significant revision.

 5. Not feasible. The project plan has major flaws or deficiencies, and cannot be simply revised to produce a sound project. If the project is not terminated, a complete

redesign and rewrite are required.

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

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

No revision
Minor revision
Moderate revision

Major Revision
Not Feasible

Revise in six weeks and start research

OPTIONS:

- Revise the plan in 10 weeks and get a second review from the original reviewers.
- 2. Start over. Place the project into a fresh review session.
- 3. Terminate the project. Re-organize the research team and feasible aspects of the plan.

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

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

Table 1. The ARS Action Class Matrix.

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

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

Documenting Your Peer Review

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

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

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

- Clearly differentiate between substantive and minor criticisms.
- Provide suggestions for correction of problems that your panel considered substantive.
- Number your recommendations and always provide a rationale for each one.
- Write your preliminary review as if it were the final review, it cuts time in writing the final and eases its readability by others on your panel.
- When citing other research, provide adequate documentation. OSQR can assist you if needed.

- Address what the Plan needs and use 3rd person statements. Avoid direct commentary that might be misconstrued as an attack on the individual scientists.
- requires reviewer expertise not represented on your panel, please immediately discuss your concern with your panel chair. He or she may consider getting an *ad hoc* reviewer's input at anytime prior to your panel's discussion.

Other Writing Tips:
Do: This Project needs
equipment because
Don't: The Panel is not sure
whether the Project has sufficient
funds to purchase
Do: This project would benefit from
the expertise of Dr at
the ARS location. We suggest
a collaboration between
Don't: Dr should be
reassigned toARS location
· —
Do: The Project is relevant to the
National Program Action Plan
Don't: The National Program Action
Plan should/should not include

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

goals.....

Thank you.

An example of a well-written set of recommendations:

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

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

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

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

Recommendations:

- I. Objective 1- The proposal needs to incorporate a more specific explanation of the steps needed to determine the effectiveness of the VSV treatment. Will naturally occurring pathogen populations be known or established?
- II. Objective 1— Although the primary focus of the research may be on reducing microbial populations on the surface of solid foods, the evaluation of the process should incorporate measurements of the process impact on product quality; color, texture, etc.
- III. Objective 1— The portion of the proposal on models and simulation of the bacterial "destruction" process needs to be developed with much more specific information on the approach to be used and the outcomes to be achieved. The models should focus on process delivery and eventual development and validation of performance standards to support food safety.

Frequently Asked Questions

1. How much time should I expect to spend on the reviews?

Most reviewers spend 4-6 hours on each of their in-depth reviews. We encourage you to start your reviews early.

2. Can I recommend an ad hoc reviewer?

Yes, please discuss your ideas with your panel chair. Your panel chair will contact us and we'll solicit the ad hoc reviewer for you. We recommend giving ad hoc reviewers at least one month to submit their input to you.

3. Can we score the projects by objective vs. assigning one score to the entire plan?

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

4. If a project plan is scientifically sound, but is poorly written, should I nevertheless consider it a good plan? When scoring the project, how much weight is put on poor presentation?

Each project plan you review should demonstrate a high likelihood of success without requiring that you make inferences or assumptions. If the plan inadequately presents the information you need to apply the review criteria, we ask that you address the inadequacy in your peer review. Depending on the type of presentation flaw, you'll need to judge which action class is most appropriate. For example, a plan that lacks a logical flow from one experiment to another may still score better than a plan that lacks detail in the contingency and milestone sections.

5. Can I call or visit with the research teams to discuss their project plans?

No, all the information you need to complete your review should be enclosed in the plan.

6. Can I establish a collaboration with the scientists associated with these plans?

Yes, but we ask that you not reveal your involvement with the peer review in your discussions with them.

7. Once I get a response to my panel's recommendations from the research team, can I respond back?

No, unless your panel's average action class score resulted in a 'major revision required' or 'not feasible', the response from the ARS research team officially completes the peer review process. If the project received a 'major revision required' or 'not feasible' score, ARS will likely ask you to provide a second review of the project.

8. Once the panel has finished is my job as a reviewer over?

Not necessarily. If any plans in your panel received a 'major revision' or 'not feasible' and it is determined by management these plans should be re-submitted for review after revision, you may be asked to review the revised plan. If you are contacted and agree to perform the re-review, this would be an ad hoc review (not panel). The re-review would not occur until approximately three months after the panel convened.

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

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