Project Plan Information, Format and Revision Handbook

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

Lead scientists are responsible for writing project plans for their prospective research every five years, in accordance with the peer review schedule designated for their primary national program. You, above all others in ARS, are responsible for creating a plan that has scientific merit and will be judged to require little or no revision by a group of your peers. Each peer reviewer is an independent expert qualified to review your plan and is most often not an ARS employee. Your success in writing an excellent plan is especially dependent upon the attention you provide to your experimental design. In addition, the following checklist is provided to show the required steps along each stage of the process. You should also consult with your Area Office and National Program Leader to determine if they have additional requirements (e.g., attendance at workshops, references to the NP action plan, and additional formatting standards). Feel free to call OSQR at 301-504-3282 or e-mail osqr@ars.usda.gov if you have questions about the review process.

General preparation:

- □ View the OSQR Video on Project Plan Development. (Your Research Leader should have a copy.)
- If possible, attend a presentation by the OSQR Scientific Review Officer. These presentations are often provided at Area-wide training or meetings and workshops sponsored by the National Program Staff.
- See Manual 500-1, The ARS Peer Review Process. Especially read policy sections on: roles & responsibilities, review criteria, action classes and matrix, reviewer information, and steps in the process.

Preliminary Planning:

- Review the prospectus instructions available from <u>www.ars.usda.gov/osqr</u>. Formulate ideas and begin discussions with the research team about your prospective research. Your National Program Leader (NPL) will soon provide input on the direction of your research.
- During discussions with your NPL, determine whether more than one panel will be held for the projects in your National Program. Understand which panel (by name or topic) your project has been assigned to. Similarly, give the NPL your suggestions for panel chairs. (Panel reviews only.)
- Begin sending OSQR nominations for panel and/or ad hoc reviewers using the form at <u>www.ars.usda.gov/osqr</u>.
- Read and acknowledge the instructional memo and informative attachments provided to you by the NPL.
- Acknowledge deadlines and work to incorporate them into your schedule. A general schedule is posted at www.ars.usda.gov/osqr/megastatus.htm and you'll receive a complete schedule within a few months prior to the deadline for OSQR's receipt of your prospectus. Your Area Program Analyst will also provide guidance on the specific deadlines.
- Begin updating your list of individuals whom you have a conflict of interest with. (See www.ars.usda.gov/osqr/COIExample.PDF.)
- Begin contacting current and potential collaborators and request a letter documenting their commitment to the prospective research. (See ars.usda.gov/osqr/TipsforCollaborationLetters.htm.)

Prospectus Development:

- Prepare your prospectus according to the guidelines at <u>www.ars.usda.gov/osqr/prospectus1page.html</u> and any additional guidelines provided by your NPL or Area Office.
- Have your Research Leader review and approve your prospectus and then forward it to the next manager in line.
- □ If not done already, submit suggestions for reviewers to OSQR ASAP.

Project Plan Development:

- Anticipate having a good draft product done in 8 weeks. Another 8-10 weeks are used to incorporate comments from your Area Office, NPL and other input you seek.
- Prepare your project plan according to the guidelines on page 5 and any additional guidelines or comments provided by your NPL or Area Office.
- Make sure every section of the plan is present as shown in the table of contents (page 33). (Explained in the instructions.) Read the peer review criteria again (page 5) and judge whether you've met them.
- Have your Research Leader review and sign off on your plan and then forward it to the next manager in line as shown on the cover sheet.
- A one-page informational update may be sent (one time only) to OSQR until the day before the panel meeting, with Area Director and NPS approval. This might apply to new collaborations, publications, or errors you discovered after submitting the plan.

Project Plan Revision and Response to the Review:

- Upon receiving the peer review results, develop reasonable and professional responses (page 43) to the peer review recommendations and develop a final revised plan¹.
- Have your Research Leader review and sign off on your plan and then forward it to the next manager in line as shown on the cover sheet. Anticipate collaboration with your Research Leader, Area Office, NPL, and fellow scientists on the responses and revised plan.
- Upon receiving a certification from OSQR, the Program Analysts will coordinate the creation of your new CRIS project that is established for the period through the next panel review session.

¹ If your project plan receives a 'major revision' or 'not feasible' action class rating, you'll need to first consult with management and NPS to determine the next steps for correcting the unfavorable aspects of the plan.

Information and Peer Review Criteria

Project plans contain a detailed description of a project's objectives, including HOW, WHEN and BY WHOM the objectives are to be met. The project plan must stand on its own, and should convey how the work described relates to other similar projects in the same National Program, and how it may relate to a minority-coded project in the same Management Unit. Be sure to follow the format closely, and be sure to include all required sections. Make the plan clear and well organized, 15 to 30 pages (depending on the number of scientists assigned to the project) are sufficient if you write concisely and eliminate redundancy. Highlight important points (limited use of bold or italic can be effective) and repeat in several places (sounds like a contradiction but it is not!). Typos, omissions, etc., suggest a lack of concern. Reviewers often assume that a sloppy project plan reflects a sloppy scientist! Make the plan easy to read, with a consistent 'message' from beginning to end.

The primary responsibility for a high quality project plan is shared between the Research Leader and the Scientists.

Peer Review Criteria

Most of the peer review process is dedicated to writing and approving research project plans. Like prospectuses, project plans require approval at the Lab, National Program Staff, and Area Levels of the ARS. Project plans are evaluated by external peers, who are asked to specifically address 3 criteria:

- 1) Approaches and Procedures
- 2) Likelihood of Success
- 3) Merit and Significance

See Exhibit 1: Panel Review Form

Action Class Matrix

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

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

Moderate Revision Required	Objectives are important to the national interest and fit the national program action plan.	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.	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
	The project has potential to lead to new knowledge and technology, or to produce results of value to customers.	The objectives may need some modification to better fit the stated goals.	Most of the necessary equipment and essential facilities are in place but some aspects could be strengthened.	plan may also need some rewriting for greater clarity.
	Similar research may be conducted at other locations suggesting some modification to the present project plan.	Moderate revision to one or more objectives may be required, and may involve changes in experimental approaches or analytical methods.	The research team is aware of most of the current literature in the area.	
Major Revision Required	One or more of the objectives may not closely fit the national program action plan.	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.	Substantial revision to one or more objectives is necessary, but the project plan should be
	The project plan as written is not likely to lead to new knowledge or new technology.	Major revision to one or more objectives may be necessary because of inappropriate	Several objectives are not in line with the resources available. Critical equipment, facilities or	sound and feasible after significant revision.
		hypotheses or inadequate experimental approaches.	experimental tools are not yet in place or available to the research team	
	Similar research is being conducted at other locations such that undesirable duplication of effort is apparent		The research team is not aware of significant current literature in the area.	
Not Feasible	One or more of the objectives may not fit the national program action plan.	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.	The project plan has major flaws or deficiencies, and cannot be simply revised to produce a sound project. If the project is not terminated,
	As written, the project plan will not lead to new knowledge or technology.	The objectives are unrelated to the stated goals.	The research team is completely unaware of current activity and literature in the area.	a complete redesign and rewrite are required.

The ARS Research Project Plan Instructions and Format

Create a Word file according to these instructions. Please name the file: NP# Lead Scientist CRIS# PostPP. Example: 303-Oscar 1234-56789-000 PostPP

The Plan should be formatted as follows:

8.5x11" letter portrait, single spaced, 1" margins all around 11-pt Arial or Helvetica font, full justified, no end-of-line hyphens

Header: Lead Scientist name flushed left, page numbers flushed right, excluding the cover page.

Footer: Version date flushed left, file name flushed right.

The version date should reflect the most recent changes. It should be the same or very close to the RL signature date.

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

You may consider submitting your electronic file through the Area office in one of the following methods:

- 1. E-mail (no more than 10 mb).
- 2. Zip Disk or CD.
- 3. Compressed, preferably with WinZip.
- 4. PDF (portable document format).

Contact your Area Program Analyst to determine whether he/she has additional or preferred formatting instructions.

The Plan should not exceed: <2 Scientific Years= 15 pages 2-3.9 Scientific Years= 20 pages 4-6.9 Scientific Years= 25 pages >7 Scientific Years=30 pages

from **Objectives** through **Milestones** and **Expected Outcomes**. Up to two pages of schemes, figures and diagrams can be included in the text and will not be counted against the page limit. This first part should flow from one section to the next without new page breaks.

The Cover Page, Signature Page (See Exhibit 2), Table of Contents (See Exhibit 3), Project Summary, Objectives, Literature Cited, Past Accomplishments of Each Investigator, Health, Safety, and Other Issues of Concern Statement, and Appendices should all be started on new pages.

Cover Page

National Program - The title of and the percent coded to the National Program(s) under which the research described below is conducted.

Dates - State the general period in which the research project will be peer reviewed. *Old CRIS Project Number* - The CRIS number for the expiring project. If projects are being combined, list those that are being combined. If a project is being split, note that the old CRIS Project is being split during this process. *Research Management Unit* - The six digit number including name of Research Management Unit (Example: 0000-00-Name of Research Management Unit). *Location* - City and State.

Title - A brief, clear, specific description of the project. Used alone, it should provide a clear indication of what the project is specifically about. It should not contain more than 140 characters including letters, symbols and spaces.

Investigator(s) - List all scientists assigned to conduct the research being planned and their percent commitment to the project. This will include all ARS Category I or IV (See Definition – Exhibit 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. You should consider adding cooperators to the list. The list need not match the SY listing in ARIS. Everyone on the list must also turn in a conflicts of interest list with the prospectus and have an accomplishments section in the back of the plan.

Scientific Staff Years - List as a decimal, i.e., 2.75. (Does not include scientists not employed by the ARS. However to determine the page limit, calculate an equivalent scientific year for non-ARS scientists.)

Planned Duration - List in terms of total months, i.e., 60 months.

Table of Contents - Insert a table of contents, whereby the pages up to the "Objectives" section are numbered in lower case Roman numerals. (See Exhibit 3: Table of contents).

Signatures - Insert the Signature Page (See Exhibit 2). Note that the signature page changes once the project plan has received a favorable peer review and is prepared for implementation.

Area Office: OSQR only accepts project plans that demonstrate all approvals. Submit completely approved plans, in an electronic and hardcopy format, before and after (the final project if there is no re-review) peer review. Attach an original copy of the signature page signed by the Area Director, to the hardcopy of the final project plan.

For labs that have a 3-tier organization (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.

Project Summary - The objectives and research approaches of the project plan should be summarized in 250 words or less on the second page. The first four pages of the project plan are not counted against the page limit.

Objectives - A clear statement must be given of the specific objectives of the project that are attainable within the project time period (not to exceed 5 years) 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. Elaborate, in paragraph form, the bullet statements from the Prospectus.

Need for Research - A statement that provides information necessary for the review of the project based on its relevance to ARS National Program action plans. Use subsections to denote the following, which must be covered:

- \cdot Description of the problem to be solved.
- · Relevance to ARS National Program Action Plan.
- · Potential benefits expected from attaining objectives.
- · Anticipated products of the research.
- · Customers of the research and their involvement. (Be specific)

Scientific Background - Try to avoid repeating information already provided in the "Need for Research" section. The "Scientific Background" section should mainly focus on presenting and

discussing relevant literature and technology relating to the stated objectives and scientific feasibility of the project plan. This section should cite relevant literature and key papers in the field, only. It is not intended to serve as a comprehensive bibliography. The literature cited should be sufficient to allow peer reviewers to conclude the investigators have current knowledge and understanding of the field of study. Results of past projects or other preliminary results of the investigators relevant to the current project plan should also be presented and discussed in this section (See Exhibit 5: Example of Discussion and Citing of Literature). This section should also include a CSREES-CRIS search ("Current Research Information System"). If applicable, try to show how your project is coordinated or associated with other ongoing research projects. For the CRIS search, cite the CRIS project number, title, location and describe in a few sentences its relationship to your project. It is not necessary to cite every CRIS project that is listed using the keywords for the search. Only include the truly relevant projects, perhaps five at most. If you are aware of other, non ARS research relevant to your project it is also a good idea to refer to them in this section. Cite the lead investigator(s), institution, and briefly describe the relationship to the research outlined in your project plan. Some of these projects might be mentioned again under "collaborations" in the "Approaches and Procedures" section (See Exhibit 6: Example of Discussion of CRIS Search). It is important that peer reviewers can conclude the investigators are aware of and are forthright about others performing similar research.

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

Approach and Research Procedures - Use four subsections under this heading to elaborate on the following:

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

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

Collaborations - Describe collaborations with scientists outside of this project (ARS and external to ARS) that are necessary to attaining the objectives. Necessary is meant to mean required for a successful project outcome. Necessary collaborations should be documented by an appended electronic letter from the scientist briefly detailing the collaboration. The letters of intent to collaborate must discuss what the collaborator will do and what level of commitment is anticipated.

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

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

Milestones and Expected Outcomes - Describe a series of milestones (significant points in the project where progress can be documented) for the life of the project. Construct 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. Describe how progress will be documented and evaluated (i.e., products of the research).

Example of a Milestones and Expected Outcome's Table with Contingencies (See Milestone Exhibit 7)

Example of a Milestone Table using a Gantt Chart (See Milestone Exhibit 8) Example of a Milestone Table (See Milestone Exhibit 9)

AT THIS POINT, the Plan should not exceed:

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

The plan can have up to two pages of illustrative material (e.g., schemes, figures, flow diagrams) that will not be counted against the page limit.

Literature Cited - Begin the Literature Cited on a new page. Literature can be listed alphabetically by author or in order of citation in the text. If papers are cited by author(s) and year, they must be listed alphabetically in the Literature Cited section. However, any citation format accepted by a scientific journal that includes all authors, article title, and complete page numbers may be used. Only 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. Meeting abstracts, unpublished materials, and non-peer-reviewed materials are not acceptable as citable materials.

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

Follow each investigator's past accomplishments with a list of all peer-reviewed publications authored by the investigator in the past 5 years and all publications by the investigator that are clearly relevant to the area of this research project during the past 10 years.

Order the publications according to publication date, most recent last. Any citation format accepted by a scientific journal that includes all authors, complete article title, and complete page numbers may be used. Multiple pages may be necessary.

Health, Safety, and Other Issues of Concern Statement - Address the safety concerns for seven issues including identification of necessary permits either in hand or requested. If not relevant, please state as such.

- · Animal Care
- · Endangered Species

• Environmental Impact Statement - Scientists and their Research Leaders shall make a determination on the potential environmental impact of the research. Many ARS research projects are conducted in contained facilities such as laboratories, greenhouses, or field plots. Such projects would be considered to the Categorically Excluded under ARS National Environmental Policy Act regulations. Project statements would then include the following statement: "THE RESEARCH PROJECT HAS BEEN EXAMINED FOR POTENTIAL IMPACTS ON THE ENVIRONMENT AND HAS BEEN FOUND TO BE CATEGORICALLY EXCLUDED UNDER ARS REGULATIONS FOR THE NATIONAL ENVIRONMENTAL POLICY ACT." The appropriate NPL(s), in discussion with the scientist about a replacement project, will decide whether it is Categorically Excluded.

- · Human Study Procedure
- · Laboratory Hazards
- · Occupational Safety & Health

· Recombinant DNA Procedures

Appendix - On a new page, list appendices by page number (if in the main file), or by filename (if additional files are submitted electronically). Letters of collaboration should be included here, as well as any other supplementary materials that are essential to the plan. Scan or paste the collaborators letters into the project plan appendices after the list of appendices page. If this is not possible, electronically submit additional files as attachments. Collaboration letters from ARS scientists may be submitted as e-mails, but must include the properties field to demonstrate authenticity of the e-mail's origin, destinations, networks, and dates. NOTE: The printout of the electronic business card's "view" may not be adequate to demonstrate both origin and destination. For example, in Groupwise and Lotus Notes this is done by right clicking on the e-mail message, select "properties", then print (See Exhibit 10: Properties Example).

Use of figures, schemes, and tables can greatly enhance the plan. Provide other explanatory material here. Remember, up to two pages of figures, schemes, and tables will not be counted as part of the 15-30 page limit.

Project Plan Components and Tips

A good project plan will:

Clearly state the problem(s) to solve or question(s) being addressed.

Demonstrate that the work proposed is important and that new technology or important fundamental knowledge *will* result.

Review relevant literature in a comprehensive and critical (but not exhaustive) manner.

Have several related and clearly stated Objectives and Hypotheses, and provide a clear conceptual framework for their development. (Avoid having too many Objectives or Objectives that are distantly related to one another).

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

Clearly describe what will be done, by whom, and what will result.

Contain concise and clear contingencies in case initial experiments do not proceed as planned.

Establish that the scientists have the necessary experience and qualifications.

Establish that necessary facilities and equipment are on hand. If anything is not in place (including a Cat. I vacancy), plans to obtain the items lacking should be presented.

Show awareness of other's work (within ARS and outside) and show how the studies fit into the bigger picture; identify your customers. Make it clear that you are not working in isolation within the Agency or within the broader scientific community. Talk to your National Program Team if you need assistance.

Have beneficial linkages with other scientists (collaborators). Utilize expertise, databases, etc, that are in the scientific community.

Be easy to read-well crafted with no typos, and definitely not sloppy. (A Project Plan that has low readability adds greatly to the time and effort required for its review and tends to antagonize reviewers).

Project Plans are written to cover the next 5 years, starting from the point the revised Project Plan is approved.

A. Title

- 140 characters (including spaces; ~ 1.5 lines)
- Descriptive, specific and appropriate
- Reflect the importance of the project
- Sets a first impression

B. Table of Contents

- Useful overview; adds to readability
- Useful as a checklist to make sure all sections included

C. Summary

- 250 words; should stand on its own as a succinct description of the proposed work.
- Really sets the first impression (read first by reviewers)
- Write it last-after the Experimental Plan is in place.
- · Make it understandable to scientists in the discipline who are not 'subject-matter experts.'
- Describe what will be done, why it is important, and why it is worth doing.

D. Objectives-1 paragraph to one-half page.

• Identify one or more broad objectives.

• Hypothesis-driven research is in most cases appropriate; identify one or more hypotheses for each objective. (Descriptive studies are usually not well received)

• Do not include a career's work-only that to be accomplished in 5 yrs.

E. Need for Research-1 page maximum in most cases.

In general, panels have found too much space devoted to this section and as a result, insufficient space given to the 'Approach and Procedures' section. Reviewers know that if your project falls within the National Program Action Plan, it is relevant and justified. Consequently, there is no need for page after page of justification, leaving little room for details of the experimental plan itself.

- Clear and concise statement of purpose:
- Problems to be solved.
- Questions to address.
- Establish relevance to the NP Action Plan
- Discuss potential benefits/products
- Anticipated products-technology/knowledge
- Identify your customers/stakeholders

F. Scientific Background- 5 to 6 pages. The reviewers will have a copy of the respective Action Plan of the National Program of the project plans under review. The Action Plan provides much of the information describing the overall mission and coordination of research projects. There is no need in this section to repeat what was already outlined in the "Need for Research" section. Also, this section is not intended to serve as a comprehensive literature review of the field. Cite sufficient current and past literature to put your project plan into a meaningful context of how your research will 'fill a gap'. Provide enough discussion of the literature so that a peer in your field of science can conclude you are up-to-date with regard to knowledge and technological developments in your field. It is useful to use subheadings in this section that correspond with each of your objectives. It is helpful to present preliminary results or progress in development of methods. This type of information supports the feasibility of the plan. It may be useful to use diagrams, photos or tables to illustrate biological, geological or engineering features of the research endeavor (Example of discussion and citation of literature). This section is also where you discuss the ongoing research of others whose goals are complementary or similar in nature to yours. Try to show 'incorporation' rather than 'disassociation' of your research endeavor with the scientific community, both ARS and non-ARS, if applicable. This section includes results of the CRIS search. You need only mention up to five, or so, of the most relevant CRIS projects listing their number, location and perhaps its title. Just provide a sentence or two describing how your project complements and is not redundant with the cited CRIS project (Discussion of CRIS search). In general, it is beneficial to convey to reviewers you are aware of other scientists who are working in a similar area. If you don't you may convey an image to the reviewers of being either ignorant of or insecure about the efforts of others in your field. Also, mention any congressional mandates or relevant patents (yours and others), if applicable, in this section.

- Describe what is known and not known.
- Provide a perspective of how your research fits within the field.
- Describe why it is essential to fill a gap.
- Use subheadings (and subsections) corresponding to the objectives.
- This is not a comprehensive literature review. Cite only the most relevant literature.

- Use illustrations, photos, tables to enhance the appearance of the plan (up to 2 pages of illustrative information are allowed which do not count towards the page limitation).
- Include prior or preliminary results supporting your research plan (preliminary results can also be included in the "Approaches and Procedures" section).
- Describe the unique features of your research, but also explain how it complements ongoing research of others, if applicable.

G. Approaches and Procedures - ~6 to 12 pages (depending on number of SYs).

This section is the core of the Project Plan, and most could benefit from more attention to this section. In general, more detailed experimental designs are needed than are being provided. The goal is to demonstrate that you can address and achieve the stated objectives. In brief, this section should tell who is going to do what, how they are going to do it, and when they are going to do it. Human and physical resources available for each portion of the work (e.g., each Objective if appropriate) should be described. Make it clear that sufficient technical and scientific support is available to carry out the work. This includes numbers and training of technicians, students, postdoctoral scientists, and collaborators. If there is a Category I vacancy, describe the scientific background of the scientist(s) that will be hired and how that background will support the project. Document availability of any substantial physical resources that are necessary for the project (e.g., electron microscope, etc).

• Lack of necessary detail has been the most common criticism of project plans. (Not all details are necessary). For example, you may explain why you are using a particular procedure or method rather than an alternative one.

• Consider an arrangement something like this:

For each Objective:

- 1. Approach(es)-describe the specific projects (specific aims) and studies that will be undertaken to address each objective. Provide one or more hypotheses that will be tested. Be sure to indicate clearly experimental design, including treatments, variables, statistical design, data analysis, etc.
- Procedures methods to be used in the approaches identified. The very specific details of a procedure are not needed, but you need to indicate what procedures will be used, especially for work carried out early in the 5-yr period.
 ->Use sub-objectives if there are multiple parts to an overall objective.
- Clearly identify staff and collaborators (SYs, postdocs, technicians, etc) associated with each Objective, sub-objective, or major experiment. Indicate specific roles, if that is important. For example, Mary Smith, the Lead Scientist, will specifically conduct experiment "A" and will oversee the results for Objectives 1 and 3. In addition, she will work with all scientists in data interpretation and will be responsible for integrating the overall results. Tom Jones will assist in the design and analysis of the ______ will contribute experiment for objective 1. John Wilson of the University of _____ will contribute expertise in ______ and do the ______ analysis using graduate student assistance. Etc. For some projects, even if this information is given, an overall 'project management scheme' might be useful. The figure (if used) and the associated text should indicate who will do what and how the information will be integrated to address the objectives. You do not need to use a figure or diagram in all cases, especially for a 1 SY project.
- If an Objective is supported by a competitive grant, it is useful to mention that.
- Include contingencies-never say "none." As an absolute minimum, statements such as the following should be provided in most

instances. "The data will be carefully analyzed to determine the need for changes in experimental design and procedures. Adjustments, such as different treatments (provide description if possible) and protocols (describe if possible), will be made if valid results are not obtained or data are not useful."

- General TIPS on the experimental plan:
 - 1. If methods are new, provide enough detail to evaluate.
 - 2. If it is unclear that an investigator has the capability to carry out a given procedure (e.g., lack of publications in the area), provide additional information to give reviewers confidence in the investigator's chances of success.
 - If one method is chosen over another, explain why. If special equipment, facilities or expertise is required, clearly document that these are in place.
 - 4. Carefully consider contingencies.
 - 5. Collaborative arrangements should be clearly explained, and the role(s) of the collaborator defined. The collaborator should tell what they intend to do and how much of their time they intend to devote to the collaboration. Relevant expertise should be included in the collaborator's letter. (Vague, general letters are not useful).

H. Milestones and Expected Outcomes - up to 1 page.

- Brief timetable for the project
- · Each objective should have at least one milestone

See Examples of Milestones on pages 37-39

Editorial Checklist

Transfer of peer review documents to OSQR from Area Offices. A hardcopy and electronic version of each project plan must be sent to our office. This procedure applies to both the prepeer reviewed project plan and the final project plan to be implemented. However, attach an ARS response file and a coversheet containing the Area Director's original signature to each final project plan (which is to be implemented). Avoid sending collaboration letters or appendices separately.

Transfer of peer review documents to OSQR from the National Program Staff. Prospectuses must be electronically sent to OSQR and the appropriate Area Offices. Conflicts of interest lists may be electronically sent as one file, but send as an attachment to their associated prospectus.

Transfer of peer reviews from the OSQR. Peer reviews are electronically sent to the appropriate Area Director and their immediate staff. Copies are sent to the National Program Team and Program Analyst.

Responsibilities. Area Program Analysts lead research teams in their documentation and formatting tasks for the Peer Review Process. The need to properly format documents should always be considered when planning to meet deadlines.

Tracking Documents

Naming files: NPS Start Up Memo: NP# Lead Scientist CRIS# Start Prospectuses: NP# Lead Scientist CRIS# PDraft Prospectuses: NP# Lead Scientist CRIS # PFinal Conflict of Interests List: NP# Lead Scientist CRIS# COI Project Plan: NP# Lead Scientist CRIS# PrePP Project Plan: NP# Lead Scientist CRIS# PostPP Certifications: NP# Lead Scientist CRIS# Certification Re-Review: NP# Lead Scientist CRIS# Certification Re-Review: NP# Lead Scientist CRIS# ReReview Example: 303 Oscar 1234-56789-000 DraftP Example: 303 Oscar 1234-56789-000 Certification

Review Form: NP# Lead Scientist RIS# ReviewForm reviewer ID When the review form comes back to us with the ARS responses, please replace the words "ReviewForm" with "Response". *Example: 303 Oscar 1234-56789-000 Review Form ABCD1234* with *303 Oscar 1234-56789-000 Response ABCD1234*

Disks: When sending a disk, please label the disk with all of the file names contained within the disk.

Electronic mail and memoranda: All electronic mail pertaining to the peer review process should note the name of the review session or the National Program on the subject line. If the message pertains to a specific project, the subject line should include the CRIS number and the lead scientist's name.

Prospectuses and Project Plans

Please see the format instructions for prospectuses and project plans. The following checklist is a simple guide to help research teams and Area Program Analysts. Always check with your Area Program Analyst to be sure a more detailed checklist isn't preferred for your Area.

Cover sheets:

- Document identification section. (Top of the cover sheet). The type of document (prospectus, project plan, revised project plan) must be stated. Even more importantly, identify the name of the review, which is the name of the national program + the type of peer review (panel, ad hoc, re-review). Also, provide a date of the review, which means the period in which the peer reviewers actually review the project plan. The months and years are acceptable, such as November-December 2002.
- Title is specific and in compliance with the ARIS 140-character limit. Titles should remain consistent throughout the process, unless changes are absolutely necessary.
- List of scientists assigned to conduct the research being planned and their percent commitment to the project. This will include all ARS Category I or IV 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. You should consider adding cooperators to this list. The list need not match the SY listing in ARIS. Everyone on the list must also turn in a conflicts of interest list with the prospectus and have an accomplishments section in the back of the plan.
- □ All sections should be complete.

Signature Pages

Completed signatures. Original signatures are required from Area Directors only, and only at the final, implementation stage of the project plan. For labs that have a 3-tier organization (vs. the 4-tier organization that is implied on the signature page), you may combined 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. Note that there are two signature pages (pre-peer review and post-peer review) for project plans, depending on whether the project plan is to be peer reviewed or implemented. OSQR will not accept plans with two or more signature pages. Submit one completed signature page. An email doesn't suffice for a signature also.

Conflicts of Interest Lists

- □ All lists should be combined into one file.
- □ Each scientist on the coversheet must have one conflicts of interest list.
- □ All names on the list must be spelled out.

General

- □ Spell check.
- □ Fonts and margins. (Arial or Helvetica, size 11 font, and one-inch margins)
- Page count. Prospectuses may go up to five pages. When complying with the project plan page-count limits, remember that tables and diagrams are not included and note the maximum is based on the number of scientific years.
- Color copying. Must provide a hardcopy in color with a note attached saying "Requires color copies." Do not type directly on plan "requires color copies." Use only when necessary.
- Elimination of budget data. Plans should not include proposals for additional funds.
- □ All sections are completed, including the table of contents for project plans.
- Header: Lead Scientist name flushed left, page numbers flushed right. Footer: version date flushed left, file name flushed right (to insert the file name in Word, insert, autotext, header/footer filename). The version date should reflect the most recent changes. It should be the same or very close to the RL signature date.
- Collaboration letters should be scanned in.
- □ Literature cited should match the actual literature citations within the plan. Caution: don't copy the literature citations list from other documents.
- Devications lists should not include publications more than five years old.

□ Revised project plans should show changes in bold text.

ARS Responses

All response boxes should be complete. Please do not use more than a size 12 font and do not bold the text. Cite page numbers of where those changes appear. (Example: See bold text on page 10).

Requirements for Letters of Collaboration

- 1. If you cite the existence of a collaboration in your project plan the individual(s) with whom you are collaborating must provide you with a letter that clearly documents the collaboration. This letter must accompany your project plan. The Lead Scientist is responsible for making sure that all appropriate letters of collaboration are included with the Plan. Request letters of collaboration as soon as possible in the Peer Review Process.
- 2. The letter of collaboration must be written on the letterhead of the institution with which the collaborator is affiliated and signed by the collaborator. (An e-mail should be used as a last resort and must be accompanied by the recipient-properties fields of the ARS lab's e-mail software.) (See Exihibit 10: Properties Example).
- 3. If you are sent a hardcopy of the letter, scan the letter and place it in your plan as a graphic insert (in the Appendix).
- 4. The letter should clearly state the following:
 - a. The full name of the collaborator and his/her institution
 - b. A statement that explicitly describes the nature of what the collaborator will provide to the research.
 - c. A brief statement which describes the experience and expertise of collaborator in his/her field (citations of a few key papers would be helpful).
 - d. A statement acknowledging that facilities and equipment are available to the collaborator.
 - e. Acknowledgement of any prior or on-going collaboration with any members of the scientific team on the plan.

Keep in mind, this letter is meant to show the peer review panel that the collaborator can provide the respective collaborative product. The panelists may not be familiar with the collaborator or his/her level of expertise. So, it is important that the letter provides this type of information.

Scanning and Editing Adobe File Tips

1. Try not to scan into a bitmap, tiff or other photographic file. Adobe does not compress them as well and the file size is huge.

2. You can scan directly into an Adobe file (if you have purchased the distiller) and the letters look beautiful! However it is harder to put the headers and footers in the documents. File size is OK.

3. Scanning letters into a Word file. Scan them as a B&W drawing with resolution of 100 (to keep file size down). However, this isn't recommended for letters of collaboration with color because you want to maintain the originality as much as possible. Crop the scan size to about 9" if letters are short. In Word, you can easily add headers and footers. The Word file containing 38 letters (about half text and half scanned) was 11,000 kb which when distilled by Adobe became a 1500kb file.

If you have the distiller Adobe package, Adobe files are editable. This should make it easy to correct your signature pages or change page #'s. Here's how:

1. In Adobe, you should have 3 lines of toolbars. At the end of the 3^{rd} line, there should be a blue T button (Touchup Text Tool button) with an attached arrow button. If you don't see the big T, bring down the menu by clicking on the arrow and then click on the T.

2. Click the big blue T (should stay depressed), and then move your cursor to the text you want to edit and highlight it by left-clicking and dragging (as for any software). Type the new text over the old text.

3. If you want to add text, it is best to move your cursor where you want the text to go. Hold down the ctrl key on your keyboard as you click on the big blue T, then type.

4. If you want to move text, click on the text, and you should see a text box (like in PowerPoint), but text should not be highlighted (unhighlight text if it is highlighted). Now go to the arrow button attached to the big blue T and pull down the menu. Click the Touchup Object Tool button just below the T button. Now go back to the highlighted text box and drag it to where you want it to be.

5. If you want to change the font, go back up to the big blue T button. Highlight the text that you want to change (left click and drag) and then right click and scroll down to attributes. Designate font type and size.

6. To underline text, click and hold the highlight text tool and drag over to the underline text tool. Drag your mouse over the text you want highlighted and the text will be underlined.

Helpful Websites

Scientific and Grant Writing Tips

The following sites provide helpful information about scientific proposal and report writing. The sites, particularly those for general writing tips, may provide more guidance and ideas to present experiments for scientists writing research project plans. Most of the resources available are intended for grant-writing audiences. Though the Office of Scientific Quality Review manages the intramural peer review of ARS's research project plans for quality and improvement purposes (vs. funding purposes), we believe the skills acquired while learning to write a grant proposal are very similar to the skills needed to write a project plan. Thus, we encourage our scientists to build their grant-writing skills, as well as their general scientific writing skills. These sites are not necessarily endorsed by the Agricultural Research Service and are intended to be used in support of internal guidance and training only. If you would like to add links to this list, please send an e-mail to mmoore@ars.usda.gov.

General Writing Tips for Scientists

Grantsmanship Hints

Article written by James S. Schepers, USDA, ARS, E. John Sadler, USDA, ARS, and William R. Raun, Oklahoma State University. Published in the Agronomy Journal 92(1):1-5, 2000 <u>http://www.ars.usda.gov/osqr/Grantsmanship_hints.pdf</u>

Bioscience

Guidelines for Writing Grant Applications http://www.bioscience.org/services/grant1.htm

Columbia University

Grant Proposal Writing http://cpmcnet.columbia.edu/research/writing.htm

The Foundation Center

The Foundation Center's Guide to Proposal Writing http://fdncenter.org/learn/useraids/proposal.html

Tips for Scientific Writing

Published by NOAA http://www.srh.noaa.gov/ftproot/ssd/html/writetip.htm

Dr. Nalini Nadkarni, Ecologist and Science-writing advisor

How to Write a Proposal or Research Report http://192.211.16.13/curricular/bgc1998/report.tips.html

Indiana University

Guides for better science research, writing, and presentation <u>http://www.indiana.edu/~cheminfo/14-05.html</u>

University of Virginia-Charlottesville

How to Write a Winning Proposal and Get Those Grants <u>http://www.virginia.edu/~trc/grantsbook.htm</u>

The Whitaker Organization

Proposal Writing <u>http://whitaker.org/sanders.html</u> **University of Wisconsin-Madison** Scientific Report Writing <u>http://www.wisc.edu/writing/Handbook/ScienceReport.html</u>

University of Wisconsin-Madison

Grants Information Center http://www.library.wisc.edu/libraries/Memorial/grants/proposal.htm

Virginia Tech Writing Guidelines for Engineering and Science Student http://filebox.vt.edu/eng/mech/writing/

National Agricultural Library Resources

The files listed on this page include references and databases at the National Agricultural Library (NAL) that will be useful for you in writing your research project plan. The NAL contact information is contained in each file.

Air Quality National Program (#203)

Animal Health National Program (#103)

Animal Well-Being & Stress Control Systems National Program (#105)

Aquaculture National Program (#106)

Crop Production National Program (#305)

Crop Protection & Quarantine National Program (#304)

Food Animal Production National Program (#101)

Food Safety National Program (#108)

Human Nutrition National Program (#107)

Manure & Byproduct Utilization National Program (#206)

Methyl Bromide Alternatives National Program (#308)

Plant Biological & Molecular Processes National Program (#302)

Plant Diseases National Program (#303)

Quality & Utilization of Agricultural Products National Program (#306)

Rangeland, Pasture & Forages National Program (#205)

Water Quality & Management National Program (#201)

CRIS Search http://cris.csrees.usda.gov/

CRIS is the USDA's documentation and reporting system for ongoing and recently completed research projects in agriculture, food and nutrition, and forestry.

To Complete a Patent Search http://www.cambiaip.org/Home/welcome.htm

CAMBIA offers free and friendly access to agricultural patents from the European Patent Office, applications provided under the Patent Cooperation Treaty, and the U.S. Patent Office. The site also offers some helpful information for novices, such as a tutorial on how to read a patent.

Websites to help complete the "Health, Safety and other issues of Concern Statement" in the Project Plan:

<u>ARS Facilities Division: Safety, Health & Environmental Branch</u> http://www.afm.ars.usda.gov/fd/SHEMB.htm

National Environmental Policy Act http://ceg.eh.doe.gov/nepa/regs/nepa/nepaegia.htm

<u>NIH's Office of Human Subjects Research</u> http://206.102.88.10/ohsrsite/ <u>NIH's Office of Biotechnology Activities</u> http://www4.od.nih.gov/oba/ <u>Occupational Safety & Health Administration</u> http://www.osha.gov/ <u>U.S. Fish & Wildlife Service</u> http://www.fws.gov/

Revision of the Project Plan After the Peer Review

After the peer review, scientists will receive the composite 'Action Class' assigned by the SQR Officer, based on individual classifications made by the peer reviewers. The composite Action Class describes the level of revision required, the timing of revision and whether the revised project plan will be re-reviewed (see Manual for details).

If the review involved a panel, scientists will receive the consolidated 'Panel Recommendations,' with expandable "ARS response" boxes inserted for their comments. Scientists must respond to each major question or recommendation made by the reviewers, and must provide an answer or explanation in each response box. The TONE of the response should be neutral and never defensive or condescending. The CONTENT of the response should indicate that the scientists have made all reasonable efforts to accommodate the suggestions made. Lack of adoption of a given suggestion must be justified. Each 'ARS response' should be sufficiently detailed an explanation to stand on its own. In other words, describe what modifications have been made to the Plan (along with citing page and line numbers of where those changes appear) or, clearly spell out why they were not incorporated.

See Example 10 of an ARS Response.

Note that the Panel Recommendation (with completed ARS responses) is sent back to the panelists, even if the revised Project Plan is not re-reviewed!

When the Project Plan has been revised, the same administrative approval process is required as for the initial Plan. Under favorable reviews, this revision process takes about 6 weeks to complete. Projects that require Major Revision may require more time to revise and will be rereviewed by the original peer reviewers. Projects that are classed as 'Not Feasible,' may be revised or may be postponed for a fresh Peer Review Process.

Exhibit 1: Panel Review Form

Project Title:

CRIS Number:

Name of the Review Session:

Date:

Lead Scientist:

Reviewer ID Number:

Panelist Review of ARS Research Project Plan

The purpose of this review is to judge the technical merit of the planned research and to make constructive comments for improvement. The principle focus of this research has been determined by ARS to be essential to its mission, and funding has been approved at the planned level. Please provide both qualitative ratings and comments on each review criteria. Please list and number each significant recommendation being made. Be sure to briefly state the rationale or basis for suggestions made or questions raised. Each recommendation can include specific instructions you believe should be addressed by the lead scientist.

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?

Project Title:	Date:
CRIS Number:	Lead Scientist:
Name of the Review Session:	Reviewer ID Number:

2. Probability of Successfully Accomplishing the Project's Objectives: What is the probability of success in light of the investigator or project team's training, research experience, preliminary data, if available, and past accomplishments? Are the objectives both feasible and realistic within the stated timeframe and with the resources proposed? Do the investigators have an adequate knowledge of the literature as it relates to the proposed research?

		29
Project Title:	Date:	
CRIS Number:	Lead Scientist:	
Name of the Review Session:	Reviewer ID Number:	

3. Merit and Significance: Are the project objectives relevant to the stated research goals and directions of the corresponding National Program? 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, comment on the value of the research to its customers.

Additional Comments or Suggestions:		
Name of the Review Session:	Reviewer ID Number:	
CRIS Number:	Lead Scientist:	
Project Title:	Date:	50

Exhibit 2: Signature Page

Pre-Peer Review

Signatures and Dates Must Be Complete Prior To Distributing this Project Plan to Peer Reviewers

[Lead Scientist, CRIS # and Title]

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

Research Leader

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

This project plan is relevant to the Agricultural Research Service's National Program _____ 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.

National Program Leader

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. To validate the plan's readiness for implementation and gain recommendations for improvement, the project plan is now available for peer review.

Area Director

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

Re-do this coversheet if the project plan requires a second peer review.

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.

. .

Date

Date

Date

Date

Post-Peer Review

Signatures and Dates Must Be Complete Prior To Distributing this Project Plan to Peer Reviewers

[Lead Scientist, CRIS # 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

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

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.

National Program Leader

The attached plan for the project identified above was created by a team of credible researchers and internally reviewed and recognized by the team's management and National Program Leader to establish the project's relevance and dedication to the Agricultural Research Service's mission and Congressional mandates. 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

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Date

Date

Date

Exhibit 3: Table of Contents

Cover Page	i
TABLE OF CONTENTS	ii
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NEED FOR RESEARCH	1
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Exhibit 4: ARS's Categories for Professional Scientific Positions

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

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

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

Category 3 (Support Scientist). Professional scientist positions which function to provide direct support or service to one or more Category 1 or 4 positions. The work of such positions is characterized by responsible involvement in one or more, but not all, phases of research (particularly not the problem selection and definition phases); responsible participation in analysis and preliminary interpretation of data (but not including responsibility for final interpretation and conclusion which relate the results to the field of research involved). Examples include but are not limited to: (1) conducting literature searches; (2) selecting procedures and conducting experiments; (3) collecting and analyzing data or specimens; or (4) preparing technical reports.

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

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

Exhibit 5: Example of Discussion and Citing of Literature

Control of seed storage product formation

Mature soybean seeds typically contain 35 to 50% protein, 15 to 25% lipid and about 10% nonstructural carbohydrate. Predominant seed storage proteins are the 11S glycinins and 7S β -conglycinins, which accumulate in membrane-bound protein bodies (Shewry et al. 1995). Lipids accumulate as triacylglycerols (TAGs) that are found in oil storage bodies surrounded by the protein oleosin or occasionally as oil droplets in the cytosol. Predominant fatty acids in TAGs are palmitate (16:0), stearate (18:0), oleate (18:1), linoleate (18:2) and linolenate (18:3). All of the biosynthetic steps leading to TAG synthesis are known (for review see Voelker and Kinney, 2001) and many of the genes encoding lipid biosynthetic enzymes have been identified (Mekhedove et al. 2000). In general, protein and oil content vary inversely and there is also an inverse relation between protein content and seed yield (Brim and Burton, 1979; Wilcox and Guodong, 1997). In order to manipulate seed composition and break the protein:yield barrier, it is essential to understand the biological mechanisms that control storage product formation in seeds. *This is one of the major long-term goals of this project.*

Soybean seeds develop in physical isolation from the maternal tissues. Assimilates (sucrose and amino acids) are obtained primarily from leaves (Rainbird et al. 1984) and are released from the seed coat into the apoplast prior to uptake by the developing cotyledons (Thorne 1980, 1981). Of particular interest to us is whether seed composition is controlled by supply of assimilates (sucrose and amino acids) or by intrinsic traits of the seed itself (e.g., inherent capacity for protein and/or oil biosynthesis). The literature provides evidence for both types of control. Briefly, evidence for assimilate (source) control comes from two types of studies. First, in reciprocal crosses of a limited number of genotypes, seed composition was less influenced by the genotype of the embryo than by the genotype of the plant on which the seeds developed (Singh and Hadley, 1968). Secondly, supply of supra-optimal N to a normal-protein soybean line resulted in seed protein contents approaching those of high-protein lines (Nakasanthien et al. 2000). These results indicate that N-availability to the developing seed is an important factor controlling storage protein synthesis and suggest that seeds of normal lines have intrinsic biochemical capacity to synthesize high protein concentrations if sufficient substrate is available.

However, control of seed composition by 'endogenous traits' is also suggested by the literature. In particular, using in vitro seed culture, Hayati et al. (1996) concluded that genotypic differences in seed protein are regulated by the cotyledons, not by N-supply. In addition, there are indications that seed composition is associated with factors such as seed P content (Bethlenfalvay et al. 1997), and the activity of certain enzymes such as phosphoenolpyruvate carboxylase (Sugimoto et al. 1989). Moreover, recent studies indicate that oil content of Arabidopsis seeds can be significantly increased by over-expression of diacylglycerol transferase (DGAT; Jako et al. 2001). Thus, the level of seed metabolites and the activities of key metabolic enzymes may also control protein:oil accumulation.

Our current working model for control of protein:oil synthesis is presented in simplified fashion in Figure 2. Assimilate supply from the maternal plant is clearly an important component, and we are speculating that in addition to the inherent capacity of the mother plant to supply assimilates from photosynthesis and N-assimilation, mechanisms may exist to keep the 'sink demand' of developing seeds in balance with provision of assimilates from 'source tissues.' It is well known that developing pods suppress cytokinin production in roots concurrent with inhibition of root growth (Noodén and Guiamét, 1989). The decrease in cytokinin production is required for monocarpic senescence of soybean (Noodén et al. 1990) and presumably the mobilization of reserves to developing seeds. Conceivably, the 'signals' that control root functions and leaf senescence are identical to those that coordinate sink demand with mobilization of source reserves during senescence. We will explore this level of control (identified as ① in Figure 2) in some novel genetic material we identified where this mechanism may not operate properly to shut down assimilate supply when sink demand is low (low pod set in male sterile plants). Additional levels of control are postulated to involve transcriptional (②) and post-translational (③)

mechanisms within the developing seed itself that mediate responses to changes in the availability of sucrose and amino acids. We are speculating that the metabolic priority of a developing soybean seed is to use available amide amino acids to form storage proteins. This will utilize some of the imported sucrose, as amide amino acid interconversions requires Cskeletons in the form of organic acids. Carbon skeletons derived from sucrose that are in excess of that needed for amino acid metabolism can be utilized for lipid biosynthesis (or accumulate as carbohydrate). It has been demonstrated with in vitro seed culture that as Nsupply is increased, protein accumulation increased while oil accumulation decreased (Hayati et al. 1996). This inverse relationship between protein and oil could simply reflect that both pathways compete for C-skeletons derived from sucrose. However, we are speculating that Nmetabolites (possibly Gln and/or Asn) may also regulate the expression of lipogenic mRNAs and thereby directly control the capacity for oil biosynthesis (shown in red in Figure 2). Furthermore, we are speculating (based on sequence analysis) that several key enzymes, including cytosolic pyruvate kinase (PK_c) and ω -6 desaturase may be regulated by protein phosphorylation, perhaps in response to metabolic signals. It is not yet clear what metabolites are transported into soybean plastids for fatty acid synthesis, but current evidence suggests that a plastid phosphoenolpyruvate (PEP)/phosphate antiporter (Fischer et al. 1997) may be providing the pyruvate required for fatty acid synthesis following metabolism of the imported PEP by plastidic pyruvate kinase (White et al. 2000). Thus, metabolism of PEP in the cytosol by cytosolic pyruvate kinase (to form pyruvate) and PEPcarboxylase (to form oxaloacetate) could supply the mitochondria with C-skeletons to form the organic acids required for amide amino acid interconversions and storage protein biosynthesis. Thus, expression of cytosolic pyruvate kinase, or modulation of activity by protein phosphorylation, could contribute to the control of sucrose utilization for protein versus oil biosynthesis.



Figure 2. Simplified schematic representation of three levels of control that may regulate metabolic reactions in a developing soybean seed leading to protein and oil biosynthesis (storage product formation). Involves signals that coordinate source supply of assimilates with sink demand; Involves control by N-metabolites of storage protein synthesis (up regulation, known to occur) and oil biosynthesis (down regulation); and Involves possible posttranslational control of key enzymes by reversible protein phosphorylation. Each of these will be explored in the proposed studies.

Exhibit 6: Example of Discussion of CRIS Search

A CRIS search of active projects on animal manure and wastewater irrigation identified 22 projects, of which two are from this research unit. CRIS projects of relevance to this research include a project by the Western Regional Research Center in Albany, CA (#5325-42000-023-00D) dealing with treatment of animal manure to prevent pathogen transmission and to gain a better understanding of pathogen ecology in agricultural settings. Another related project is being conducted by the U.S. Meat Animal Research Center in Clay Center, NE (#5348-42000-006-00D) dealing with the prevention of zoonotic pathogen transmission from animal manure to human food. Both of these research projects are similar to my proposed research in that they use a molecular biology approach for the detection and identification of specific pathogens including Campylobacter from environmental samples however, they are addressing potential contamination through animal waste rather than municipal waste used for agriculture. Another related project is being conducted by ARS in Athens Georgia (#6612-13610-002-09R) "Subsurface transport of Cryptosporidium and Giardia from grazing lands to drinking water supplies" to help understand the transport of pathogens in the subsurface to a stream, however it uses polystyrene microsphere in place of the pathogens. A project by the University of California, Riverside (CRIS #5310-42000-001-02S) includes the fate and transport of pathogenic microorganisms in surface water, groundwater and the atmosphere from animal Also, a CRIS project (5344-42000-013-00D) is being waste (beef or poultry) products. conducted in my research unit as a companion study to my proposed project. This study addresses the fate and transport of organic chemical present in wastewater used for irrigation including endocrine disruptors. In addition, CRIS #4344-42000-013-01S by Arizona State University is being conducted within my laboratory to see if pharmaceutically-active compounds present in wastewater can pose a threat to groundwater quality.

Several CSREES projects were identified that are considered complimentary to the research proposed herein. However, some of these projects may no longer be active. CSREES #96-35102-3839 "Role of subsurface drainage in transport of *Cryptosporidium parvum* oocysts" conducted by Cornell University, Ithaca, NY addresses the transport of *Cryptosporidium* in the subsurface through preferential flow paths in the soil. CSREES #ARZT-319650-G-21-512 "Role of irrigation water in contamination of imported and domestic fresh food" is a project using wastewater irrigation conducted by the University of Arizona, Tucson. The irrigation waters from canals used for crop irrigation were assessed for the presence of pathogens, however the impact of irrigated forests for timber and wildlife" conducted by Pennsylvania State University uses municipal wastewater as irrigation to study abundance and distribution of plant communities.

Exhibit 7: Milestones and Expected Outcome's Table with Contingencies

Example of a useful "Milestone and Expected Outcomes" table. (This particular milestone format was specifically identified by several of the Food Safety Panelists as being useful.) This table is not included in the page count.

Milestones and Expected Outcomes

Research Study- Component	Months of study			
	14	32	48	60
New chemical treatments (Fett, Ukuku, Sapers, Hicks)	Complete studies on synthetic antimicrobials	Complete studies on antimicrobials from plants	Optimize parameters, patent technology	Finish studies, transfer technology
Non-chemical interventions (new SY, Fett, Ukuku)	Complete library of potential antagonists, bioassays on sprouts testing on microwaves	Complete assays on other commodities testing of other physical methods	Optimize parameters, patent technology	Finish studies, transfer technology
Endogenous, exogenous factors (Liao)	Complete library of resident microflora on produce	Complete studies on interactions between residents and human pathogens	Complete studies on detection	Finish studies, transfer technology

Publications and presentation of results will occur as significant outcomes arise.

Research	Months of study				
Study-Component	14	32	48	60	
By-product Studies (Jones, etc.)	complete laboratory composting by-product evaluation for P and N immobilization and conservation	complete growth chamber studies for fertilizer content of by- product manure mixtures	complete field composting tests of by- product treatment candidates	Final evaluation and recommend ation treat ment product manure mixtures	
Algal Scrubber Studies (Smith)	complete lab studies of dairy, swine and poultry manure	complete field scale treatment of dairy manure	complete swine manure field study	recommend treatment systems for manures	
Alkaline Stabilization (etc.)	complete lab and field disinfection of bacterial pathogens; disinfection of <i>C. parvum</i> , Helminth ova	complete lab and growth chamber studies on alkaline product use as liming agent in acid soils	complete field study on utilization of alkaline products on acid and sulfidic clay soils	complete bacterial regrowth and saprophytic colonization studies	
Bioaerosols (etc.)	complete method adaptation, baseline studies in dairy unit, correlate with odor and particulate emissions	complete downwind transport studies with liquid manure field applications	complete studies on dairy and poultry solids handling	complete exposure modeling scenarios and prepare exposure assessment publication	
Pathogen Studies (etc.)	complete detection methods for <i>E coli</i> using nucleic acid and immunology	complete methods testing for <i>E coli</i> in environmental of manure and soil samples	complete studies of <i>E coli</i> movements and survival in environment, begin other pathogen studies	complete studies in survival and movement of selected additional pathogens	

Exhibit 8: Milestone Table Using a Gantt Chart

Gantt Chart of activities broken down by objective and subobjective, part 2. Milestones usually coincide with completion of activity. Primary publication events are indicated by (P) in the text field, and occur at completion of the indicated task.



Exhibit 9: Milestone Table

Sub- Objective	12 months		24 months	36 months
2.1 Source- sink control	Confirm unusual genotypes with high seed protein when male sterile	YES	Identify extreme genotypes	
		NO	Compare near- isogenic lines differing in protein and oil content.	(Pursue as appropriate)
2.2 Metabolic priorities	Do N- metabolites regulate lipid genes?	YES	Identify metabolites involved as signals	Identify seed enzymes regulated by protein phosphorylation.
		NO	Does N-availability reduce C-flux to lipid?	

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Exhibit 11: ARS Response

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

Lead Scientist: Kozempel National Program: 108 Food Safety-Postharvest

Reviewer Number: NNCK1120

2.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 focussed 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 or work (see Bold text on page 32). Specifically, we will use Null hypothesis to determine statistically significant differences between the treated and control, within 1 day, across 3 days, over weeks and seasons. Each company will have their own specific tests to run to determine effectiveness.

We will test for *Campylobacter* and generic *E. coli* at Athens. One company has expressed an interest in looking at *Salmonella*. At that plant, they will test for it. It is the objective to develop the process for commercial adoption. We expect individual companies will do more specific tests and share the data. In all cases in which it is feasible, we will try to establish the pathogens present.

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

ARS Response: We agree, but that is best left to the companies to do. They are the 'product specialists' and are much better equipped to do those studies. They have the equipment, experience and

personnel to do them. We added text to indicate that industry will do these tests as part of our collaborative arrangements.

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 new appendix 5). 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 bold text on page 11).

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

ARS Response: We expanded the text to give the details of the planned experiments (see bold text on page 22). We are performing an engineering study to develop a process based on a nonthermal effect. The first step is to prove such an effect exists and is significant. If it is small it might be of scientific interest but is unlikely to form the basis of a new process. The effect must be large enough to justify developing a process. Therefore, we will look for a non-thermal effect within the framework of a steady state process.

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

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