

{Animal Biosecurity Coordinated Agricultural Projects - PANEL SUMMARY

The panel decision regarding your proposal is based on the input provided by the reviews and the collected expertise and judgment of the individual panel members. This panel summary reflects the consensus opinion of the panel regarding your proposal.

Proposal Number: 2008-00817 Project Director: Rowland

Proposal Title: Integrated Strategies to Control and Reduce the Impact of PRRS Virus

{Positive Aspects of the Proposal}

PRRSV is a significant, worldwide, agricultural concern related to animal health and causes large economic losses to producers. New and perhaps more virulent PRRSV strains have been recently discovered in Asia. As entry of these strains into the North American herds would likely be catastrophic, PRRSV could also be considered a "foreign animal" disease. Therefore, the significance of this proposal is regarded as extremely high.

The key personnel are well-qualified, have the expertise to bring the proposal to successful completion and have been recruited from across the country. Their roles in the program have been clearly defined. In summary, the research, education and extension team represents a "Who's Who" of PRRSV research, diagnostics, and extension.

Adjustments of the management plan in CAP2, compared to CAP1, were considered excellent. In addition, the adjustments/improvements made in the management plan gives the review panel confidence that if any problems develop during the administration of CAP2, the management team can appropriately and quickly address them.

The leadership by the project director of PRRSV CAP2 was considered excellent. Based upon the organization of the proposal, the letters of support and the support demonstrated by participants at the reverse-site visit, the panel has unequivocal confidence in Dr. Rowland to manage this significant project. To provide maximum support for his project management and leadership, the panel suggests that Dr. Rowland seek a highly qualified associate administrator (administrative assistant) with an advanced degree (e.g., M.S. or Ph.D.) and experience or knowledge of the swine industry (if a suitable candidate is available). A well qualified associate administrator (administrative assistant) will be essential to help Dr. Rowland avoid becoming overburdened with too many day to day details (e.g., requesting subcontracts from institutions, follow-up, and assembling them each year via www.grants.gov for submission to CSREES, etc., etc.) that can be easily delegated.

For the most part, the logic model was deemed excellent (see below). The panel felt that the logic model was instrumental in the significant improvements made in the current proposal.

The panel applauded the change in title from "Elimination of PRRSV" to a more appropriate "...Control and Reduce the Impact of PRRS Virus". It

was felt the new title was more accurate, resulted in better focus in some areas of the proposal, and (for the most part) provided for more specific deliverables (again, see below).

The panel highly commends the PRRSV CAP team for the excellent job in addressing the concerns of the previous review. The reverse-site visit significantly abrogated all initial concerns arising from the current review based on the individual reviews.

Relative to the application itself, the proposal was well written and clearly articulates the overall goals of a well-planned, long-term coordinated agricultural project. The major project objectives are progressively integrated and are clearly described to address research, education and extension at multiple levels from producers to basic scientists. Relative to the research aims, they are clearly stated, scientifically sound and follow a logical sequence. The extension and education sections of the CAP2 resubmission were significantly improved over the first CAP2 submission.

{Negative Aspects of the Proposal}

The expected achievement bar is raised for a CAP2 renewal. With that in mind, while no significant weaknesses, nor fatal flaws, were identified by the panel to impede funding for PRRS CAP2, several areas are described below. By addressing these, PRRS CAP2 will be even better positioned to exceed the achievements of PRRS CAP1.

The objectives of the proposal will be realized by request for applications focused upon the objectives deemed important by the stakeholder board (vaccine/diagnostics, ecology/epidemiology, host genetics). The current planned advertisement of the RFA is not broad enough and may miss people or groups that could submit proposals with significant impact. The panel recommends dissemination of the RFA to reach a wider audience, including use of associations such as USAHA, AAVLD, and research offices at land grant colleges. Furthermore, a more significant effort to reach under-represented groups (minority applicants) should be made.

In addition to what was perceived as a passive engagement of under-represented groups to solicit their proposal ideas, direct involvement of under-represented institutions in decision making of the CAP was lacking (i.e. participation in the management structure, stakeholder board or internal advisory board).

It was the general consensus of the panel that Objective 3 was weak. This opinion does NOT imply a lack of importance for the genetics objective or anything considered scientifically unsound. Rather, the objective was considered weak because it was extremely too ambitious to likely accomplish what was proposed. Furthermore, as solid as the Logic Model was in most areas, the impact/outcomes for Objective 3 were extremely vague, and not helpful as a benchmark for evaluation of the success or failure of the objective.

Objective 4a was ambiguous and incompletely disclosed how control and elimination of PRRSV from herds and regions will be implemented. Also, similar to Objective 3, the impact/outcomes for Objective 4 were broad and not specific enough to be of benchmark value.

The development of the databases linked to Objectives 1, 3 and 4, without forethought at the development stage for a strategy or mechanism to make them interoperable, was considered a significant weakness that needs to be corrected.

Given the obvious goal to work towards better and likely commercially available vaccines and improved diagnostic testing (esp. related to DIVA), the panel felt that it would be extremely prudent to have mechanisms in place (now) for at least a dialogue with APHIS CVB and perhaps the Biopharma industry. Without these relationships in place, there is the potential for major headaches and roadblocks in the journey ahead.

The CAP identified the urgent need for a standardized animal model especially for use in vaccine development. Specifics regarding the implementation of this model were lacking. Furthermore, the PRRSV community needs to define what constitutes "heterologous protection" as this has a significant impact on evaluation of vaccines within the proposed model system.

{Synthesis Comments}

The panel congratulates the PD, the project leadership team, and the entire PRRS CAP2 membership for the development of an excellent proposal to guide the next 4 years towards significant achievements. The panel recognizes the significant coordination efforts among research, education, and extension areas that occurred over the past year. PRRS CAP1 has made important contributions in the area of PRRS, and is expected to accelerate significantly now during CAP2. The panel has full confidence in the PD and the larger PRRS CAP2 community to successfully lead the project to important advances that will benefit the swine industry. For those reasons (and others detailed above under Positive Aspects of the Proposal, as well as in individual reviews), the panel enthusiastically recommends funding this proposal with a high priority. During the panel discussion, including the very productive reverse site visit dialogue with the PD and other team members, the panel concentrated on ways to further strengthen an already strong submission. While no fatal flaws exist in the proposal, nor weaknesses that would compromise overall project health and success, the panel did identify six areas for attention. Therefore, prior to the release of funding, satisfactory written responses should be sent to the CSREES Program that describe plans to address the following areas during PRRS CAP2. These plans will then be incorporated by CSREES and PRRS CAP2 into the original proposal folder.

(1) Summarize an active strategy to include participation by under-represented and/or minority institutions. Participation includes the opportunity to compete for funding due to broader RFA advertisement, as well as consideration to fill an advisory role within the management structure of the CAP.

(2) Articulate a mechanism or strategy to ensure that interoperable databases are developed within the different objectives (1,3 and 4) of the CAP. In other words, those involved with the database developments need to coordinate PRIOR to initiation so that each database team is "aware" of what the other is planning FROM THE

OUTSET to make interoperability more easily doable in the future. There are examples of databases that were intended to be interoperable, however, because coordination and communication only began after they were completed, poor interoperability was achieved. The panel does not want PRRS CAP2 to repeat such an oversight that is easily avoidable.

(3) Revise the impact/outcome sections of Objectives 3 and 4 to be more clearly defined with attainable outcomes. This will be extremely beneficial to the CAP, particularly each year during the evaluation of milestones and deliverables. For Objective 3, for example, the panel felt that with the time and resources available, establishing a phenotype of the experimentally PRRSV-infected pigs with characterization of viral load, immune responses, creation of tissue banks, etc. for use in future long term studies (genomic, translational, proteomic) would be a focused, achievable goal. If more is subsequently achieved in a particular year, the projected outcomes for the following year can always be revised. Without focused, measurable outcomes at the start, however, it will be difficult for the stakeholder board to critically assess progress towards specific endpoints / milestones each year.

(4) Summarize the strategy (including approximate timeline) that will be used for development of the pig model for vaccine studies. This would include arriving at an acceptable (to the community) definition for heterologous protection. Furthermore, given the important role that ecology and epidemiology of disease play in strategies for protection, a separate, but integrated epidemiological model could also be developed as a natural extension of the vaccine model (or perhaps vice versa).

(5) The CAP should commit to initiating and maintaining a dialogue with APHIS-CVB and biopharma industry relative to vaccine and diagnostics development. One way to accomplish this could be through specific designation or assignment within the CAP management structure of a liaison who initiates a dialogue with APHIS-CVB shortly after PRRS CAP2 initiation. Such an open dialogue with APHIS-CVB will be mutually beneficial to all involved and can avoid commercialization delays in the future.

(6) Summarize how CAP2 will formalize interactions between the vaccine and diagnostic focus subgroups to foster more intimate interactions that might not otherwise "naturally" occur at larger group meetings. In other words, the panel believes it is important for at least one dedicated meeting or workshop to occur each year for the vaccine and diagnostic groups.

(7) Please indicate the approximate date of the 1st PRRS CAP 2 annual meeting that will bring together all funded PRRS CAP 2 investigators, as well as the stakeholder board, similar to the annual meetings held by CSREES' Avian Influenza and Johne's CAP projects. At this initiation stage, it is acceptable to indicate spring, summer, fall, winter. The annual meeting should be separate from the very successful International PRRS Symposium held during CRWAD each year so that neither effort is diluted.

Also, please comment on the following suggestion: The program urges

PRRS CAP 2 to initiate a dialogue with NPB to determine if it is feasible within the constraints of NPB funding and policy to include some or all of the NPB funded researchers in the PRRS CAP 2 annual meeting. Such an integration would be an excellent joining of activities between the two funding partners and expected to lead to new productive collaborations and enhanced insights. For example, the Avian Influenza CAP 2 has implemented a joint annual meeting with the NIH Avian Influenza Center grants.