# Final Report: Findings and Recommendations on the Phase II Review of the Animal Care and Well-Being at the Agricultural Research Service to the REE Under Secretary

Final Report Date: July 23, 2015

**Agricultural Research Service – Animal Handling and Welfare Review Panel Members:**
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This report summarizes the findings and recommendations of the Phase II review of the research animal care and well-being policies, procedures, and standards for agricultural livestock in research at the USDA, Agricultural Research Service.

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# Background

The Agricultural Research Service (ARS) Animal Handling and Welfare Review Panel (ARS-AHWRP) was established under the authority of section 1409A(e) of the National Agricultural Research, Extension, and Teaching Policy Act, as amended (7 U.S.C. 3124a(e)), to review ARS agency-wide research animal care and well-being policies, procedures, and standards for agricultural livestock in ARS research. This review consists of two phases: Phase I includes an immediate review of the U.S. Meat Animal Research Center (USMARC) to be completed in 60 days; Phase II charges the panel with reviewing additional 3-5 ARS locations where livestock research is conducted. This report focuses on Phase II of the charge.

In regards to ARS facilities using animals in research, the ARS-AHWRP was charged to:

1) Visit 3-5 ARS locations where livestock research is conducted.
2) Inspect facilities, pens, fields, etc., where animals are housed or involved in experimentation.
3) Review the composition of each location's Institutional Animal Care and Use Committee (IACUC), records of its meetings, and evidence of compliance with agency P&Ps.
4) Review processes used to select and evaluate experimental designs and protocols under the IACUC at each location.
5) Assess care and well-being training needs for staff having responsibility for handling animals at each location.
6) Prepare a draft report for the Under Secretary that summarizes findings for each site visited, and generalized for ARS agency-wide; reaches conclusions as to whether the care and handling of animals and the capacity of facilities and staff at each location are in compliance with institutional P&Ps and industry standards, taking into account that ARS has a research mission, not a production mission; make location-specific and agency-wide recommendations to improve compliance, if necessary, with institutional P&Ps and industry standards; and make recommendations, if appropriate, for changes to institutional P&Ps providing oversight of livestock animal care in ARS's research settings.

The ARS-AHWRP is made up of four members and one ex-officio member appointed by the Secretary of Agriculture: Dr. Aaron Olsen, Chair (Director, Laboratory Animal Research Center, Utah State University); Dr. Lonny Dixon (Director/Attending Veterinarian, Office of Animal Resources, University of Missouri); Dr. Stephen Ford (Endowed Professor, University of Wyoming); Dr. Mo Salman (Professor and Director, Animal Population Health Institute at Colorado State University); and Dr. John Clifford, Ex-Officio Member (Chief Veterinary Officer, USDA, Animal and Plant Health Inspection Service (APHIS)).

In compliance with its charge, the ARS-AHWRP members visited 5 ARS locations using animals in research for Phase II of this review. Brief summaries of the site visits, including dates, panel members present, facility overview, the composition and function of the IACUC, and research site-specific comments and recommendations are below. Although some of these site visits were limited to 2-3 panel members, the site visit reports were shared with all panel members for the final recommendations.

# Site Visit Methodology

ARS locations were independently selected by the panel members based upon a review of all ARS facilities where animal research is conducted. The intention was to select sites with diversity in their missions and experiments. Factors considered in selecting sites were geographic location, co-location with other research institutions (such as a college or university), the number and type of animals used at each facility, and the nature of the research being conducted. The panel members recognized the

highly diverse nature of research programs supported by ARS, and sites were selected in an effort to evaluate a broad spectrum of research and animal care programs. Preference was given to facilities with larger animal care programs based on the presumption that this would provide the best opportunity for panel members to directly observe animal care and handling and associated research activities.

Prior to each visit, the location was requested to have the following documents available for review:

- Last 3-4 IACUC meeting minutes
- Last 2 IACUC semi-annual facility inspection reports
- Representative sampling of IACUC protocols (or equivalent document)
- If an external IACUC is conducting protocol reviews, any MOUs with that organization/university
- Standard operating procedures regarding IACUC function and protocol review; animal husbandry, welfare, and veterinary care
- Animal Health records

Each site visit consisted of an inspection of facilities and direct observation of animals and animal handling, interviews with researchers and key members of the animal care team, and review of documents relevant to animal use and care.

In the course of facility inspections, priority was given to areas where animals were currently being housed and panel members had the opportunity to directly observe the handling and care of research animals in those facilities.

Group and individual interviews were conducted at each location. These interviews focused on identifying how the IACUC functioned at each location, including how protocols were reviewed and approved or disapproved. Individuals in key positions were interviewed at each location, including the ARS Center Director or Research Leader, the Attending Veterinarian, ARS researchers, members of the animal care team, the IACUC chair, and members of the IACUC. At some locations, the support scientists and technicians were also interviewed.

At all sites, the documentation review included standard operating procedures (SOPs) or equivalent documents guiding both animal care and IACUC actions, any written cooperative agreements between the ARS facility and associated research institutions, applications submitted to the IACUC for review and approval detailing animal research activities (e.g. IACUC Protocols), and facility inspection reports. The documents reviewed were based upon requests by the ARS-AHWRP members.

In conducting the review of SOPs and IACUC protocols, all such documents were readily made available to the panel members for review. In accordance with its charge, the panel focused its review efforts on current and active research projects, and all current and active research protocols were made available for review. Priority was given to those activities and protocols that had the potential for increased pain and distress of research animals, such as research involving surgery or infectious diseases.

During interviews and review of documents, the panel also reviewed training programs and records for individuals involved in animal care.

At the conclusion of each site visit, the ARS-AHWRP members conducted an “exit interview” with representatives of the ARS facility. This provided an opportunity for the panel to present an overview of its findings, emphasize areas of strengths observed, highlight areas for improvements or gaps in the animal oversight process, and include a dialogue about how the location could improve its processes in the context of each individual animal care program.

# Location Reviews

## Livestock and Range Research Laboratory

Miles City, Montana
Date of Site Visit: May 13, 2015
Panel Members Present: Aaron Olsen, Mo Salman

Facility Summary

The Livestock and Range Research Laboratory (LARRL) is located at Fort Keogh, near Miles City, Montana. The research facility is focused exclusively on beef cattle, particularly in the context of pasture and range grazing management systems. All animals used at the LARRL are owned and managed by Montana State University (MSU), while experiments are conducted by LARRL staff. The relationship between LARRL and MSU is governed by a written Memorandum of Agreement.

The Institutional Animal Care and Use Committee (IACUC) consists of six voting members, including a local, private veterinarian and a local religious leader. The local veterinarian serves as the Attending Veterinarian on the IACUC and provides veterinary care and oversight for the facility on a fee for service basis. He has provided veterinary care for the LARRL for over 20 years.

The research site consists of over 80 square miles of rangeland. The site visit included inspections of several outlying range areas with animals, animal handling areas, and observation of animals being handled as part of a research project.

It is the opinion of the panel members that all animals observed were healthy and well cared for. This conclusion is based upon the direct observation of the animals, noting the overall appearance and condition of animals. The physical facilities were adequate and appropriate for the nature of the research being conducted. The observation of animal handling showed individuals with skill and care in working with the animals. The IACUC was found to be properly constituted and in compliance with ARS Policies and Procedures. The IACUC appeared to be functioning as ARS Policies and Procedures would intend.

Strengths of the LARRL Animal Care Program

- All animals observed appear to be well cared for and healthy.

- The IACUC meets the standards established in both the *Guide* and the *Ag Guide,* and is thus compliant with ARS Policies and Procedures.

- LARRL and MSU have a clearly written Memorandum of Agreement which details the arrangements between LARRL and MSU, including the oversight of animal use by the IACUC. Additionally, representatives of the MSU IACUC visited LARRL prior to the completion of the memorandum and found the IACUC function to be consistent with the standards of MSU.

- There is evidence of good communication between LARRL and MSU in regards to animal use oversight. This communication was highlighted by the presence of a MSU representative at the AWHRP site visit, despite the distance of over 140 miles from the Billings, Montana campus.

- The veterinarian was fully engaged in all aspects of veterinary care and was, by all reports, providing high quality veterinary care.

- The IACUC members and animal care staff had records of training and recent Beef Quality Assurance Certification. The institution has recently begun using the CITI online training modules as a component of its animal care training program.

- The IACUC community member was highly engaged and expressed a feeling of being fully vested in the IACUC functions.

- Contact information for veterinary care and IACUC representatives were clearly posted in animal handling areas.

- IACUC meeting minutes showed evidence of discussion and resolution of animal health issues as they arose.

Recommendations for the LARRL Animal Care Program

The panel members are of the opinion that the LARRL is a well-run facility, and the IACUC is both properly constituted and functioning as intended. We offer the following recommendations as potential refinements to the existing processes in place:

- The IACUC bylaws or other standard operating procedure documents should clearly state the authority of the Attending Veterinarian to oversee all aspects of animal well-being, including the authority diagnose disease, prescribe treatment, and, especially, to remove an animal from a study and/or euthanize an animal, if necessary, according to the professional opinion of the Attending Veterinarian.

- A written process or policy for how the IACUC will respond to concerns about animal welfare should be available.

- Clarification is needed for the procedure of how and when the IACUC will make use of the Designated Member Review (DMR) process for review and approval of IACUC protocols

- Clearly state that protocols not covered by the Animal Welfare Act must be fully reviewed and approved by the committee at least once every three years for ongoing protocols. At this time all research protocols at the LARRL would fall under the non-AWA covered category and can be eligible for up to a three year approval.

- Clarify the authority of the IACUC to suspend ongoing research activities when the committee votes to do so by a majority of a quorum present.

- A copy of an appropriate “whistleblower” policy should be posted in animal handling facilities.

- An expanded use of standard operating procedures (SOPs) or equivalent documents for some aspects of animal handling or veterinary care should be available. Common procedures, such as pregnancy detection using an ultrasound, may be appropriately detailed in a SOP, which in turn may be referenced within an IACUC protocol using that procedure.

- Establish a clear method to include minority opinions in semi-annual inspection and IACUC meetings. Meeting minutes can include a section for minority opinion, even if left blank due to the absence of a minority opinion.

- Seek additional opportunities for training of IACUC members via conferences, webinars, etc.

## Livestock Behavior Research Unit

West Lafayette, Indiana
Panel Members Present: Aaron Olsen, Mo Salman
Date(s) of Site Visit: May 15, 2015

Facility Summary

The Livestock Behavior Research Unit (LBRU) is co-located with Purdue University in West Lafayette, Indiana. The LBRU emphasis is research aiming to improve welfare of livestock animals by focusing on animal behavior to develop best animal care practices.

The Purdue University farms are accredited by the Association for Assessment and Accreditation for Laboratory Animal Care (AAALAC) International. The LBRU is fully integrated into the Purdue University animal care program. The vast majority of animals used are owned by Purdue University. Almost all animal handling is conducted in Purdue owned facilities, with the exception of a large animal room owed by ARS (which is also included in the AAALAC accreditation). Researchers at the LBRU carry adjunct faculty status with Purdue University, which allows them to use University resources in the same manner as regular University faculty. LBRU researchers and staff members are required to meet the same training requirements as Purdue University faculty and staff members, and documentation of training and qualifications of personnel is maintained by the Purdue Animal Care and Use Committee (PACUC) office.

The panel members visited the Purdue dairy and swine holding facilities. At the time of the site visit only a limited number of animals were involved in LBRU directed research, although the sites visited had been used for ARS sponsored research in the past and are expected to be involved in future ARS projects. All animals observed appeared healthy and well cared for. The physical facilities were well maintained and were adequate for all research and animal handling needs.

Purdue University features a properly constituted and robustly functioning animal oversight committee (the PACUC) which reviews all animal research at Purdue, including ARS sponsored research conducted by LBRU personnel. In the past, LBRU researchers have served on the PACUC and may do so again in the future.

It is the opinion of the panel members that research conducted at the LBRU is fully compliant with both the letter and the spirit of ARS Policies and Procedures in regards to animal care and oversight.

Strengths of the LBRU Animal Care Program

- All animals observed appear to be well cared for and healthy.

- The IACUC meets the standards established in both the *Guide* and the *Ag Guide,* and is thus compliant with ARS Policies and Procedures.

- As noted above, the entire animal care program at Purdue University is AAALAC accredited. This is highly commendable and demonstrates a commitment to animal health and welfare by both LBRU personnel and Purdue University.

- The relationship between LBRU and Purdue University may represent a potential model for other ARS facilities to meet the animal use oversight requirements.

Recommendations for the LBRU Animal Care Program

At this time the panel members do not have any recommendations specifically for the LBRU and its University partner, Purdue. We continue to note the opportunity and need within ARS to share best practices for animal care and handling as well as the challenges and solutions associated with animal oversight between ARS units. We believe that due to its strong oversight model in association with Purdue University, and in particular because of the LBRU research focus on animal welfare, this unit may be in a position to play a leadership role in promoting best animal welfare practices across ARS facilities.

## Southeast Poultry Research Laboratory

Athens, Georgia
Panel Members Present: Mo Salman, Lonny Dixon
Date(s) of Site Visit: June 15-16, 2015

Facility Summary

The Southeast Poultry Research Laboratory (SEPRL), located in Athens, GA, is a research laboratory focusing exclusively on avian diseases, particularly infectious bacterial and viral diseases. The facility includes production units of eggs and live birds exclusive for experiments, biosafety laboratory level (BSL) 2, and BSL-3. The production unit includes specific-pathogen-free (SPF) eggs and birds. All animals used at the SEPRL are owned and managed by ARS with the ability to collaborate with other scientists using the facility under the authority and supervision of the researchers from SEPRL. The facility is within a complex that is currently being reorganized with the Russell B. Russell Agricultural Research Center to form the U.S. National Poultry Research Center.

The Institutional Animal Care and Use Committee consists of 7 voting members, including two local community representatives, who act as alternates for one another. Veterinary care is provided by a designated full-time attending veterinarian who also contributes to hands-on training with a certification process. In the absence of the Attending Veterinarian (AV) at SEPRL, the Attending Veterinarian delegates the responsibilities for animals in writing to another veterinarian of the facility to ensure that adequate veterinary care is provided at all times.

The site visit included a tour of several buildings in which birds (chickens and turkeys) were housed. Animal handlers and animal technicians were interviewed in addition to the leading scientists, researchers, and support scientists/technicians, and IACUC members.

It is the opinion of the two panel members that participated in this visit that all birds observed (three SPF flocks and several BSL-2 study birds) were healthy and well cared for and there was no evidence of animal mistreatment. The physical facilities were aged and in need of constant repair and judged marginal by the site visitors for the type of infectious research conducted. While the state of the physical facilities did not present a concern in regards to animal welfare, inadequate biocontainment

facilities can present a risk to facility employees. Processes and procedures were in place to allow safe and biosecured research to continue for the time being. The observation of animal handling showed individuals with skill and care in working with these birds. The IACUC was found to be properly constituted, in full compliance with ARS Policies and Procedures, and appeared to be functioning as intended.

Strengths of the SEPRL Animal Care Program

- All animals observed appear to be well cared for and healthy.
- The IACUC meets the standards established in both the *Guide* and the *Ag Guide,* and is thus compliant with ARS Policies and Procedures.
- The animal care and use program at SEPRL has a current assurance (#A4298-01) with the National Institutes of Health, Office of Laboratory Animal Welfare (OLAW) that will expire May 31, 2018.
- SEPRL maintains a strong functioning IACUC that was established over 20 years ago. The IACUC composition complies with regulatory requirements. The IACUC chair and its entire members were highly engaged and expressed a feeling of being fully vested in the IACUC functions. There appears to be a fully engaged community member and alternate community member. The IACUC functions meet compliance requirements of the *Guide* and the Animal Welfare Act. Humane endpoints are required for all protocols and are strictly adhered to.
- Training of scientists, technicians, animal care staff, and IACUC members is excellent and extensive and includes hands-on training and proficiency demonstration for all animal procedures. Training is well documented.
- There is evidence of excellent communication between IACUC members, researchers and animal care personnel in regards to animal use and oversight.
- The attending veterinarian was fully engaged in all aspects of veterinary care and was, by all reports, providing high quality hands-on training and veterinary care.

Recommendations for the SEPRL Animal Care Program

The panel members are of the opinion that the SEPRL is a well-run facility with high quality of research and the IACUC is both properly constituted and functioning as intended. We offer the following recommendations as potential refinements to the existing processes in place:

- Although the hands-on training program is excellent for the facility employees, independent recognition of its certificate should be explored through neighboring universities such as University of Georgia (UGA).
- Upgrades and/or replacement of aged BSL-2, BSL-3, and breeding facilities is critical for SEPRL to meet its research goals. ARS needs to recognize the importance of improving these facilities and provide adequate resources to support these functions. Monies have been allocated to renovate and replace some facilities. However, significant additional monies are required to complete the overall facilities improvement needs.

- Because of the focus on infectious disease research at SEPRL, a particularly important consideration is to reevaluate the pay grade level of biosafety professionals so that qualified professionals can be recruited and retained.
- IACUC operation requires administrative support in its daily operation and should not be left to the chair to handle all of the required documentation;
- Although the "whistleblower" policy is known to the staff members who were interviewed, the IACUC is encouraged to post the availability of this option to all employees in the various buildings of SEPRL.
- It was announced during our site visit that both SEPRL and RRC would be under the leadership of one Center Director. This may be an ideal opportunity to consolidate and harmonize IACUC and other compliance activities (i.e., biosafety officer) between sites using common resources. Combining IACUC functions would allow efficient use of resources and provide the opportunity for administrative support for the joint IACUC.

## Richard B. Russell Agricultural Research Center

Athens, Georgia
Panel Members Present: Mo Salman, Lonny Dixon
Date(s) of Site Visit: June 15-16, 2015

Facility Summary

The Richard B. Russell Agricultural Research Center (RRC), located in Athens, GA, is a research laboratory focusing exclusively on avian products including safety and quality. The facility includes 5 research units: Egg Safety & Quality, Quality & Safety Assessment, Toxicology & Mycotoxin, Poultry Microbiological Safety & Processing, and Bacterial Epidemiology & Antimicrobial Resistance. Research activities in some of these units are not engaged with live birds. Birds are supplied to the Center either from commercial sources or the UGA, there were presently no breeder flocks housed. The birds are supplied by UGA through a Memorandum of Understanding. Laboratory mice are maintained within the Center for specific research activities with mycotoxin.

The IACUC consists of nine voting members, including a community member who is also an employee of a maintenance contractor with the center. Some of the veterinary care is provided by the veterinarian who serves as a member of the IACUC but they do not serve as the Attending Veterinarian. All scientists engaged in using live animals for their research are requested to be members of IACUC. The chair of the IACUC provides training at UGA on euthanasia of poultry. Student trainees receive a university approved certification after completion of the training. Facility inspections and program reviews were completed but not of the frequency required by regulations.

The site visit included tours of the building in which mice are housed, the pilot poultry slaughter plant, and an offsite building used to house live birds. Demonstrations of various stunning and euthanasia methods were performed as part of the site visit. Scientists, animal handlers, and IACUC members were interviewed.

It is the opinion of the two panel members that participated in this visit that all experimental animals observed were healthy and appeared well cared for. The physical facilities for housing live poultry were adequate and appropriate for the nature of the research being conducted. The pilot poultry processing

plant was well maintained, clean, and functional. The area used for housing mice requires some modifications to meet the intent of the *Guide*. Leadership and staff members were aware of the needs and a plan for the facility modifications is currently approved and funded.

The IACUC consisted of scientists, non-scientists, a chair, a veterinarian, and a community representative, as required by ARS policies and procedures. However, the community representative was employed by a service company contracted to provide maintenance for the facility. While this meets the definition of a non-affiliated or community representative, it is the opinion of the panel that the individual's employment may be viewed as contingent upon continuation of the facility maintenance contract, therefore, there may not be sufficient separation from the facility to fully meet the spirit of having a non-affiliated community representative.

Strengths of the RRC Animal Care Program

- All animals observed appear to be well cared for and healthy.
- The IACUC meets the standards established in both the *Guide* and the *Ag Guide,* and is thus compliant with ARS Policies and Procedures*.*
- In spite of less emphasis on the use or need of live animals in research, all the scientists who are engaged in the use of live animals are members of the IACUC;
- There is good scientific interaction between the Center and UGA. This is manifested by inter-institutional transfer of birds from UGA protocols to RRC protocols.
- There is a link to UGA in certifying training individuals/employees in euthanasia of birds. This type of independent recognition of the training program is encouraged.

Recommendations for the RRC Animal Care Program

The two panel members are of the opinion that the RRC is a well-run facility with high quality of research. We offer the following recommendations as potential refinements to the existing processes in place:

- There is a need to appoint an attending veterinarian that is fully engaged in all aspects of veterinary care as defined in the Animal Welfare Act and the *Guide*.
- The IACUC community member is employed by a company that provides contract maintenance and support services to RRC. It is recommended that the community member be completely unaffiliated with the RRC.
- IACUC functions, as required by the Animal Welfare Act and the *Guide*, should be reviewed and the activities of the IACUC should be increased to be compliant, including facility inspections, program review, and animal care and use protocols.
- Rodent housing facilities should be evaluated for appropriateness for future intended mycotoxin work. Animal rooms currently have a positive pressure differential to the hallways and not all surfaces are impervious to moisture and readily decontaminated. Some mice were routinely housed in wire bottom cages. Whenever possible, mice should be socially housed in solid

bottom cages with bedding and appropriate environmental enrichment. Exceptions to these requirements can be made for scientific reasons, if approved by the IACUC.

- Although the "whistleblower" policy is known to the staff members who were interviewed, the IACUC is encouraged to post the availability of this option to all employees in the various floors and offsite building of RRC.
- It was announced during our site visit that both SEPRL and RRC would be under the leadership of one Center Director. This may be an ideal opportunity to consolidate and harmonize IACUC and other compliance activities (i.e., biosafety officer) between sites using common resources. Combining IACUC functions would allow efficient use of resources and provide the opportunity for administrative support for the joint IACUC.

## National Animal Disease Center

Ames, Iowa
Panel Members Present: Aaron Olsen, Mo Salman, Lonny Dixon, Stephen Ford
Date(s) of Site Visit: June 17-19, 2015

Facility Summary

The National Centers for Animal Health (NCAH), located in Ames Iowa, is a multi-center facility consisting of the National Veterinary Services Laboratory (NVSL), the Center of Veterinary Biologics (CVB), and the National Animal Disease Center (NADC). Of these units, the NVSL and the CVB are components of the Animal and Plant Health Inspection Service, Veterinary Services (APHIS, VS) while the NADC is operated by the ARS. NCAH animal holding facilities serves ARS and APHIS for their research needs. At the current time, one IACUC serves the ARS program while a separate IACUC serves the needs of the two APHIS units. However, NCAH operates a single animal care program serving both APHIS and ARS units, which is operated solely by ARS staff members. The APHIS and shared components of NCAH animal care and use program is currently accredited by AAALAC, although the ARS components are not similarly accredited. The site members visited and observed areas holding animals associated with ARS research projects, but did not observe areas holding animals used exclusively for APHIS supported research projects. With the exception of veterinary and animal care staff that serve both ARS and APHIS, APHIS staff did not participate in the site review.

The research programs at the NADC focuses primarily on infectious diseases with the potential to impact livestock. As such, a substantial number of the animals are housed under BSL-2 or BSL-3 conditions. The animal care program at NADC is unique in that it makes use of multiple atypical research species, such as bison, elk, raccoons, and white tailed deer, in addition to domestic livestock species and rodents.

During the site visit panel members observed (either directly or via video camera) all areas holding research animals, including outdoor pastures and pens, indoor infectious disease laboratories, and a rodent vivarium.

The ARS IACUC was considered to be properly constituted and in compliance with ARS Policies and Procedures. The IACUC included 11 voting members, including the Attending Veterinarian who oversaw the animal care program, a community member, and research scientists and technicians. In addition, the IACUC was supported by an administrative staff member acting as an IACUC Administrator.

It is the opinion of the panel members that research animals observed appeared healthy and well cared for. There was no observable evidence of misuse or abuse. Furthermore, it was noted that substantial efforts had been made to identify best practices when working with atypical animal species. The small animal vivarium and the relatively new BSL-3 large animal holding facility may be considered exceptionally good facilities while other animal holding areas would be considered adequate. The physical facilities did not negatively impact animal welfare. However, it was noted that some facilities were limited in their ability to provide enhanced animal welfare, such as organic bedding material in large animal BSL-2 facilities, due to limitations of plumbing and other infrastructure to handle bedding waste. The animal care staff is aware of these limitations and is routinely seeking ways to mitigate the limitations imposed by physical facilities.

Strengths of the NADC Animal Care Program

- All animals appear to be well cared for and healthy.

- The IACUC meets the standards established in both the *Guide* and the *Ag Guide,* and is thus compliant with ARS Policies and Procedures*.* The community representative was present at our meeting and appeared fully engaged in the IACUC review process.

- The animal care program is managed by highly engaged and knowledgeable animal care staff, including the veterinarians and the IACUC administrator.

- Extensive efforts have been made to develop best practices for working with atypical research species. In particular, the innovative animal enrichment program and the white-tailed deer breeding program deserve special note.

- Review of animal care protocols found evidence of well-developed humane endpoints, particularly for animals involved in infectious disease research.

- The animal care and use program at NADC has a current assurance with the National Institutes of Health, Office of Laboratory Animal Welfare (OLAW).

Recommendations for the NADC Animal Care Program

The panel members are of the opinion that the NADC is a well-run facility, and the IACUC is both properly constituted and functioning as intended. We offer the following recommendations as potential refinements to the existing processes in place:

- A research veterinarian should not also fill the role of Attending Veterinarian for treatment or handling animals beyond the required research protocol. In some instances, IACUC protocols listed the researcher (who is also a veterinarian) as the only contact for veterinary care issues. Although individuals may be fully qualified as a researcher, they should not act as his or her own attending veterinarian as such a situation removes the appropriate oversight role of a veterinarian. This does not limit the ability of a researcher who is a veterinarian from providing any required care, but it does necessitate that animal health issues be communicated to the veterinary staff providing oversight.

- Animal use protocols should include more robust justifications for the number of animals requested for research projects. Multiple methods may be used to establish that justification,

including power analysis, previously published research, or specific experimental design requirements.

- Animal care contact information and copies of whistleblower policies should be more broadly posted. Many, but not all, animal facilities included postings of such information.

- Train all staff on site on how to report welfare concerns. NADC makes use of a private security firm to provide on-site security, including monitoring cameras in some animal holding areas. Explicit training of all staff, including contract security personnel, on how to report animal welfare or illness concerns would broaden the ability of animal care staff to learn of potential illness or injury.

- A research technician serving as IACUC chair is less than ideal. It was noted that the current chair of the IACUC is a research technician. Although the engagement of research technicians and animal handlers in IACUC composition is encouraged, the ideal chair of the committee should be an individual with in-depth experience in research animals and sufficient stature and standing within the local research community to help implement a robust animal care program.

- The opportunity for IACUC members to serve more than a single 3-year term on the committee and committee chairs more than a single one-year term, should be considered. It was noted that IACUC members routinely served a single 3-year term on the committee before rotating off, and chairs serve a single one-year term in the chairmanship. This arrangement is intended to limit intellectual stagnation within the committee. However, a mix of newer and more experience committee members may be ideal. The opportunity for committee members to serve two or three consecutive terms can be beneficial in providing continuity in IACUC functions. Similarly for the chair position, an extended appointment can allow a chair to both understand the needs of an animal care program and develop and implement program improvements.

- Additional and ongoing training of all IACUC members is strongly encouraged. Multiple training opportunities currently exist in the form of literature, webcasts and webinars, and training conferences. It is the opinion of the panel that in-person training opportunities, such as IACUC 101 meetings, are the preferred option, when possible.

- Consideration should be given to combining IACUCs and other oversight functions between ARS and APHIS research teams. The APHIS research units and the ARS research unit maintain separate IACUCs, although there is a single animal care program, and the IACUC administrator and Attending Veterinarian serve concurrently on both committees. The panel recognizes that the APHIS and ARS research units have different missions and goals. However, we suggest that combining the IACUCs be considered as it is the opinion of the panel that this would introduce efficiencies in the IACUC process and help ensure that expectations of animal care at the site are consistent across all units.

# Agency Wide Findings and Recommendations

## ARS Policies and Procedures

ARS Policies and Procedures number 635.1, *Humane Animal Care and Use,* identifies *The Guide for the Care and Use of Agricultural Animals in Research and Teaching* (the Ag Guide), produced by the Federation of Animal Science Societies, as the primary document guiding the use of agricultural animals at ARS sites, and *The Guide for the Care and Use of Laboratory Animals* (The Guide) as the primary guiding document for the care of non-agricultural animals. The Guide and the Ag Guide serve as a vital reference documents for the care and oversight of animals used in research for ARS. The panel, therefore, strongly supports the use of the current iterations of the Guide (Eighth Edition, 2011) and the Ag Guide (Third Edition, 2010) as the guiding documents in regards to care and use of animals at ARS facilities.

## Animal Care and Handling within ARS

It is the strong opinion of the panel that there was no evidence for misuse or abuse of animals at the ARS sites visited. Interactions with veterinarians and animal care staff found individuals committed to the health and well-being of the animals under their care. Direct observations of animals found the animals to be healthy in appearance, well fed, and with no external signs of injury or abuse. When able to observe the handling of animals, the panel found individuals who exhibit care and professionalism in working with all species.

## Animal Research Oversight within ARS

### Finding 1

**The role and expectations of the Institutional Animal Care and Use Committee and Attending Veterinarian is not uniformly understood at all ARS sites.**

The panel members have observed a variety of models for implementing an effective animal care oversight program and a robustly functioning IACUC. The models observed have ranged from complete integration of an ARS research unit into the animal care program of a co-located academic institution (as observed with the Livestock Behavioral Research Unit located with Purdue University), to a complete stand-alone IACUC and animal care program (as observed at the National Animal Disease Center in Ames, Iowa). The other sites visited had varying degrees of interaction with associated academic institutions. It is the opinion of the panel that any of these oversight models can fully meet the expectations for research oversight and high quality animal care. Indeed, due to the **diverse nature of ARS research centers it is important that individual sites be allowed flexibility to meet the oversight requirements within the context of their specific size and organizational structure and to meet their specific research missions**.

A primary function of the IACUC is to act as an agent for the welfare and wellbeing of animals used in research. To properly fulfill this function, the committee members must fully understand the role and importance of the IACUC. In particular, the Attending Veterinarian plays a crucial role in promoting animal welfare. The panel, however, has noted inconsistencies in the understanding of the roles, expectations, and functioning of the IACUC and its members. This may, in part, be attributed to the nature of small and isolated research sites where individuals are required to divide time and attention between multiple, divergent responsibilities.

### Recommendation 1

**ARS should work to harmonize expectations of the IACUC across all sites using animals in research. To accomplish this recommendation, the panel suggests:**

- **Explicitly state the roles, responsibilities, and authority of the IACUC and Attending Veterinarian in ARS Policies and Procedures.**
- **Provide adequate administrative and financial support for an IACUC to complete its assigned functions.**
- **Provide expanded training opportunities both within and without ARS on the role and function of an IACUC.**
- **Develop means for greater communication both between ARS units and with institutions outside of ARS to expand understanding of the proper role and function of an IACUC.**
- **ARS sites cooperating or collaborating with academic or other research institutions should do so under clearly written agreements that include requirements for animal welfare oversight.**

For an IACUC to fulfill its welfare and oversight functions, it is vital to have adequate administrative and financial support. It is beyond the purview of the review panel to set specific guidelines for support and each research site will have unique needs**. We, therefore, encourage facility directors to make animal welfare oversight responsibilities a priority when considering budgetary needs, and providing strong administrative support to individuals tasked with participating in oversight activities**.

The expectations of an IACUC have become somewhat standardized at academic and industry research institutions, while still providing sufficient flexibility to accommodate different research emphases within a wide variety of research programs. Consequently, a wide variety of training resources have become available for individuals involved in the activities of animal research oversight. The panel emphasizes the need for adequate training of all IACUC members, but especially committee chairs and Attending Veterinarians as these individuals carry special responsibilities in regards to animal welfare oversight. It is not the role of the panel to prescribe specific training programs that must be followed. But based on the experience of several panel members, the IACUC 101 training conferences presented by the organization Public Responsibility in Medicine and Research (PRIM&R) are highly recommended for members of IACUCs at ARS sites.

In addition to enhanced training of IACUC members, increased communication between individuals associated with animal welfare oversight across the ARS organization can provide great benefit to ensuring consistency and quality of animal care and oversight programs across ARS. This type of communication will permit dissemination of effective techniques for operating a robust IACUC and meeting all other animal research oversight requirements. The chairs of the IACUC committees across all ARS location are encouraged to establish regular communications in order to share experiences and policy implementation practices. For example, the biosafety officers in ARS meet regularly to share best practices and updated policies and procedures.

Due to the broad and diverse nature of research programs at academic institutions, they often have well established and robust animal oversight organizations already in place. Where appropriate, the panel encourages ongoing and even enhanced cooperative and collaborative efforts between ARS and academic research institutions, both in fields of scientific inquiry and in fulfilling animal welfare oversight activities. Where ARS sites do cooperate with academic or other research institutions in sharing oversight responsibilities, ARS members are encouraged to serve on IACUCs both to provide input to the committee function and to gain valuable experience in the appropriate function of an IACUC.

## Finding 2

**Service on oversight committees, such as the IACUC, may be viewed by some ARS employees as a diversion from overall job duties.**

Institution oversight committees, such as the IACUC, serve vital functions to the operations of research organizations. The IACUC in particular provides a means for oversight of animal welfare. Ideally, the IACUC can also help promote high quality, scientific efforts by encouraging researchers to refine their research technique, experimental goals, and experimental design early in the process of developing an experiment. For an IACUC to function well and meet its ideal operation, it requires a substantial time commitment on the part of all committee members, but especially on the part of the Attending Veterinarian and the IACUC chair. This time is required to adequately understand the IACUC processes as well as the proposed research activities. However, in conversation with researchers and other ARS staff members, participation on the IACUC is not adequately considered during performance evaluations, and the time required to perform oversight functions is not considered when evaluating research output. Consequently, ARS employees may view service on an IACUC as a diversion from research duties, or worse, a hindrance to achieving personal and professional goals.

### Recommendation 2

**Participation in research oversight activities, such as service on IACUCs, should be an important part of an individual's career development path. Such service should be appropriately considered and recognized during routine personnel evaluations and as part of considerations for advancement or promotion.**

The time commitment necessary to fulfill oversight responsibilities has the potential to impact other employment duties, such as research output by scientists. This consideration may make some ARS employees reluctant to serve on the committee, or limit their engagement on a committee when serving. By acknowledging, and appropriately recognizing the value of oversight committee service, the ARS administration will help emphasize the vital role such committees play in serving their research communities. Furthermore, including oversight committee service as a key component in an individual's career development within ARS can have the benefits of encouraging highly capable individuals to serve and engage with oversight activities, and can help educate ARS scientists and other staff members on the important role that these oversight committees play in supporting research activities.

## Physical Facilities and Equipment

ARS operates multiple research locations across many states. Oftentimes these sites are geographically isolated from other research institutions due to the nature of the research being conducted. This arrangement provides both unique opportunities and challenges. The opportunities arise from the ability to address research needs targeted at specific user groups and stakeholders in various branches of the agriculture industries. The challenges arise from the need to maintain facilities ranging from complex integrated biosafety laboratories to extensive outdoor pasture and rangeland.

It is the opinion of the panel that in most instances the physical facilities were adequate for the research being conducted, and in some instances physical facilities were excellent. However, the advancing age of some facilities was apparent. Individuals at research sites were aware of the limitations of existing animal facilities and were actively seeking innovative means to achieve research goals in existing facilities. Maintaining aging facilities will become an increasingly difficult challenge, and long range plans must include consideration for significant upgrade or replacement of existing facilities if ARS is to continue to meet its research mission in regards to animal agriculture.

### Recommendation 3

**Adequate funding should be provided to maintain current facilities, and to upgrade or replace aging facilities.** ARS fulfills a vital research role in support of agriculture and public health. Among its unique strengths is the ability to implement and maintain long-term research projects. Physical facilities are a

key component in the ability of ARS to meet its research goals, particularly in areas such as infectious disease research which require intensive physical facilities to safely perform the research. While facilities are currently adequate, failure to maintain and eventually upgrade or replace aging facilities may eventually limit research capabilities at ARS sites.

## Animal Handling and Veterinary Care

### Finding 3

**Individuals within ARS display appropriate and sometimes exceptionally good animal handling and care. However, there is limited opportunity to disseminate best animal care practices between ARS facilities or to the broader research and agricultural communities.**

As indicated previously, it is the opinion of the panel members that individuals working with animals routinely displayed care and professionalism in completing their animal handling duties. Indeed, there were several instances where individuals had developed improvements and refinements to animal care handling practices that enhance overall animal welfare. When such efforts and actions occur they are highly commendable. Furthermore, some sites, such as the U.S. Meat Animal Research Center, had developed internal criteria for recognizing skill in animal care providers, while others, such as the RRC, had provided opportunity to receive some training and certification outside of the research facility. However, these arrangements to recognize excellent knowledge and skill in animal care appear to be the exception rather than the standard.

### Recommendation 4

**ARS should provide means for animal care staff to share innovations and best practices both within and without the ARS organization. Concurrent with sharing best practices ARS should develop means to identify and appropriately recognize individuals who provide exceptionally good animal care and/or develop unique and innovative techniques which lead to improved animal welfare.**

It is beyond the scope of the panel's charge to determine the exact means by which best practices can be shared between ARS sites, and between ARS and the broader agricultural and research communities. However, the panel notes that multiple organizations exist which focus on the enhancement of care for animals involved in research. These existing organizations may provide an outlet for sharing of animal care practices, or may serve as a model for how to organize and disseminate animal care techniques.

In addition to providing avenues for sharing best animal care practices, veterinary and animal care staff should be actively encouraged to share best practices and innovative animal care techniques. The panel members recognize that the primary role of animal care and veterinary support staff is to provide ARS researchers with the ability to achieve their research goals. Our recommendation in regards to sharing best practices does not envision changing this role for animal care staff. However, when animal care or veterinary support staff members wish to display initiative in developing animal care techniques which can enhance animal welfare, such as improved animal enrichment processes, they should be encouraged in their efforts, and appropriately recognized. This includes considering animal care activities that promote animal welfare in performance evaluations and, when appropriate, allowing animal care staff and research technicians to act as co-authors or lead authors on scientific publications

Broadly speaking, substantial components of the panel's recommendations for improvements in the ARS animal care programs focused on enhanced training of IACUC members and animal care staff and additional opportunities to disseminate best animal care practices. Traditional methods of helping to meet these recommendations would involve travel of ARS individuals to training seminars or scientific conferences. Several ARS individuals noted the difficulty in complying with these recommendations due

to travel caps within the federal government. The panel is very careful about prescribing specific steps in the efforts of ARS to meet the panel's recommendations. However, in this case one suggestion may be to exempt travel associated with efforts to improve animal welfare from the existing travel caps. Such an action would communicate to ARS employees the importance the agency assigns to promoting animal welfare while simultaneously signaling to the general public that animal welfare is a priority.

## Conclusion

The Agricultural Research Service - Animal Handling and Welfare Panel visited 5 ARS research sites: The Livestock and Range Research Laboratory at Miles City, Montana; the Livestock Behavioral Research Unit in West Lafayette, Indiana; the Southeast Poultry Research Laboratory**,** in Athens, Georgia; the Richard B. Russell Agricultural Research Center in Athens, Georgia; and the National Animal Disease Center in Ames, Iowa. Based upon the observations of the panel members **no evidence** of poor animal handling, animal abuse, or inadequate veterinary care was observed or identified. Furthermore, the facilities were found to be in compliance with ARS Policies and Procedures, particularly in regards to the composition and function of the local animal care oversight committees, although operations of the IACUC varied between facilities. The panel has provided recommendations and refinements specific to each site to improve compliance with both the letter and spirit of ARS Policies and Procedures in regards to animal welfare and oversight. Additionally, the panel has provided recommendations which we believe will encourage improvements in the overall animal care and oversight programs operated within ARS.

# Appendix A – Summary of Public Comment

The open comment period was held between June 29, 2015, and July 14, 2015. Written comments were submitted to a specific email box or the REE Advisory Board Office. A total of six written comments were received during this time frame. At the public meeting on March 18, 2015, verbal comments were received from three organizations. Below is a summary of the public comments received:

**Written Comments**

- Six written comments were received.
- One commenter clarified that the National Animal Disease Center currently has an assurance with the National Institutes of Health, Office of Laboratory Animal Welfare (OLAW).
- Five commenters encouraged the panel to add additional information and clarification on how the locations were selected by the panel and the methodology for the site reviews.
- Four commenters encouraged ARS to comply with the Animal Welfare Act, register every ARS animal research facility with the Animal and Plant Health Inspection Service (APHIS), and seek APHIS inspections of all animal facilities.
- Three commenters suggested that ARS should more fully utilize the National Agricultural Library's Animal Welfare Information Center.
- One commenter suggested that ARS should standardize the operation of the IACUCs, update the ARS Strategic Plan to include references to animal care and well-being, and utilize additional measures to upgrade facilities and facility management plans.
- One commenter suggested that ARS should formulate and disseminate new policies and procedures on animal welfare and train employees on the new policies and procedures.
- One commenter suggested that each IACUC should have two non-affiliated members on the IACUC; one of these non-affiliated members should be a bio-ethicist.
- One commenter was complimentary of the development and implementation of the ARS Animal Welfare Action Plan.

**Verbal Comments**

- A total of three verbal comments were received.
- All three commenters suggested adding additional information and clarification on how the locations were selected by the panel and the methodology for the site reviews.
- The commenters agreed with the findings and recommendations and encouraged ARS to harmonize and standardize the IACUCs across all ARS locations.
- One commenter praised ARS for the development and implementation of the Animal Welfare Action Plan.
- One commenter suggested that ARS should more fully utilize the National Agricultural Library's Animal Welfare Information Center.

In conclusion, the independent panel made the following edits to the report based on the comments received:

- Added information to the section on the Strengths of the Animal Care Program at the National Animal Disease Center indicating that the Center currently has an assurance with the National Institutes of Health, Office of Laboratory Animal Welfare (OLAW).
- Added a section on methodology, including information on how the locations were selected and how the site visits were conducted.