United States Department of Agriculture
Agricultural Research Service

Animal Welfare Action Plan

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Dated March 20, 2015
Updated June 17, 2015 (Edited)
Introduction
The Agricultural Research Service’s (ARS) Animal Welfare Action Plan contains three primary emphasis areas: policies and procedures, training, and oversight. While the health and well-being of the animals in the care of ARS and of all animals in the agricultural industry have always been of high significance to us, we are taking the events of recent months as an opportunity to further strengthen and then institutionalize a continuous improvement system for animal welfare in ARS. In the coming months and years, ARS animal handling policies and procedures will be updated, a new training program for all who come into contact with animals at work will be rolled out, and the establishment of an internal structure to increase coordination and oversight of animal research will be realized.

1 Policies and Procedures
ARS has two official Policies and Procedures (P&P), 635.1 and 130.4, that govern animal care and handling. Upon receipt of recommendations from the external panel and deliberations from the internal ARS Animal Welfare Leadership Committee and Task Force, the two existing P&Ps will be consolidated, updated, and reissued. In addition, an implementation plan will be developed to lead ARS’ path forward toward executing upgrades to the Animal Welfare Program.

1.1 Inputs to Formulate Policies and Procedures

USDA External Animal Handling and Welfare Review Panel (USMARC and ARS Review)
The Secretary of the United States Department of Agriculture (USDA) has appointed an external Animal Handling and Welfare Review Panel. The panel consists of animal research and welfare experts from land grant universities, and is charged with evaluating animal use, care, and well-being at the U.S. Meat Animal Research Center (USMARC), with a complete report by March 20, 2015. During the next six months, the panel will produce a recommended course of action to strengthen animal handling protocols, procedures, and practices across all ARS animal research facilities. This input will be used to formulate updated policies and procedures within ARS. The panel’s operating charter is included in Appendix A.

USDA Office of the Inspector General Audit
The Office of the Inspector General is performing an audit with the objectives to review the research practices and operations of the USMARC to evaluate the concerns expressed by Congress and reported by the media regarding animal welfare. They will also examine ARS’ oversight and monitoring of USMARC as it relates to animal welfare. Their audit results, anticipated January 2016, will also inform ARS policies and procedures going forward.
1.2 Animal Welfare Ombudsman
In addition to reinforcing the Whistleblower Protections available to all Federal employees, the updated ARS policies and procedures will include guidance on a new option to report findings to the Animal Welfare Ombudsman. The Animal Welfare Ombudsman provides confidential, impartial, and independent assistance to individuals and groups who have complaints or concerns related to animal welfare in ARS animal research facilities. The Ombudsman provides a safe and confidential forum for internal and external individuals or groups who work on ARS grounds to service complaints or concerns about animal welfare. The Ombudsman provides reports to the ARS Administrator on at least an annual basis including the number of complainants assisted, problem categories, issues and observations, trends, concerns, and recommendations. In addition to summarizing the results of the year’s work, the annual report will alert the ARS leadership to problems and trends and help decision-making within ARS to foster a renewed culture of animal welfare.

On January 23, 2015, ARS Administrator Dr. Chavonda Jacobs-Young appointed Dr. Eileen Thacker the first Animal Welfare Ombudsman at ARS. Dr. Thacker is a veterinarian with a Ph.D. in pathology, and is currently the ARS National Program Leader for both Food Safety and Animal Health and is Board Certified in Veterinary Microbiology. The ARS Animal Welfare Ombudsman can be reached via email at animalwellbeing@ars.usda.gov, and encourages internal and external communications about ARS animal welfare concerns or complaints.

More information on the Animal Welfare Ombudsman program is found in Appendix C.

2 Training
The Animal Welfare Act (AWA) and the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals provide guidance and regulations to ensure that all animals used for research in the United States are treated in a humane manner. It has been the policy of ARS to follow all regulations of the AWA and PHS to ensure that the animals used in research by the Agency are treated appropriately and humanely. An integral part of both the AWA and the PHS guidelines is a comprehensive animal welfare training program. Therefore, the ARS Animal Welfare Training Program is designed to meet AWA and PHS requirements for basic and specialized training in the humane care and use of animals, and will train researchers, post-docs, or technicians who use or plan to use animals; Institutional Animal Care and Use Committee (IACUC) members; animal care staff; animal surgery staff; and management or administrative staff of animal handling facilities.

All such ARS employees need to receive training within the first 60 days of implementation of this plan or within the first 60 days of employment. Employees of locations co-located with Universities and receiving training associated with the University would be required to provide documentation of all training within the first 60 days of implementation. Completion of all training requirements listed is required within 12 months of the official announcement of this action plan.
More specific information on training, including sources and curriculum, is available in Appendix D. This training plan is implementation-ready, as it is an integral part of the ARS Animal Welfare Program moving forward.

3 Oversight

3.1 ARS Animal Care and Use Officer (ACUO)

ARS will establish a new Animal Care and Use Officer (ACUO) at Headquarters to lead the oversight to ensure all animal research locations are in compliance with ARS policies and procedures on animal welfare. The ACUO will be a professional with a DVM degree, and possibly a DVM-PhD, who is qualified to evaluate animal care, use, and well-being, as well as policies, procedures, and experimental plans and methods that may affect animals in research settings. The ACUO's primary responsibilities will include receiving and reviewing IACUC minutes from labs across ARS, overseeing training requirements, and reviewing or coordinating reviews of experimental protocols for animal research in ARS.

3.2 ARS Animal Welfare Leadership Committee and Task Force

ARS has established two bodies—the ARS Animal Welfare Leadership Committee and the Animal Welfare Task Force—to coordinate, review, and strengthen relevant ARS programs and offices with the aim of assisting Agency leadership in fulfilling its responsibilities to the animals under ARS care. This Leadership Committee is comprised of senior program and line managers in ARS and chaired by the Deputy Administrator for Animal Production and Protection, Office of National Programs. The Leadership Committee will provide guidance to the Animal Welfare Task Force, comprised of field and headquarters leaders, plus an animal welfare program leader from the Animal and Plant Health Inspection Service (APHIS). As recommended in the report Critical Role of Animal Science Research in Food Security and Sustainability⁴, the Leadership Committee will also be tasked with ensuring the consideration of social and environmental aspects of animal research are included in the national program planning process. ARS will work with the National Academy of Sciences to address the recommendations of the report to more closely integrate socioeconomic and animal science research. The Task Force will also oversee, lead, and often participate in ARS animal welfare program inspections to identify gaps in current ARS animal care and use protocols and procedures and to develop implementation plans to address identified gaps.

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⁴ Committee on Considerations for the Future of Animal Science Research; Science and Technology for Sustainability Program Policy and Global Affairs; Board on Agriculture and Natural Resources Division on Earth and Life Studies; National Research Council of the National Academies; National Academies Press, Washington, D.C. 2015.
Together, these groups working in concert with ACUO are charged with promoting and maintaining a vigilant, community-owned, animal welfare culture across ARS locations. More about the groups is available in Appendix B.

3.3 Accreditation and Inspection Pilot Program with APHIS

ARS intends to voluntarily register its animal research locations with APHIS. ARS is also exploring options to make an arrangement with APHIS Animal Welfare Inspectors for periodic review of ARS animal care and use at the various locations. Third party animal welfare accreditation is an option that may be feasible for some ARS locations. The ARS Animal Care and Use Officer will work closely with the Animal Welfare Task Force to provide resources and assistance to those ARS locations that will explore third party accreditation.

APHIS and ARS are also collaborating to develop a pilot project to assess the animal welfare standards, compliance monitoring, and Institutional Animal Care and Use Committee (IACUC) oversight of animals used at specific ARS research facilities. The results of the pilot project will be carefully evaluated and next steps formulated. ARS and APHIS will develop a formal partnership and program that will ensure ARS facilities maintain consistent practices for adhering to all necessary animal welfare standards, including those outlined in APHIS’ animal welfare regulations. Key steps being planned include:

- APHIS will review existing ARS animal welfare and IACUC oversight and guidelines for its animals used in research.
- APHIS will evaluate the application of the guidelines at selected ARS facilities to establish baseline compliance measurements.
- APHIS will work with ARS to develop inspection procedures, checklists, results reporting mechanisms, and other necessary supporting documentation for the pilot inspection program.
- APHIS and ARS will conduct pilot facility inspections.
- ARS will review results and develop a formal partnership and facility inspection program.

4 Animal Welfare Program Implementation Timeline

ARS is fully aware that without its research animals, ARS’ vital studies on animal and human health and food safety would not be possible. The implementation roadmap identifies specific steps and milestones to continuously improve ARS’ management and research practices and reaffirm its commitment to meet the highest standards of animal use, care, and well-being. The following table summarizes the implementation roadmap.
<table>
<thead>
<tr>
<th>Dates</th>
<th>Milestones/Deliverables</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/2015</td>
<td>Established an Animal Welfare (AW) email portal.</td>
<td>Established <a href="mailto:animalwellbeing@ars.usda.gov">animalwellbeing@ars.usda.gov</a> to encourage internal and external communications about ARS animal welfare concerns.</td>
</tr>
<tr>
<td>01/2015</td>
<td>Appointed an Animal Welfare Ombudsman.</td>
<td>Dr. Eileen Thacker, a veterinarian with a Ph.D. in pathology, was appointed as ARS’ first Animal Welfare Ombudsman on January 23, 2015.</td>
</tr>
<tr>
<td>01/2015</td>
<td>Established an Animal Welfare Leadership Committee.</td>
<td>Leveraged and expanded the ARS Biosafety, Safety and Health Leadership Steering Committee to include animal welfare. The committee is chaired by Dr. Steve Kappes.</td>
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<tr>
<td>01/2015</td>
<td>Analyzed existing Animal Welfare training programs.</td>
<td>Evaluated and analyzed existing Animal Welfare training programs across ARS locations.</td>
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<tr>
<td>02/2015</td>
<td>Formed an external review panel.</td>
<td>An Animal Handling and Welfare Review Panel (AHWRP) was formed with experts from land grant universities.</td>
</tr>
<tr>
<td>02/2015</td>
<td>Conducted external panel review of USMARC Animal Welfare program.</td>
<td>The AHWRP started their review on February 24 and provided its initial findings to the Secretary on March 9. A finalized report incorporating NAREEE board comments was due by April 2015. The Secretary received these comments on April 30, 2015.</td>
</tr>
<tr>
<td>02/2015</td>
<td>Established an Animal Welfare Task Force.</td>
<td>Dr. Don Lay with 6 ARS and APHIS subject matter experts chairs the Task Force.</td>
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</table>
Began updating ARS Policies and Procedures No. 130.4 – Animal Care and Use Committee.  
These will be updated based on the recommendations provided by the independent panel review during its second phase.                                                                                       |
<p>| 03/2015 | Standardize agency-wide Animal Welfare training curriculum.                              | Leverage existing ARS training courses, APHIS courses, and third party training courses.                                                                                                                  |</p>
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<tbody>
<tr>
<td>03/2015</td>
<td>Implement AHWRP’s USMARC review recommendations.</td>
<td>The AHWRP provided its draft USMARC review report with seven recommendations:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Develop and implement written agreements with University of Nebraska Lincoln (UNL) and any other research or teaching partners. To be completed by July 2015.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Develop and implement an animal handling training and documentation program. Began training development in March 2015. On March 27, 2015, 64 ARS employees and 66 UNL employees completed training developed by UNL Attending Veterinarian Dr. Kelly Heath and his assistant, Kathy Pinkerton, based on the AHWRP recommendations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Extend the electronic medical records database to include all species housed at USMARC. The sheep database was implemented on April 1, 2015. The addition of sheep health records to the electronic database means that all animals at USMARC are now tracked in the database.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Develop and implement processes that promote a robustly functioning IACUC with proper training.</td>
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<td></td>
<td></td>
<td>• A new IACUC composed of 11 members and 2 alternates was named on April 27, 2015. All members and alternates have completed required training. Training certifications are recorded via the American Association for Laboratory Animal Science (AALAS) online system.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Appropriate training for IACUC members on processes, requirements, and expectations. All members completed by April 16, 2015.</td>
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<tr>
<td></td>
<td></td>
<td>• Properly convened meetings be held regularly, and that criteria be developed for what types of research proposals should receive additional review and discussion at IACUC meetings and those that may be appropriately reviewed by designated IACUC members outside of a convened meeting. Meetings held May 5 and May 14. Any research proposal that requires an animal to...</td>
</tr>
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</table>
- Development of a consistent IACUC review process that will review and evaluate the topics related to animal welfare as indicated by the Ag Guide. A Standard Operating Procedure has been developed for the IACUC review process and other IACUC activities.

- All individuals associated with animal care or research receive training on the role and importance of the IACUC in animal welfare and oversight. Kelly Heath, UNL Attending Veterinarian, provided General Regulations Training to all individuals associated with animal care.

- IACUC members should inspect all areas where animals are held, handled or used, even if animals are not present at the time of inspection. The IACUC SOP (standard operating procedures) addresses facility inspections.

- Reviews of proposed research or facility inspections should not be conducted unless a properly constituted IACUC is in place. The IACUC has been properly reconstituted; the reconstituted IACUC met for the first time on May 5, 2015, to review a set of the most time-sensitive research protocols.

- Attending Veterinarian should not serve as the chair of the USMARC IACUC. A new panel chair has been appointed. USMARC research physiologist Jeff Vallet, who is not the USMARC attending veterinarian, has assumed the role of Chair of the IACUC. Completed as of March 13, 2015.

- Use of all vertebrate animals at USMARC should be reviewed and approved by the IACUC. Completed as of March 13, 2015.
<table>
<thead>
<tr>
<th>Dates</th>
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</thead>
<tbody>
<tr>
<td>04/2015</td>
<td>Begin progress reporting.</td>
<td>Monthly report on the implementation of AHWRP recommendations.</td>
</tr>
<tr>
<td>04/2015</td>
<td>Enhance pasture lambing and calving protocol.</td>
<td>Review and enhance USMARC pasture lambing and calving.</td>
</tr>
<tr>
<td>04/2015</td>
<td>Conduct external panel review of ARS Animal Welfare programs.</td>
<td>The AHWRP will start its review in April and report to the Undersecretary in August 2015.</td>
</tr>
<tr>
<td>05/2015</td>
<td>Conduct ARS’ internal Animal Welfare program inspections.</td>
<td>Ongoing assessment to continuously improve the effectiveness of Animal Welfare programs through assessments and evaluations.</td>
</tr>
<tr>
<td>06/2015</td>
<td>Implement recommendations from internal Animal Welfare program inspections.</td>
<td>Continuous improvement of Animal Welfare programs.</td>
</tr>
<tr>
<td>06/2015</td>
<td>Begin agency-wide training.</td>
<td>Ongoing Animal Welfare training based on the training plan defined.</td>
</tr>
<tr>
<td>06/2015</td>
<td>Voluntarily apply for APHIS registration.</td>
<td>Register ARS animal research facilities with APHIS. Complete the registration of ARS animal research facilities in 18 months.</td>
</tr>
<tr>
<td>06/2015</td>
<td>Begin ARS and APHIS Collaborative Pilot Project.</td>
<td>Begin APHIS Animal Care and ARS collaboration to establish baseline measures, resources, and operational requirements.</td>
</tr>
<tr>
<td>07/2015</td>
<td>Establish an Animal Care and Use Officer (ACUO).</td>
<td>The ACUO would be a GS-15 professional with a DVM or DVM-PhD degree at the Headquarters.</td>
</tr>
<tr>
<td>10/2015</td>
<td>Implement AHWRP’s ARS Agency-wide review recommendations.</td>
<td>Periodically review Animal Welfare practices and ensure that Animal Welfare is incorporated as an Agency value at all levels.</td>
</tr>
<tr>
<td>12/2015</td>
<td>Begin accreditation and certification.</td>
<td>Work with associations and industry to begin certifying ARS laboratory animal research facilities. Complete the accreditation of all ARS laboratory animal research facilities in 5 years.</td>
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Appendix A – Animal Handling and Welfare Review Panel Charter

Independent External Panel Review

An external Animal Handling and Welfare Review Panel (AHWRP) has been appointed by the Secretary of the United States Department of Agriculture (USDA) under the authority of section 1409 A(e) of the National Agricultural Research, Extension, and Teaching Policy Act. The panel consists of animal research and welfare experts from land grant universities. The panel has been charged with evaluating animal use, care, and well-being at the U.S. Meat Animal Research Center (USMARC), with a complete report within 60 days. During the next six months, the panel will produce a recommended course of action to strengthen animal handling protocols, procedures, and practices across all ARS animal research facilities.

1.1 Panel Operating Charter

The objective of the AHWRP is to review ARS agency-wide animal care, use, and well-being policies, procedures, standards, and practices. The AHWRP will begin with an immediate review of USMARC and subsequently expand to review several other ARS animal research facilities. The AHWRP will report its findings and recommendations to the Secretary of USDA and the Undersecretary of Research, Education, and Economics (REE). The panel was charged with conducting an open, transparent, and independent review. The AHWRP review will be carried out in two phases. For the first phase, the panel was tasked to:

- Review ARS/REE/USDA Policies and Procedures (P&Ps) providing requirements and guidance for care, use, and well-being of animals used in research.
- Visit USMARC at Clay Center, Nebraska.
- Inspect facilities, pens, fields, etc., where animals are housed or involved in experimentation.
- Review the composition of the location’s Institutional Animal Care and Use Committee (IACUC), records of its meetings, and evidence of compliance with agency P&Ps.
- Review processes used to select topics, and evaluate experimental designs and protocols under the IACUC.
- Assess care and well-being training needs for staff having responsibility for handling animals.

This was accomplished by the following timeline:

- February 24-26, 2015 - The AHWRP members visited USMARC
- March 9, 2015 – Panel provided draft report of findings to the Secretary
- March 9, 2015 – Notice of public meeting published in the Federal Register with a link to the draft report; Secretary Vilsack orders ARS to take steps to begin the implementation of immediately actionable recommendations contained within the report
• March 9-18, 2015 – Public comment period
• March 18, 2015– Panel’s public meeting (via teleconference) to present report and provide opportunity for oral comments
• March 18-23, 2015 – Panel updates report to address public comments
• March 23, 2015 – Panel provides report to National Agricultural Research, Education and Economics (NAREEE) Advisory Board
• March 30, 2015 - Notice of public meeting published in the Federal Register with the link to the updated report
• March 30-April 14, 2015 – NAREEE Board holds a second public comment period
• April 14, 2015 – NAREEE Board public meeting to discuss the final report with opportunity for verbal public comments
• April 14-21, 2015 – NAREEE Board finalized response and included public comments
• April 30, 2015 – NAREEE Board provided response to Secretary, Under Secretary, and ARS Administrator.

The AHWRP has completed its review of USMARC and prepared a report of its findings and recommendations to the USDA Secretary and the REE Under Secretary. The panel also met in a public forum to present its findings and recommendations and accept public input.

As a result of the discussion on April 14, 2015, the NAREEE Advisory Board identified the following recommendations to USDA:

• The USMARC and University of Nebraska Lincoln (UNL) agreements identified in Recommendation 1 of the Final Report from the ARS-AHWR Panel should also include clearly documented provisions on the appropriate animal handling and use policies and procedures.

• USDA should continue to ensure that the recommendations submitted by the ARS-AHWR Panel are appropriately implemented at USMARC and continue to be followed, either through site visits or another appropriate agreement or mechanism.

• NAREEE supports the Secretary in requiring that the Institutional Animal Care and Use Committee (IACUC) must be properly constituted prior to any additional reviews or approvals of research protocols. Anything short of following 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) is unacceptable. These standards are an appropriate and effective way to ensure animals are cared for and used appropriately in research protocols.
The second phase of the review will be completed in 180 days. The AHWRP will:

- Visit three to five ARS locations where livestock research is conducted.
- Inspect facilities, pens, fields, etc., where animals are housed or involved in experimentation.
- Review the composition of the location’s IACUC, records of its meetings, and evidence of compliance with agency P&Ps.
- Review processes used to select topics, and evaluate experimental designs and protocols under the IACUC.
- Assess care and well-being training needs for staff having responsibility for handling animals.

Below is the projected timeline for the second phase:

- May 11 through June 30, 2015 – Panel will conduct site reviews and draft report
- July 6, 2015 – Provide draft report to the REE Under Secretary, publish report on website
- July 6-14, 2015 – Public Comment period and Public Meeting
- July 21, 2015 – Submit final report to REE Under Secretary, publish report on website
- July 21-August 19, 2015 – Public Comment period and Public Meeting, NAREEE Board comment period
- August 19, 2015 – NAREEE submits additional advice and recommendations to REE Under Secretary to finalize report

The panel is composed of five individuals who are experts in animal science research, veterinary medicine, and animal care from U.S. land grant universities. The panel is balanced in its membership in terms of points of view represented and the functions to be performed. One ex-officio member of the panel is the Chief Veterinary Officer of the Animal and Plant Health Inspection Service (APHIS). One member serves as the chairperson who leads the group in a fair and focused manner.

1.2 USMARC Review

The AHWRP members visited USMARC on February 24-26, 2015. They were given full access to the entire facility and inspected all animal housing sites and fields where animals were located and research activities that were underway. They observed animal handling and interviewed USMARC employees. They also reviewed processes for research and animal welfare oversight, the composition and function of the IACUC, on-site veterinary medical care, upkeep, maintenance, and regular review of animal facilities, and training of the Center’s personnel.

The AHWRP has provided a draft USMARC review report to the Secretary and released the report for public review and comment on Monday, March 9, 2015. In late March 2015, the panel held a public hearing teleconference call to receive inputs and comments on the draft
report from interested stakeholders. Public comments will be reviewed, and then the panel will finalize its report in April 2015. The AHWRP has made the following seven major recommendations:

- **Develop and implement written agreements with University of Nebraska, Lincoln (UNL) and any other research or teaching partners.** This draft document is under review by the UNL Office of General Counsel and USDA Office of General Counsel. We expect this to be finalized in late July 2015.

- **Develop and implement an animal handling training and documentation program for all individuals involved with the handling and use of animals in research.** UNL Attending Veterinarian Dr. Kelly Heath and his assistant, Kathy Pinkerton developed training based on the initial Panel recommendations. On March 27, 2015, 64 ARS employees and 66 UNL employees completed the training. Dr. Heath certified completion for the participants. Appropriate information on how to report concerns was also provided and posted. The whistleblower policy is an aspect of the posted material.

- **Extend the electronic medical records database to include all animal species housed at USMARC.** The sheep health database was implemented on April 1, 2015. The addition of sheep health records to the electronic database means all animals at USMARC are now tracked in the database.

- **Develop and implement processes that promote a robustly functioning IACUC with proper training.** A new IACUC composed of 11 members and 2 alternates was named on April 27, 2015. All members and alternates have completed required training. Training certifications are recorded via the American Association for Laboratory Animal Science (AALAS) online system.
  
  - Appropriate training for IACUC members on processes, requirements, and expectations. All members completed by April 16, 2015.
  
  - Properly convened meetings be held regularly, and that criteria be developed for what types of research proposals should receive additional review and discussion at IACUC meetings and those that may be appropriately reviewed by designated IACUC members outside of a convened meeting. Meetings held May 5 and May 14. Any research proposal that requires an animal to undergo major surgery (as defined by the Federation of Animal Science Societies’ guidelines) or be euthanized must be reviewed during full committee meetings.
  
  - Development of a consistent IACUC review process that will review and evaluate the topics related to animal welfare as indicated by the Ag Guide.
Standard Operating Procedure has been developed for the IACUC review process and other IACUC activities.

- All individuals associated with animal care or research receive training on the role and importance of the IACUC in animal welfare and oversight. Dr. Kelly Heath, UNL Attending Veterinarian, provided General Regulations Training to all individuals associated with animal care.

- IACUC members should inspect all areas where animals are held, handled or used, even if animals are not present at the time of inspection. The IACUC SOP (standard operating procedures) addresses facility inspections.

- Reviews of proposed research or facility inspections should not be conducted unless a properly constituted IACUC is in place. As outlined above, the IACUC processes have been revised, new committee membership has been appointed, and training for each member has been completed and certified by the AALAS. The revised IACUC process received REE approval, and is now fully functional and approved to renew research protocols and facility inspections. USMARC’s revised IACUC met officially for the first time on May 5, 2015, to review a set of the most time-sensitive research protocols proposed for USMARC investigations and approved all five that were evaluated. In fact, all ARS facilities have reviewed or are reviewing their existing IACUC protocols for conformity to existing policies and will make revisions as appropriate.

In addition, ARS is working with APHIS to actively review the feasibility of implementing APHIS inspections of ARS research facilities (as outlined by the Action Plan). If the review finds this to be a viable and appropriate course of action, USDA will move to put this proposal into effect. This arrangement would provide APHIS inspections of ARS facilities similar to those provided to other AWA-exempt organizations, such as the National Zoo.

- Attending veterinarian should not serve as the chair of the USMARC IACUC. A new panel chair has been appointed. USMARC research physiologist Jeff Vallet, who is not the USMARC attending veterinarian, has assumed the role of Chair of the IACUC.

- Use of all vertebrate animals at USMARC should be reviewed and approved by the IACUC. This has been implemented and will continue to be an ongoing practice.

ARS’ goal is to continuously improve its management and research practices and has taken immediate actions to address AHWRP recommendations. Of the seven AHWRP recommendations listed above, three were completed in March. An additional two were completed in May. We anticipate the completion of the final recommendation by July 2015.
1.3 ARS Review

The AHWRP will begin its review of ARS animal welfare programs in April 2015. The panel plans to visit three to five ARS locations where animal research is conducted. The AHWRP will prepare a report in October 2015 to the REE Under Secretary summarizing its findings and recommendations. The report will summarize the panel’s findings specific to each location visited and generalized findings for ARS agency-wide. The report will identify the panel’s conclusions as to whether the care and handling of animals and the capacity of facilities and staff at each location are in compliance with ARS Policies and Procedures (P&Ps) and industry standards, taking into account that ARS has a research mission, not a production mission. In addition, the report will make location-specific and agency-wide recommendations to improve compliance, if necessary, with ARS P&Ps and industry standards and, if appropriate, for changes to ARS P&Ps providing oversight of livestock animal care in ARS’ research settings.
Appendix B – Animal Welfare Leadership Committee and Task Force

An Animal Welfare Leadership Committee and an Animal Welfare Task Force lead the ARS animal welfare program. The purpose of the Animal Welfare Leadership Committee is to provide a focused forum for coordinating and collaborating on mechanisms to review and strengthen relevant ARS animal welfare programs and to assist Agency leadership in fulfilling its responsibilities to provide oversight and support of the implementation and effectiveness of the Agency’s animal welfare procedures, policies, programs, and initiatives. The Animal Welfare Leadership Committee promotes and encourages the highest level of ethics within the profession of laboratory animal science. The Animal Welfare Leadership Committee provides guidance to the Animal Welfare Task Force and oversees the development and implementation of the roadmap. The Animal Welfare Leadership Committee members include:

- Dr. Steven Kappes, Deputy Administrator, Office of National Programs (Chair)
- Ms. Lisa Baldus, Associate Deputy Administrator, Administrative and Financial Management (AFM) (Alternate)
- Dr. Deborah Brennan, Director, Southeast Area
- Dr. Larry Chandler, Director, Plains Area
- Mr. Nino Fleri, Director, Facilities Division, AFM
- Dr. Andrew Hammond, Director, Pacific West Area
- Mr. Pete Jovanovich, Branch Chief, Safety, Health and Environmental Management Branch, Facilities Division, AFM
- Mr. Joseph Kozlovac, ARS Agency Biosafety Officer
- Dr. Bob Matteri, Director, Midwest Area
- Mr. Joon Park, Deputy Administrator, AFM
- Dr. Dariusz Swietlik, Director, North East Area

The purpose of the Animal Welfare Task Force is to oversee, lead, or participate in the ARS Animal Welfare program inspections, to identify gaps in current ARS animal care and use protocols and procedures, and to develop implementation plans to address identified gaps. The Animal Welfare Task Force members include:

- Dr. Eileen Thacker, DVM, PhD, DACVM, National Program Leader, Food Safety and Animal Health, Office of National Programs, Beltsville, MD
- Ms. Janice Boarman, Program Analyst, Animal Production and Protection, Beltsville, MD
- Dr. Deborah Brennan, DVM, MPA, Director, Southeast Area, Stoneville, MS
- Dr. Donald Knowles, DVM, PhD, DACVP, Research Leader, Animal Disease Research Unit, Pullman, WA
- Mr. Joseph Kozlovac, ARS Agency Biosafety Officer, Beltsville, MD
- Dr. Donald Lay, Jr., PhD, Research Leader, Livestock Behavior Research, West Lafayette, IN
- Dr. Nora Wineland, DVM, MS, DACVPM, Director, APHIS Center for Animal Welfare, Kansas City, MO
Appendix C – Animal Welfare Ombudsman

On January 23, 2015, ARS National Program Leader (NPL) Eileen Thacker was appointed as the first Animal Welfare Ombudsman at ARS. Since 2010, Dr. Thacker has overseen and validated the collection of ARS animal welfare data and ensured that the makeup of the IACUC committees met all requirements of the Animal Welfare Act. Dr. Thacker, a veterinarian with a Ph.D. in pathology, is an NPL for both Food Safety and Animal Health and is Board Certified in Veterinary Microbiology.

The ARS Animal Welfare Ombudsman provides confidential, impartial, and independent assistance to individuals and groups who have complaints or concerns related to animal welfare in ARS animal research facilities. Key operational principles include:

- Confidential – The Animal Welfare Ombudsman maintains the privacy of the identity of individuals or groups as well as the content of their complaints or concerns. The Animal Welfare Ombudsman may contact individuals within ARS whose help is necessary to resolve a complaint or concern.

- Impartial – The Animal Welfare Ombudsman has no personal interest or stake in and incurs no personal gain or loss from the outcome of any complaint or concern process. The Animal Welfare Ombudsman attempts to promote fair processes but does not advocate for individuals or groups on the basis of affiliation or constituency status.


The ARS Animal Welfare Ombudsman is impartial and independent of the management structure within ARS. The Animal Welfare Ombudsman reports directly to the ARS Administrator. This reporting structure aims to demonstrate ARS’ commitments to animal welfare and establish the credibility of the Animal Welfare Ombudsman.

1.1 Primary Functions

The ARS Animal Welfare Ombudsman does not replace but rather complements and supplements other programs or resources within ARS. The Animal Welfare Ombudsman works in concert with different programs or services in ARS to help with resolution of Animal Welfare complaints or concerns, but does so in a manner that preserves the confidentiality of the individual(s) or group(s) who seek ombudsman services. The Animal Welfare Ombudsman performs a number of functions in carrying out her responsibilities. The primary functions include:

- Provide a safe and confidential forum to service complaints or concerns about animal welfare from internal and external individuals or groups.
- Listen to and help clarify complaints or concerns. Help identify underlying issues and interests. Explore possible options through formal or informal channels.
- Help identify undetected and/or unreported unethical behavior, policy violations, or ineffective animal care and use programs.
- Help employees become empowered and take responsibility for creating humane care and use of animals to support research.
- Provide an early warning diagnosis system that identifies and alerts ARS leaders to any negative trends.
- Provide ARS with an independent and impartial voice, which fosters consistency between ARS’ values and actions. Make systemic recommendations for change.
- Collect general data on emerging trends and patterns in ARS’ use and care of animals. Provide upward feedback to management about agency trends.

### 1.2 Communications and Reporting

The Animal Welfare Ombudsman serves as a central point of information and referral resource for Animal Welfare policies, processes, and resources within ARS. The Animal Welfare Ombudsman establishes and monitors an email portal, animalwellbeing@ars.usda.gov, to encourage internal and external communications about ARS animal welfare concerns or complaints.

The Animal Welfare Ombudsman provides reports to the ARS Administrator on an annual basis. Reports should be provided without jeopardizing individuals' confidentiality. The Ombudsman’s annual report will include the number of complainants assisted; complainant demographics (e.g., gender, constituent group, college, major or discipline, etc.); problem categories; issues and observations; trends; concerns; and recommendations. In addition to summarizing the results of the year’s work, the annual report will alert the ARS leadership to problems and trends and help decision-making within ARS to foster a renewed culture of animal welfare.
Appendix D – Animal Welfare Training Program

1. Animal Welfare Training

The Animal Welfare Act (AWA) and the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals provide guidance and regulations to ensure that all animals used for research in the United States are treated in a humane manner. It has been the policy of ARS to adhere to and follow all regulations of the AWA and PHS to ensure that the animals used in research by the agency are treated appropriately and humanely. An integral part of both the AWA and the PHS guidelines is a comprehensive animal welfare training program.

2.1 Training Objectives and Scope

The Animal Welfare training program is designed to meet USDA and ARS requirements for basic and specialized training in the humane care and use of animals. Major objectives include:

- Ensuring that research staff members performing experimental manipulation, including anesthesia and surgery, are qualified through training or experience to accomplish such procedures humanely and in a scientifically acceptable fashion.
- Ensuring that individuals who use or provide care for animals are trained and qualified in the appropriate species-specific housing methods, husbandry procedures, and handling techniques.
- Ensuring compliance with any initial and continuing education regarding ARS P&P requirements for care, use, handling, and well-being of animals to support research.

The ARS training program has been designed to meet the training needs of:

- Researchers who use or plan to use animals
- Post-docs
- Technicians
- IACUC members
- Animal care staff
- Animal surgery staff
- Management or administrative staff

For researchers and laboratory staff, training on the safe and humane care for each of the species of animals on which research is conducted would be required, or, if staff already has been trained, documentation would be provided. Training on new procedures and protocols would be required and oversight provided by the IACUC to ensure adequate familiarity with each species and technique. Training and documentation of training would also be required for animal caretakers on all species of animals with which they interact. In addition, all researchers and laboratory personnel would be required to be familiar with the American Veterinary Medical Association (AVMA) Guide on Humane Euthanasia protocols to ensure the appropriate procedures are practiced to euthanize animals (https://www.avma.org).
All employees at ARS locations with animals need to receive training that provides an overview of Animal Care and Use and the AWA within the first 60 days of approval and implementation of this plan or within the first 60 days of employment. Employees of locations co-located with Universities and receiving training associated with the University would be required to provide documentation of all training within the first 60 days of implementation. All training requirements listed would be required to be completed within 12 months of the official announcement of this action plan.

2.2 Training Resources

The animal welfare training program covers general principles of ethical care and use of animals in ARS research as well as specifics on the care and use of particular species. ARS has identified two major animal welfare training resources: The American Association of Laboratory Animal Science (AALAS) learning library and the Collaborative Institutional Training Initiative (CITI) at the University of Miami. These two resources contain a variety of courses designed for laboratory animal professionals at different career levels. A set of animal-specific courses are available that provide information pertinent to specific animals including Amphibians, Cats, Dogs, Ferrets, Fish, Gerbils, Guinea Pigs, Hamsters, Horses, Mice, Non-Human Primates, Rabbits, Rats, Swine, and Zebra-fish. These courses provide an introduction to the regulatory mandates and biological components of individual animals. Additional courses are also available that provide training on the role and responsibilities of ARS management and administrative staff responsible for animal care and use programs.

Both AALAS and CITI training courses are web-based and accessible online at any time and from anywhere. ARS will expand existing arrangements to establish an agency-wide contract to enable all animal research locations to access these training courses. Most of these online courses have test questions to evaluate learning outcomes and ensure that learning objectives are achieved. Additional free animal welfare training courses, webinars, and podcasts are available through University of Newcastle in Australia, Canadian Council on Animal Care, The Canadian Aquaculture Institute, Animal and Plant Health Inspection Service (APHIS), and the National Institutes of Health’s Office of Laboratory Animal Welfare. The following table lists Animal Welfare training sources and associated delivery methods.

<table>
<thead>
<tr>
<th>Training Sources</th>
<th>Delivery Methods</th>
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<tbody>
<tr>
<td>American Association for Laboratory Animal Science (AALAS) learning library</td>
<td>Online with test</td>
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<tr>
<td><a href="https://www.aalaslearninglibrary.org/pages/Home.aspx">https://www.aalaslearninglibrary.org/pages/Home.aspx</a></td>
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<tr>
<td>The Collaborative Institutional Training Initiative (CITI) at the University of Miami, Animal Care and Use</td>
<td>Online with test</td>
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<tr>
<td><a href="https://www.citiprogram.org/index.cfm?pageID=91">https://www.citiprogram.org/index.cfm?pageID=91</a></td>
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2.3 Training Curriculum

Currently, ARS has many locations that either have animals or have had a recent history of animal research. There is a great diversity by location in the type of research, the animal species involved, and the composition of the IACUC. The types of research conducted by ARS are variable and may involve biomedical research, animal surgery or challenge of animals with pathogens, as well as non-invasive research to understand production and management strategies. Species involved in ARS research include small rodents, cattle, swine, sheep, poultry, and fish. Therefore, training for each of the locations must be tailored to the type of research and species of animals used to ensure animal welfare and care are specific for each location and research project.

The animal welfare training curriculum consists of basic, elective, and refresher training courses. Basic courses provide a general understanding of Federal policies and regulations governing animal welfare and industry best practices. Elective courses offer animal-specific and specialized courses to learners based on their research activities. Refresher training on animal welfare basics would be required annually for all staff involved in the care and use of animals or oversight of the ARS animal welfare program. Species- or project-specific training will occur prior to work being conducted and refresher/update training as needed due to protocol changes or once every three years or in conjunction with the new program cycle in the appropriate areas for all relevant personnel. Finally, ARS is exploring options with APHIS to jointly develop customized courses on selective topics. Typically, training begins with basic courses, followed by elective courses, and reinforced by refresher courses that ARS staff would complete annually.

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<thead>
<tr>
<th>University of Newcastle, Animal Welfare and Training Unit</th>
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<tr>
<td>Canadian Council on Animal Care</td>
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<td>The Canadian Aquaculture Institute</td>
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<td>APHIS</td>
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<td><a href="http://aast.cfsph.iastate.edu/AWIC/awic0020.htm">http://aast.cfsph.iastate.edu/AWIC/awic0020.htm</a></td>
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<tr>
<td>Education Resources, Office of Laboratory Animal Welfare, NIH</td>
<td>Webinars/Podcasts</td>
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<tr>
<td><a href="http://grants.nih.gov/grants/OLAW/educational_resources.htm#a_04052009">http://grants.nih.gov/grants/OLAW/educational_resources.htm#a_04052009</a></td>
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<tr>
<td>Categories</td>
<td>Objectives</td>
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<tr>
<td>Basic</td>
<td>Understand Federal policies and regulations governing animal welfare and animal welfare best practices.</td>
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<tr>
<td>Elective</td>
<td>Understand job-specific roles, responsibilities, and best practices.</td>
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| Refresher | Understand latest changes and updates | All employees at ARS locations with animals | • Complete one refresher basic course annually.  
• Complete one refresher elective course annually. |
|-----------|---------------------------------------|--------------------------------------------|------------------------------------------------|
| Customized Training | Understand USDA and ARS policies and procedures governing animal welfare. | Selective ARS staff members | • ARS-specific training courses  
• ARS and APHIS jointly developed courses |