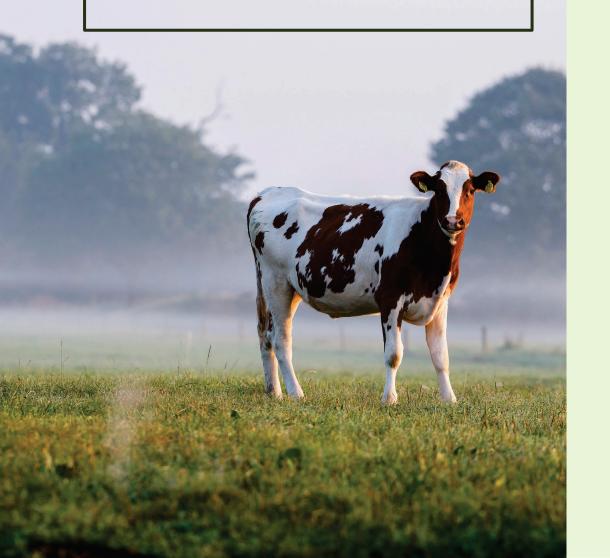
#### Research Using Agricultural Animal Species



March 21, 2024



#### PUBLIC HEALTH SERVICE (PHS) POLICY DEFINITION OF ANIMAL



"Any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes." - PHS Policy III.A.



## WHERE THE PHS POLICY APPLIES

- Animal activities funded by the PHS and HHS
- Animal activities that are subject to the PHS policy because the funding entities have memoranda of understanding with OLAW
  - National Science Foundation (NSF)
  - Department of Veterans Affairs (VA)
  - National Aeronautics and Space Administration (NASA)

## WHEN THE PHS POLICY APPLIES, AN ANIMAL WELFARE ASSURANCE IS REQUIRED

- Contract with federal government
- Description of the institutional program of animal care and use
- Documents institutional commitment
- Principal method for compliance oversight
- You will be held to what is described in your Assurance (even if the Assurance exceeds regulatory requirements, such as covering animals not subject to the PHS Policy)

### ANIMAL WELFARE ASSURANCES





## WHAT ABOUT ANIMALS NOT SUBJECT TO THE PHS POLICY OR COVERED BY THE ASSURANCE?

OLAW FAQ A.1.

It may be generally impractical to separate activities based on the source of funding Institutions must ensure that ensure that any standards that might not be consistent with PHS Policy do not affect or pose risks to PHS supported activities.

https://olaw.nih.gov/faqs#/guidance/faqs?anchor=50285



# GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS (GUIDE)

The PHS Policy requires institutions to use the *Guide* as a basis for developing and implementing an institutional program for activities involving animals. (IV.A.1.)

The Guide provides standards of care for animals subject to the PHS Policy.

- a. Laboratory animals are generally defined as any vertebrate animal (i.e., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research, testing, or teaching
- b. Does not address in detail agricultural animals used in production, agricultural research or teaching, wildlife and aquatic species studied in natural settings, or invertebrate animals (e.g., cephalopods) used in research, but establishes general principles and ethical considerations that are also applicable to these species and situations

(Guide, 8th Edition, Ch 1, p.2)

# GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS

Special Considerations for IACUC Review (*Guide*, 8<sup>th</sup> Edition, Ch. 2, pp. 32–33)

#### Agricultural animals:

- Subject to the same ethical considerations as for other animals in research, whether classified as biomedical or agricultural research
- Such classifications have led to a dual system with different criteria for evaluating protocols and standards of housing and care for animals of the same species
- Sometimes classification of research is unclear, posing issues for IACUCs
- Institutions expected to provide oversight of all research animals and ensure that pain and distress are minimized.



#### GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS



Special Considerations, Continued (Guide, 8<sup>th</sup> Edition, Ch. 2, pp. 32-33)

#### Agricultural animals:

- a. The protocol, rather than the category of research, should determine the setting (farm or laboratory).
- b. The *Guide* applies to agricultural animals used in biomedical research, including those maintained in typical farm settings.
- c. For animals maintained in a farm setting, the Guide for the Care and Use of Agricultural Animals in Research and Teaching (Federation of Animal Science Societies) is a useful resource. Agricultural engineers, animal science experts may also be helpful

## AGRICULTURAL ANIMAL SPECIES ARE ALSO ADDRESSED IN OTHER GUIDE SECTIONS

Guide Chapter	Pages	Topic
Ch. 2 Animal Care and Use Program	29	Restraint
Ch. 3 Environment, Housing, and Management	43-44	Temperature and humidity
Ch. 3 Environment, Housing, and Management	60-63	Recommended minimum space
Ch. 4 Veterinary Care	117-118	Surgical facilities, Surgical procedures
Ch. 5 Physical Plant	137-138	Floors, drainage
Ch. 5 Physical Plant	144-145	Special Facilities: Surgery
Ch.5. Physical Plant	148	Hazardous Agent Containment (agricultural pathogens)
Appendix A: Additional Selected References	176-177	Species-Specific References—Environment, Housing, and Management: Agricultural Animals
Appendix A: Additional Selected References	191-192	Species-Specific References—Veterinary Care: Agricultural Animals

#### **OTHER RESOURCES**

#### OLAW FAQ G.7

- Assured institutions may use the Ag Guide only as a supplement to the Guide and not as the primary guidance when farm animals are used or intended for use in biomedical or behavioral research, research training, biological testing or for related purposes.
- https://olaw.nih.gov/faqs#/guidance/faqs?anchor=50384
   OLAW Commentary on specific protocol scenarios\*
- <u>Lab Animal 2019; 48(02).</u> A Word from OLAW and APHIS. All in the barn: who oversees agricultural research animals?
- <u>Lab Animal. 2006; 35(4).</u> Conference wet lab: is an IACUC needed?

\*The recommendations in this column are provided in response to the specific scenario as written and may not be generalizable. Institutions are encouraged to contact OLAW to discuss individual circumstances.



# Horses and Other Farm Animals and the Animal Welfare Act

Louis DiVincenti, DVM, MS, DACLAM, DACAW Senior Veterinary Medical Officer - Research USDA APHIS Animal Care National Policy Staff

#### "Animal" under the Animal Welfare Act (AWA)

The term 'animal'... excludes:

- (1) birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research,
- (2) horses not used for research purposes, and
- (3) other farm animals ... used or intended for use as food or fiber, or ... for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.



## Regulation of Horses and Other Farm Animals Used for Biomedical or Non-Agricultural Research

 Since 1970 AWA amendments, horses and farm animals used for biomedical and non-agricultural research are covered.

 As a matter of policy, prior to 1990, USDA did not regulate horses and other farm animals.



#### Horses used for research are covered.

 When horses are used for any research, they are 'animals' under the Act.

 Compliance with all regulations and the standards in Subpart F is required.



http://www.equineresearch.org/horse-research.html

#### Exceptions

- Client-owned animals
  - Patients
  - Clinical trials
  - Teaching



https://www.vetmed.ucdavis.edu/news/success-uc-davis-equine-pet-scan-research-racehorses-translates-clinical-breakthroughs-sport

#### Farm animals used for agriculture are not covered.

- Farm animals used for food or fiber
- Research involving improving animal nutrition, breeding, management, or production efficiency



Research meant to improve the quality of food or fiber





#### Biomedical and non-agricultural research/ teaching is covered.



- Area of science devoted to the study of processes of life and the prevention and treatment of disease
- Study of biological processes and diseases with the ultimate goal of developing effective treatments and cures
- Includes translational and animal-targeted medical research



https://fbri.vtc.vt.edu/research.html

#### Any "animals" here?



https://americanhistory.si.edu/explore/stories/how-horses-helped-cure-diphtheria





https://www.vet.upenn.edu/about/news-room/news-stories/news-story-detail/on-the-farm-with-penn-vet-s-field-service





### Any "animals" here?



https://www.mprnews.org/story/2014/09/25/sounds-voices-bison

### It can be complicated.



https://www.wsj.com/articles/SB123561039911777481

#### The purpose of the activity matters.



Not an "Animal"



"Animal"

#### When in doubt, ask!



https://robertkaplinsky.com/never-ask-question-horse-answer/

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# Research Using Agricultural Animal Species

Susan B. Harper, DVM, MS, DACLAM, DACVPM, RBP (ABSA)

March 21, 2024

#### Disclaimer

I am participating in today's webinar in my personal capacity and would like to acknowledge that the views expressed are my own and do not necessarily represent the views of the National Institutes of Health or the United States Government.

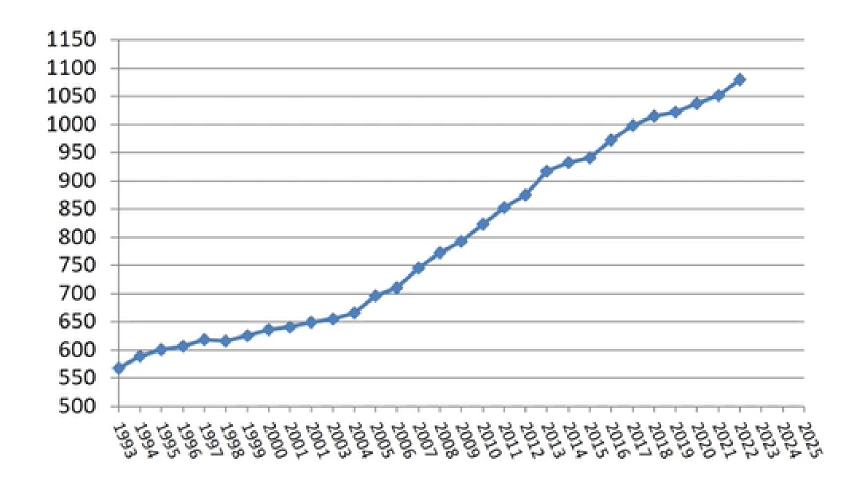


#### What is AAALAC International?

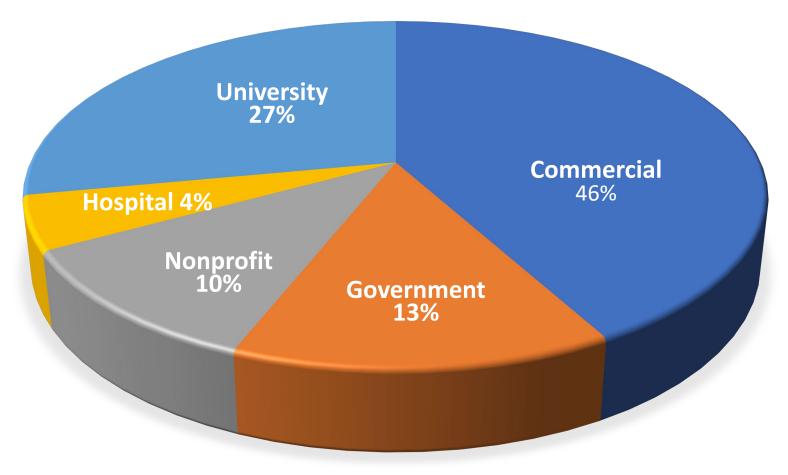
- An international private, nonprofit organization that promotes humane treatment of animals in science through a voluntary accreditation and assessment programs.
- Accreditation provides global assurance of an institution's commitment to maintaining the highest standards of animal care.
- Participation promotes quality, scientific validity, harmonization, and accountability on a global scale.
- More than 1,100 companies, universities, hospitals, government agencies, and other research institutions in over 50 countries have earned AAALAC accreditation.



#### **Growth of Accredited Programs**



#### **Accredited Programs by Industry Sector**

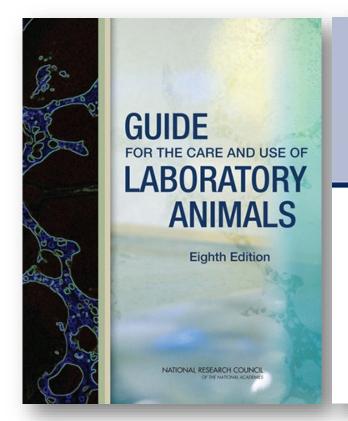


#### **Accreditation Principles**

- AAALAC is not a regulatory body and does not make or enforce regulations.
- AAALAC publishes "Rules of Accreditation" that describe the minimum criteria institutions must meet to apply for accreditation.
- AAALAC relies on widely accepted guidelines, such as the Guide for the Care and Use of Laboratory Animals (NRC 2011), and other resources.
- AAALAC also publishes "position statements" as supplemental guidelines for certain issues (e.g., occupational health and safety, adequate veterinary care, farm animals, etc.).



#### **AAALAC's Three Primary Standards**



Guide for the Care and Use of Agricultural Animals in Research and Teaching

Federation of Animal Science Societies

Third edition

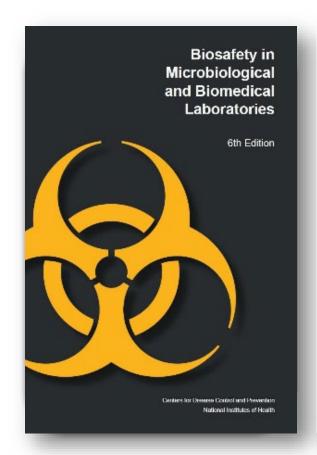
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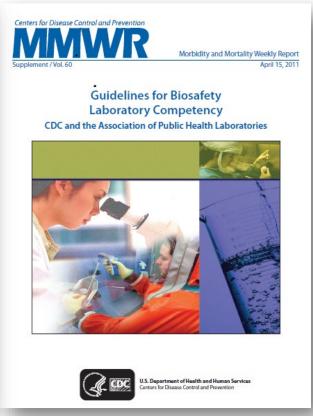


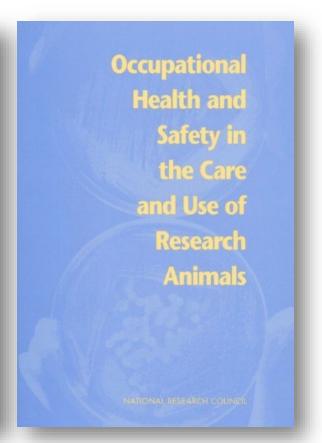




#### Reference Resources



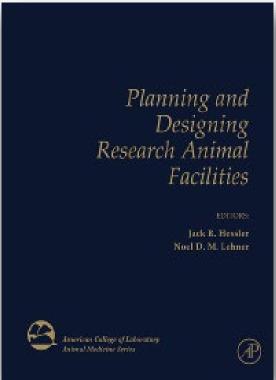


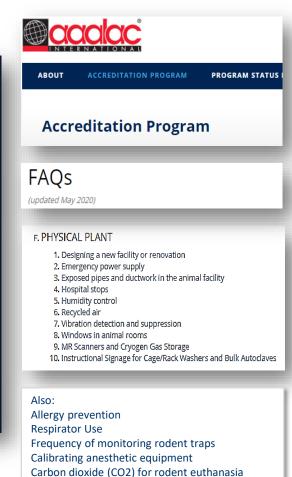




#### **Additional References**









#### **Accreditation Process**

- The institution completes a comprehensive self-assessment that is submitted to the AAALAC Executive Office (**Program Description**).
- The Executive Office assigns identifies a Site Visit Team (lead Council member, ad hocs, subject matter experts).
- An on-site program evaluation (document reviews, tours, interviews) is conducted, with recommendations for accreditation status.
- Preliminary feedback includes commendations, mandatory findings, and suggestions for improvement.
- The report is reviewed and discussed by other Council members (peer review) before the final decision on accreditation is made.
- Visits are confidential and take place every 3 years.
- Accredited institutions provide annual updates and promptly notify the Executive Office of any significant adverse events involving animals.



### **Key Terms**

Must	Should	May
Required actions that are critical for humane animal care and use	A strong recommendation	Optional recommendations that could be beneficial
Mandatory Finding	Suggestion for Improvement (SFI)	Not used by AAALAC
Any deficiency that <i>must</i> be corrected to award or continue "Full Accreditation"	Recommendations that should be considered to enhance or improve quality	



# **Engineering vs Performance**

 Specifies in detail a method or technique for achieving the desired outcome



 Does not provide for interpretation or modification of the technique should an alternative be equally acceptable  Defines the desired outcome in detail and provides measurable criteria for assessing whether the outcome is achieved



 Requires professional input, sound judgment, and a team approach to achieve specific goals







#### INTRODUCTION

PI SUBMITS
THE PROTOCOL
TO THE
LACUC

PROTOCOL
REVIEWED BY
IACUC
COORDINATOR FOR
COMPLETENESS

PROTOCOL
IS ASSIGNED TO
DESIGNATED OR
FULL COMMITTEE
REVIEW

PROTOCOL
MAY REQUIRE
CLARIFICATION
OR MODIFICATION

PROTOCOL IS APPROVED



PROTOCOL IS
RETURNED TO THE
PI FOR REVISIONS
AND
RESUBMISSION

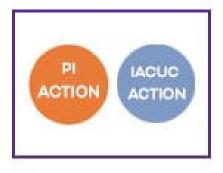
PROTOCOL IS RETURNED TO

THE IACUC

process continues

until Reviewers are satisfied







#### Today's Topics:

- Use Case
  - Agricultural Research
  - Biomedical Research
  - Training:

Vet students/residents/technicians

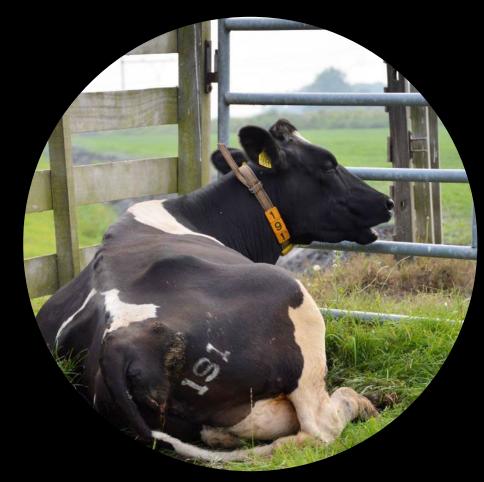
Ag students

Others (e.g., biomedical researchers) 40

- Special challenges with agricultural species
- Optimizing welfare
- Protocol review & compliance considerations
- Oversight perspectives
- Special challenges with agricultural use
- Useful resources
- Others?

# OVERVIEW OF WHY FARM ANIMAL USE HAS SPECIAL CHALLENGES

- Whose rules apply
- Use (Ag or Biomedical)



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#### **Funding**

#### Is activity subject to the PHS Policy?

- Yes, if meeting PHS Policy definition of animals & funded by NIH, HHS
- Yes, if funded by VA, NSF, and NASA (directives / guidance requiring compliance PHS Policy
- Assurance required
- What does the Assurance say? You will be held to whatever is stated, even if voluntary - such as all animals and areas being held to PHS Policy requirements!

#### Activity

#### Activities exempt from AWA regulation:

- Regulated species used for food/meat, fur/fiber, feathers
- Animals (e.g., horses, llamas) when used solely as work/pack animals
- Fairs/exhibitions intended to advance agricultural arts and sciences
- Research for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber
- Federal Facilities

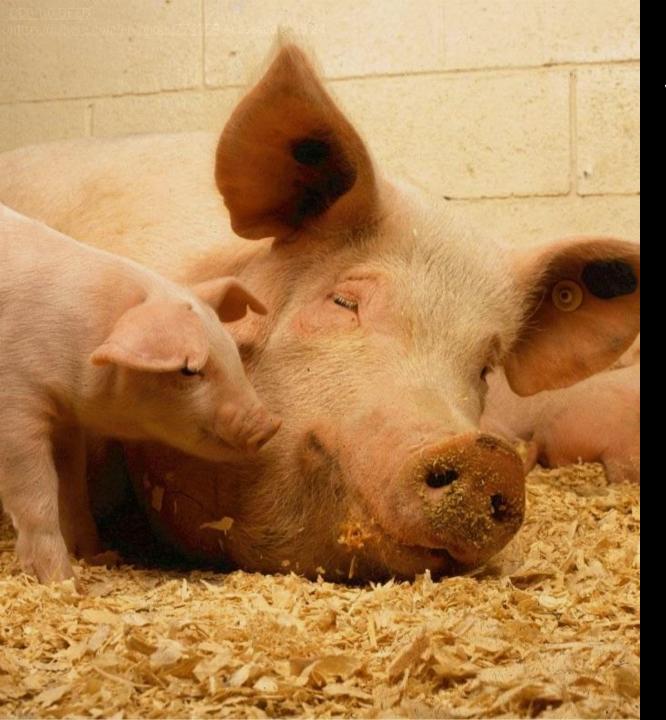
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Location

#### The location matters!

- Ability to impact regulated species?
- AAALAC International accredited location?





### Special challenges

- Housing challenges/care and husbandry
- Pain recognition
- Behavioral needs and behavioral concerns
- Handling considerations
- Welfare standards
- Teaching activities
- Emergency management and disaster planning
- Regulatory and Compliance challenges

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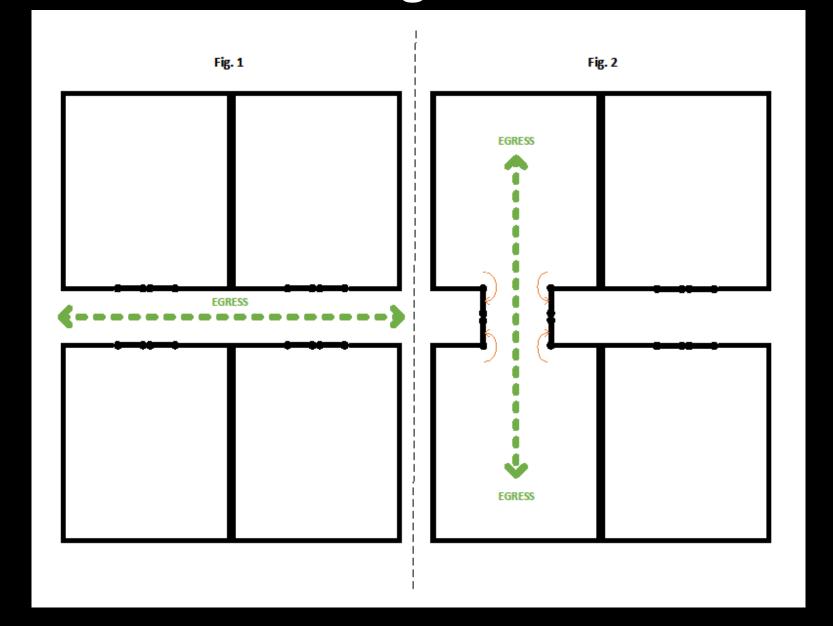
#### SCENARIOS - WHAT WOULD YOU DO?

- A PI requests to use a non-dedicated space for group of weaned calves.
- IACUC inspection and correction of all reported deficiencies
- Space has been inspected and all factors considered and IACUC approved
  - Ag Guide 4<sup>th</sup> edition does not have a group of weaned calves space requirement
  - Ag Guide 3<sup>rd</sup> edition has space requirements
  - Industry standard and based on scientific justification; approved by the IACUC

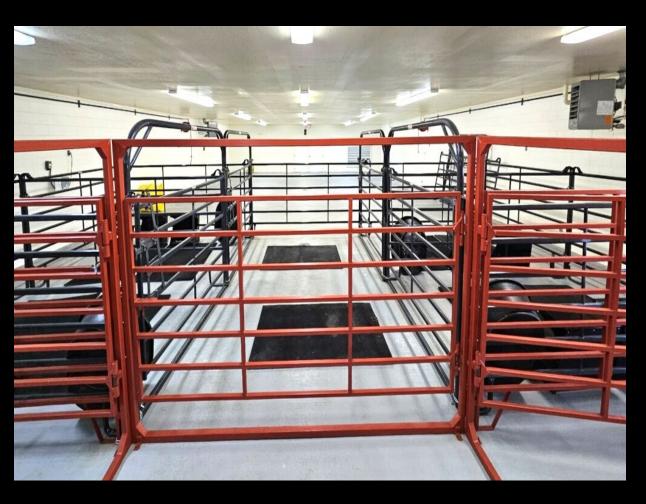


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# Diagram



#### GROUND LEVEL VIEW





### ELEVATED VIEW





#### SCENARIOS - WHAT WOULD YOU DO?

#### **Housing Challenge**

- Weaned calves coming in two days and a HUGE arctic front arriving in 3 days.
- Contingency plans
  - Redundancy heaters (4 gas heaters)
  - Space (electrical) heaters
  - Bedding (straw)
  - Pony blankets
- Failsafe system set on air exchange system and heaters ignite if temperature dropped to certain threshold
- Emergency notification sent when temperature in room drops to 45 degrees
- Emergency veterinary care MUST be available after regular business hours, including weekends, and on holidays.



# OPTIMIZING ANIMAL WELFARE IN AGRICULTURAL SPECIES

Guide for the Care and Use of Agricultural Animals in Research and Teaching

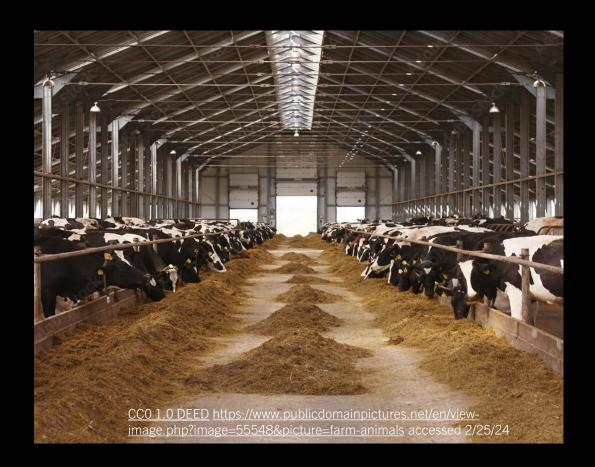


#### SCENARIOS - WHAT WOULD YOU DO?

#### Application of Welfare Standards (culture shift)

- Dairy cattle facility and pain recognition
- "Told Doc all dairy cattle are lame"
- Veterinary care essential

Emergency veterinary care <u>MUST</u> be available after regular business hours, including weekends, and on holidays.



#### SCENARIOS - WHAT WOULD YOU DO?

#### Behavioral needs

- Swine group housing
- Mixed as transition from weaned / breeding/ farrowing
- Discussed floor space —with visual blocks
- Enrichment
- Feed Bunk and water space
- Veterinary Care



Emergency veterinary care <u>MUST</u> be available after regular business hours, including weekends, and on holidays.



ANIMAL CARE AND
COMPLIANCE
CONSIDERATIONS FOR
AGRICULTURAL ANIMALS
IN AGRICULTURAL
RESEARCH



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# ANIMAL CARE AND COMPLIANCE CONSIDERATIONS FOR AGRICULTURAL ANIMALS IN AGRICULTURAL AND BIOMEDICAL RESEARCH



https://www.fwi.co.uk/livestock/youngstock-management/how-stress-freedisbudding-can-benefit-calf-units

- Communication
- Common issues include animals receiving adequate veterinary care, and that the Attending Veterinarian (AV) is informed of all animal health issues.
- Farm Managers and Staff will commonly provide care, which can lead to failure to communication with AV
- Farm Staff may be less aware of need to keep accurate veterinary medical records as compared to veterinarians and veterinary technicians in biomedical research settings

# ANIMAL CARE AND COMPLIANCE CONSIDERATIONS FOR AGRICULTURAL ANIMALS IN AGRICULTURAL AND BIOMEDICAL RESEARCH- CONT.

- Standard Operating procedures approved, signed and dated by AV clarifies care and expectations
- Farm Managers are making decisions about what vaccines/deworming program they want to use, often unaware of the expectation for the AV/designee to approve standard treatments and preventive care.
- Communication of expectations between both parties is crucial to determining welfare of animals, as well as managing expectations.

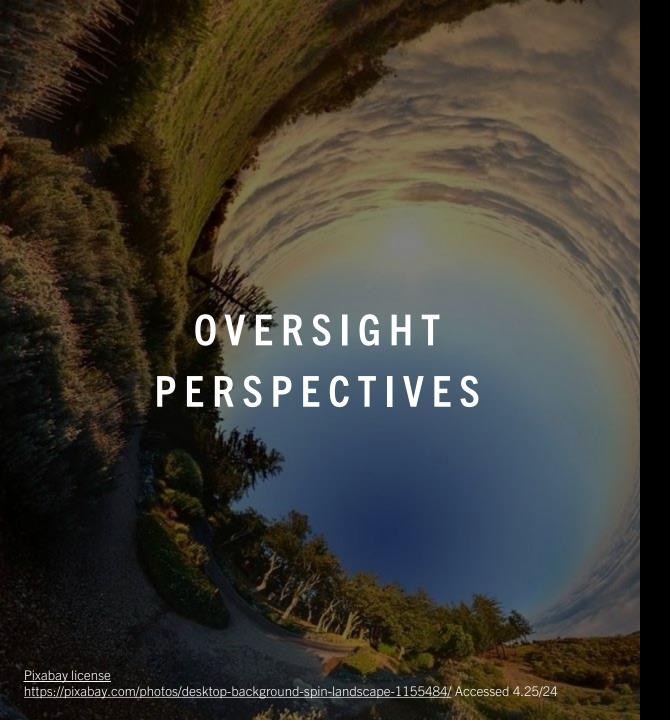


# OVERSIGHT PERSPECTIVES

 USDA and OLAW/NIH typically do not get involved with agricultural animal use

 USDA involved with Animals used in teaching scenarios to train Veterinary students or Veterinary Technicians, or in biomedical research protocols.





- Care and use standards for agricultural animals in agricultural settings are very different from those animals kept in laboratories.
- Farms cannot be held to the same standards
- AAALAC looks to see a "well-managed farm".



- One of the top challenges facing
   University Animal Science programs is declining budgets
- Fewer people going into farming, changing population demographics, and fewer students attending universities in all major categories creates tighter University wide budgets





 Continuing to maintain teaching herds of farm animals has become a difficult decision for universities

 Maintain expensive animal herds to continue to teach to Animal Science and Veterinary students?
 Or balance the budget?

# SUMMARY



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#### Resources

BQA through the FARM program:

https://nationaldairyfarm.com/resource-library/farm-program/?

\_program=animal-care

BQA Calf Care Quality Assurance: <a href="https://training.calfcareqa.org/">https://training.calfcareqa.org/</a>

**USDA Tech Note on Pain category:** 

ac-tech-note-categorizing-animal-pain-or-distress PDF (<u>WWW.APHIS.USDA.GOV</u>)

Temple Grandin Livestock handling resources <a href="https://www.grandin.com/">https://www.grandin.com/</a>

Emergency management resources for livestock
<a href="https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/emergency-management/protecting-livestock">https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/emergency-management/protecting-livestock</a>

#### **Next Webinar**



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