**ILAR J**

Volume 60, Number 1, 2019

***Responsible Science and Research Animal Use***

**Warmbrod et al.** [**The Scientist Citizen and the Citizen Scientist: Blurring the Lines**](https://academic.oup.com/ilarjournal/article/60/1/5/5689711)**, pp. 5-8**

Domain 6: Education

SUMMARY: All fields of scientific study and practices, while different in terms of scope, all seek to provide a better understanding of the world and the human experience. The study of science is inherently human and performed by humans, however the human element in science can be lost in the shuffle of competition to produce results and the need to maintain objectivity in scientific studies. This and other factors have led to a blurring of the lines between scientists and citizens and have created barriers for scientific advocacy and citizen involvement in the scientific process. This article argues that it is vitally important for scientists to participate as citizens of society and why citizens must continue to make active contributions to science.

Throughout history, scientists have advocated as vocal citizens and citizens have made contributions to the scientific domain. The history of animal research and animal welfare reform presents a good example of the way citizens can participate in science and scientists can advocate in society. The development of the US Animal Welfare Act demonstrates how citizen involvement in the scientific enterprise, in this case animal research, can lead to improvements in the attitudes and practices of scientists using animals in research studies. The Animal Welfare Act came about in response to a social movement in the United States in the 1960s that advocated for a higher ethical standard in the treatment of animals.  Public concerns about the unethical acquisition and treatment of some animals used in research resulted in the original Laboratory Animal Welfare Act becoming law. The AWA was amended later to include the establishment of Institutional Animal Care and Use Committees and specifically requires the membership of at least one person who is unaffiliated with the institution performing the research, thus providing another way to ensure citizens play a part in science. This bill has evolved since the 1960s and continues to be refined to work toward more moral and ethical scientific research. On the other side, many scientists have taken action to recognize and stop unethical practices in animal research when confronted with these scenarios. Whistleblowing in scientific and animal research represents the scientific commitment to uphold a societal precedent.

The developments in technology and communication have made it possible for citizens and scientists to interact in new and different ways. It is crucial now more than ever, that scientists connect their research to their civic responsibilities. Many countries allow the public to directly affect and shape their scientific enterprises and many barriers that may have impeded citizens' ability to participate in the scientific community are now gone. Science is becoming more complex, while science literacy remains unchanged. There is also a growing distrust in science among the public and the easy spread of misinformation on social media and other news outlets can undermine scientific evidence and objectives that could benefit society. While not all of this is can be controlled by the scientific community, efforts to make research easier to understand, more accessible and transparent, and doing more to engage the community in scientific endeavors can help show "lay" people how the results of research can help society as a whole. Citizen engagement as advocates for change and continual improvement in science and animal research will help keep scientists accountable. These measures can help rebuild some of the trust in scientists that has been lost in recent years.

QUESTIONS

1.   What are the 3 Rs of animal research?

a.   Reduce, reuse, recycle

b. Replace, refine, replenish

c. Reduce, refine, replace

d. Refine, react replace

2. When and where was the famous article “Concentration Camps for Dogs”, which revealed unethical practices in the acquisition and treatment of dogs used in medical research, published?

a. 1966, Life magazine

b. 1967, Sports Illustrated magazine

c. 1966, The New York Times

d. 1967, Readers Digest

3.   In what year was the Animal Welfare Act amended to include the requirement of Institutional Animal Care and Use Committees?

a. 1967

b. 1970

c. 1976

d. 1985

ANSWERS

1. c

2. a

3. d

**Barbee and Turner.** [**Incorporating Laboratory Animal Science into Responsible Biomedical Research**](https://academic.oup.com/ilarjournal/article/60/1/9/5612730)**, pp. 9-16**

Domain 3: Research

Domain 4: Animal Care

SUMMARY: Vivarium conditions and animal care involve factors which affect research variability and validity and scientist should be aware of. This fact is sometimes described as a “parallel laboratory”, i.e. the disregarded environmental factors that occur in parallel to the main experimental factors. There are guidelines and legislation which address these issues; however these should always be complemented with a study of currently published information and consultation of experts. Such vivarium/care factors include temperature, humidity, light, noise, vibration, transportation, space and caging, sanitation, behavioral management, handling and restraint, pain management, microbiota. These shall be considered for all animals, including rodents: mice and rats, and shall be adequately reported in publications.

A summary of concerns related to these factors follows. Because of their high body surface to body weight ratio, mice loose more heat faster. Hence, it is important to offer them the company of conspecifics, sufficient bedding and nesting material so they can control their temperature. Mice are commonly housed to 20-22oC, which is 10o lower than their thermoneutral zone of 30oC. This chronic cold stress might affect metabolism, food intake, oxygen consumption, heart rate, blood pressure, response to lipopolysaccharide and infectious organisms, immune responses, tumor growth rates. On the other hand, housing in the thermoneutral zone results in smaller organ sizes. Sex-dependent disease models, such as nonalcoholic fatty liver disease, might also be affected by temperature.

Relative humidity might affect virus infectivity, animal water and thus drug-in-water consumption, urine osmolality, interpretation of pharmacokinetic and metabolic parameters measured in urine.

Light exposure affects rodent metabolism, reproduction, behavior and might cause retinal damage especially to albino animals. Intensity, wavelength, proximity to the light source, photoperiod should be considered.

Noise and vibration may affect stress hormones, blood pressure, cardiac size (hypertrophy), muscle angiogenesis, body weight, fertility – reproduction. Noise and vibration are often underestimated. Main factors to consider are for noise: sound intensity, sound frequency (rodents can hear ultrasounds >20kHz that humans can’t), human-origin and work-related noises, equipment noises (note also lamps, alarms…), and for vibration: IVC rack blowers, generators, movement of equipment.

Transport, even of short duration, can impact sympathetic tone, body weight, food consumption, behavior, metabolism, and can cause stress. Special consideration must be given to the duration of the acclimation period. For example, blood pressure might need 3-6 weeks to return to normal levels.

Cage size, cage type, stocking density or single housing, cage enrichment objects can affect social hierarchy, aggression, behavior, phenotype, comfort, stress hormones. Special consideration should be taken with metabolic cages as they stressful to mice and rats. IVCs may cause cold stress due to up to 60 air changes per minute. In-cage enrichment resources are necessary to maintain normal physiologic state.  Type of bedding must also be considered. Corncob absorbs more ammonia but is shown to be less comfortable and may cause disrupted sleep patterns, thus affecting performance in learning/memory tasks, behavior, glucose metabolism, hormone physiology.

Bedding and cage changes result in behavioral, cardiovascular alterations lasting for several hours, as well as increased aggression in mice. Old nesting material can be transferred to the new cage to reduce aggression. IVC housing can reduce changing frequency. There is suggestion that cage-changing days should not be used for experimental procedures.

Other parameters may affect variability, such as behavior, stress related to social factors and handling, as well as pain. Abnormal behavior in mice may be observed as stereotypic behavior, abnormal nest building or burrowing. Social housing, cage enrichment, habituation and training to techniques, refinement of techniques should be considered. Pain in rodents may be scored by facial grimace scales, nesting material consolidation, grooming transfer or other methods and analgesia shall be provided.

Gut microbiota is a new consideration that is not easily documented. Gut microbiota might be affected by housing in different facilities, simple transportation, changes in bedding, caging, diet.

QUESTIONS

1. Which is FALSE regarding housing mice in a temperature of 20-22oC?

a. This temperature is 10o lower than their thermoneutral zone of 30oC

b. They must be provided with the company of conspecifics, sufficient bedding and nesting material so they can control their temperature

c. They will have smaller organ weights

d. They might experience chronic cold stress

2. List 5 factors of vivarium conditions and/or animal care that may affect experimental results.

3. Which of the following is a source of noise that humans/personnel are NOT able to detect without specialized equipment?

a. Low music that is used for white noise

b. Alarm sounds

c. Sounds of 20Hz to 20kHz

d. Ultrasounds of frequency > 20kHz

4. The gut microbiota might NOT be affected by:

a. Transport

b. Experimental techniques

c. Housing conditions

d. Diet

5. What is described as a “parallel” laboratory in biomedical research?

a. The disregarded environmental factors that occur in parallel to the main experimental factors

b. Two laboratories performing the same experiment

c. The animal vivarium

d. The laboratory handling the samples

ANSWERS

1. c

2. Any 5 of: temperature, humidity, light, noise, vibration, transportation, space and caging, sanitation, behavioral management, handling and restraint, pain management, microbiota.

3. d

4. b

5. a

**Macleod and Mohan.** [**Reproducibility and Rigor in Animal-Based Research**](https://academic.oup.com/ilarjournal/article/60/1/17/5612731)**, pp. 17-23**

Domain 3: Research

T3: Design and conduct research

SUMMARY: Reproducibility of experiments has become a major issue in research overall. The inability to replicate studies has altered our approach to develop experiments. In animal research, there are many biological variables which can impact research results such as sex of the animal, housing conditions, and circumstances of testing. These and many other factors can influence the reproducibility of already published data. One of the issues is that there is a risk of bias within researchers that may play a role when developing studies or evaluating the data. Researchers should come up with a hypothesis and then design an experiment to test it rather than develop a hypothesis to explain a series of observations and then claiming that this was the hypothesis they tested. This idea may create bias in either general aspects of experimental design or specific to the research field at study. Many times, the blinding of studies is not reported or possibly not even performed. The authors cite an article where a sample of publications from PubMed published between 2008 and 2012, reported randomization was 33% and blinding to experimental group was only 7%. Another issue with publications is the fact of removing an animal or data point from analysis without justification or it being described in the publication. Another important factor of journals and their publications is the accessibility of the information. Now with open access journals and open data access, all the information is available and therefore it can be completely evaluated by any party. It is important for journals to implement guidelines such as the PREPARE and ARRIVE guidelines and enforce these guidelines to improve the quality of the research being published.

QUESTIONS

You have an outbreak of a disease in your facility and you are evaluating how efficient your lab is at testing for the disease against the gold standard diagnostic. Use the table to answer the following questions:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Disease + | Disease - | Total |
| Test + | 20 | 6 | 26 |
| Test - | 3 | 80 | 83 |
| Total | 23 | 86 | Total Population: 109 |

1. What is the sensitivity of the test?
   1. 20/86
   2. 20/23
   3. 3/23
   4. 80/109
2. What is the Negative Predictive Value of the test?
   1. 80/109
   2. 6/86
   3. 80/83
   4. 23/109

ANSWERS

1. b
2. c

**McCormick-Ell and Connell.** [**Laboratory Safety, Biosecurity, and Responsible Animal Use**](https://academic.oup.com/ilarjournal/article/60/1/24/5550511)**, pp. 24-33**

Domain 5: Regulatory responsibilities

SUMMARY

Hazards: Animal research is related with various hazards, related to laboratory work and animals. These are mainly chemicals (experimental chemicals, drugs, anesthetics, toxins, disinfectants etc.), biological materials (microorganisms, zoonotic diseases, animal allergens etc.), radiological materials and physical hazards (noises, injuries, ergonomic issues personnel faces during animal husbandry and cleaning).

Hazard Mitigation: Environmental Health and Safety (EHS) professionals need to consult veterinary staff and related legislation and guidelines to inform their recommendations, as well as review IACUC protocols. Open communication and detailed training is essential.

The hazards are analyzed and mitigation strategies are designed specifically for the hazard and the job classification. A combination of controls are employed: engineering (facility design, housing requirements, biosafety cabinets, IVCs etc.), good work practices (procedure SOPs and relevant training and oversight), administrative controls (facility inspections, medical clearance, training etc.) and PPE (all kinds, to protect from allergens, disinfectants etc.).

Special Considerations: A hazard sign on the outer door of procedure rooms indicates the PPE requirements, engineering controls and waste-handling procedures.

Carcass and waste disposal should be considered under the scope of state laws and Environmental Protection Agency-listed wastes. Each case is unique depending on the type of research and materials used, however they are usually disposed as medical waste. For example, animals shedding viruses or injected with human cell lines, water treated with chemicals are considered hazardous waste and there should be a plan for their disposal.

Caging: Caging shall balance protection from outside pathogens and containment of experimental pathogens and animal allergens. This can be achieved with positive or negative pressure (respectively) cages, racks or rooms, appropriate cleaning, disinfection and autoclaving, or use of disposable caging and appropriate disposal of hazardous waste (cages, bedding etc.).

Decontamination: Exposure to the substance(s) used and to their residues must be considered. An SOP should be generated with instructions for use of equipment, disinfectant or sterilant, chemical-monitoring devices, chemical and biological indicators to test efficacy, documentation of the process and results, including also method of aeration or neutralization of the chemical. The NIOSH guide shall be consulted to determine the levels when it is safe to re-enter the facility.

Transport: Status (infected, uninfected) health and safety (temperature, caging type, air filter, vehicle conditions) of the animals and the personnel (protection from hazards, allergens), as well as relevant regulations must be considered during transport. Persons performing the transport must be trained.

Containment: It is important to check all applicable regulations and guidelines (listed in article’s table) as they may overlap or complement each other. Different considerations apply depending on the biosafety level. Mitigation practices such as facility design, housing, work practices, PPE and specific training are even more important in high containment BSL3 and 4, and have specific details for agricultural animals. Housing in negative pressure is important, containment curtains are sometimes added, however other ergonomic and practical issues might arise especially for lower cages or larger animals. The use of anesthetics, restraint, PPE, special procedures and devices (e.g. for agent aerosolization or intranasal infection),  and emergency plans, might have to be adjusted for higher protection. Carcass and waste are usually sterilized or treated before disposal. Materials leaving the facility must also be sterilized or inactivated. For example samples for histopathology must be inactivated – this can be achieved by formalin fixation or irradiation. These procedures must be validated. Finally, ensuring proper function of equipment and having back-ups is critical.

QUESTIONS

1. List 4 types of hazards encountered in laboratory animal facilities.

2. Which of the following is NOT a control measure employed for hazard mitigation?

a. Engineering

b. Good work practices

c. Administrative

d. PPE

e. Motivation

3. True or False: Transport of laboratory animals does NOT require specific training in terms of hazard mitigation.

4.  Which is TRUE for materials leaving high containment facilities:

a. No special procedure is required for materials

b. They cannot leave the facility

c. They can only be sterilized

d. Materials can leave the facility if treated with a validated method

ANSWERS

1. Physical, chemical, biological, radiological hazards.

2. e

3. False

4. d

**MacArthur Clark et al.** [**Communicating About Animal Research with the Public**](https://academic.oup.com/ilarjournal/article/60/1/34/5490288)**, pp. 34-42**

Domain 6

SUMMARY: Either directly or indirectly the public is the ultimate funder of most biomedical research.  Since the late 1800’s there have been people and organizations against the use of animals in research and the animal rights movement continued to grow in profile and power, particularly during the second half of the 20th century, utilizing increasingly unpleasant and violent tactics.  This was true in Europe as well as the United States.  The USA passed the Laboratory Animal Welfare Act in 1966 in response to two high profile cases of mistreatment of dogs used in research.  As animal rights groups brought more attention to the laboratory animal field the field became more closed off to the public and more defensive.  Following greater pressure from activists the USA passed the Animal Enterprise Terrorism Act (AETA) in 2006 which gave relief to researchers and their families.

Understanding public opinion and how best it can be influenced is critical to effective communication about the issue of the role of animals in research.  Public opinion on this topic is not homogeneous and generally in Great Britain, acceptance of animal research increases with age, with educational attainment, and with affluence.  Over the years there has been a drop in the percent of people that accept animals in research when there is no viable alternative as well as a drop in the trust of the scientist that use them.  This slide has also been seen in the United States with a steady decline in support from 65% in 2001 to just 51% in 2017.

In light of the decline in public acceptance, many groups around the world have been taking action to counter the extremist groups and bring awareness to the importance of the proper use of animals in research.  One common thread amongst the research community is a need to increase the openness of the field so that the public can more fully understand what researchers and animal care staff do in their day to day work with animals.  Some of these initiatives include the Basel Declaration Society, the Concordant on Openness, and BRAD (Biomedical Research Awareness Day).  Openness has been further established through allowing the public to see videos and pictures from inside facilities.  Some facilities even allow people (especially students) into their research spaces so that they can see what “our world” is really like.  Part of showing them our world is letting the public know about the regulations that exist in their field and letting them see how those regulations are balanced with animal welfare and assisting researchers in meeting their objectives.

There is much work to be done to counter the loss of trust from the public, but it is important to do in order to help science move forward.

QUESTIONS

1.   Passed in 2006, what is AETA?

a.   A piece of animal protection legislation for animals used in neuroscience research

b.  An amendment to the AWA outlawing freeze branding

c.  Law passed aimed to protect researchers from animal right extremists

d.  Legislation that required greater openness for research involving animals

2.  In the United States, how can the public’s acceptance of animals in research be described over the last 20-30 years.

a.   Mostly unchanged with small variations from year to year

b.   Steadily climbing each year

c.   Sharp decline in the late 90’s, but staying roughly unchanged since then

d.  Steady decline

3.  What is the AALAS AREA program?

a.   Program aimed at reaching college students to get them involved with biomedical research

b.   Website designed to teach high school aged adolescents about how animals are treated in research

c.  Program focusing on middle school aged kids each year at the AALAS national meeting

d.  A lobbying group focused on ensuring that research animals can still be transported on commercial airlines

ANSWERS

1.  c

2.  d

3.  c

**Mohan and Huneke.** [**The Role of IACUCs in Responsible Animal Research**](https://academic.oup.com/ilarjournal/article/60/1/43/5618668)**, pp. 43-49**

Domain 5

SUMMARY: Since the Health Research Extension Act of 1985, The PHS Policy requires that all institutions using live vertebrate animals in PHS supported research must have an institutional animal care and use committee (IACUC) to oversee the care and use of its animals.  The institutions are required to use *The Guide* to design and implement the work that happens with animals as well as the Animal Welfare Act (and its regulations).  Due to the composition and function of the IACUC they are able to contribute to the scientific quality of the research of their institution.  The IACUC has purview over care and use of the animals and therefore can influence the data that are collected from the experiments.  The central role of IACUCs in research animal use and oversight helps it safeguard responsible animal research by ensuring ethical, scientifically sound, standardized practices in animal research.

Reviews by the IACUC are designed to protect animal welfare and to ensure that animals are being used in a meaningful way. Part of the analysis that each IACUC performs is examining the benefits of the research against the harm that will be caused to those undergoing the research.  Because there are no regulatory guidelines for conducting a harm-benefit analysis, most IACUCs use the 3Rs that were brought forth in the oft-cited Russel and Birch paper.  To uphold the principles of the 3Rs it is necessary for the IACUC to request that researchers seek out alternatives to animals work, whether that be to reduce the number of animals used or refine the work to make it less distressful on the animals.

When examining the best animal model for a proposed project, the IACUC takes into account not only the existing body of knowledge in the field, but also the experience of the investigators, the resources available at the institution, and the institutional experience of handling those specific animal models. The plan of the proposed research should be understood by all members of the committee, including the non-scientist.  The IACUC should agree with the proposed group numbers and sizes as well and ensure that the proper power analysis has been done to ensure that meaningful data can be captured from the experiment.  Another aspect of the IACUC’s review process includes making sure that the research can conform to the ARRIVE and PREPARE guidelines that are needed to help with the reproducibility crisis in research.

Once a protocol has been reviewed and approved it is necessary to follow up on the research.  This can occur through post approval monitoring and renewal of protocols in accordance with the regulations.  There should also be a mechanism in place in which researchers can report unanticipated problems and that all animal users can report welfare concerns.  It is also critical that the IACUC help ensure that animals used in research are humanely euthanized.

Management of an Occupational Health and Safety Program (OHSP) requires coordination with the IACUC, researchers, environmental health and safety, and other institutional programs.  This requires that these bodies help ensure that risks associated with animal research are mitigated to the extent possible.  This will involve monitoring, reporting, and responding to issues that arise as the research progresses.  Training of research personnel also falls under the purview of the IACUC and helps to minimize risks to both humans and animals involved in research.

QUESTIONS

1.  In the context of reporting findings of biomedical search, what do the acronyms PREPARE and ARRIVE stand for?

2.  US Government Principle II addresses which of the following?

a. Animal pain tolerance

b.  Living conditions of animals in research

c.  Harm vs. benefit analysis

d.  Qualifications of researchers to do research

ANSWERS

1.   Planning Research and Experimental Procedures on Animals: Recommendations for Excellence and Animal Research: Reporting In Vivo Experiments

2.   c

**Mohan and Foley.** [**Everything You Need to Know About Satisfying IACUC Protocol Requirements**](https://academic.oup.com/ilarjournal/article/60/1/50/5541554)**, pp. 50-57**

Domain 5

SUMMARY: The Animal Study Protocol, or the IACUC protocol, is a detailed description of the proposed use of animals prepared by the researcher for IACUC review and approval. Activities involving animals in research, testing, and teaching can begin only after they have been reviewed and approved by the IACUC.

What the IACUC Looks for During Review:

a.   Study Objectives and Scientific Justification

b.  Rationale for Animal Use and Search for Alternatives (Consideration of 3Rs)

c.   Species and Strain Justification

d.  Justification of Animal Numbers

e.  Description of Experimental Procedures

f.    Surgical or Invasive Procedures

g.  Anesthetics, Analgesics, Sedatives, and Tranquilizers

h.   Nonsurgical Procedures

i.   Post procedural Care

j.    Pain and Distress

k.  Endpoints and Euthanasia

l.   Other Relevant Information

-     Nonstandard Housing or Husbandry

-   Movement of Animals in and out of Housing Facility

-     Species-Specific Enrichment

-    Use of Nonpharmaceutical Grade Substances

-    Hazardous Agents

-    Biological Materials

-   Personnel on the Protocol

-    Training and Qualification

-     External Performance Sites and Collaborations

-   Field Studies

-     Contract Research Organizations (CRO)

-    Updates and Revisions

-     PI Assurances

QUESTIONS

1. The various topics the IACUC evaluates on the protocol include:

a.   The rationale for proposed animal use and numbers,

b.   Search for alternatives,

c.  Detailed descriptions of procedures including surgical procedures,

d.  Impact on the animals’ well-being,

e.  Availability and use of appropriate anesthesia and analgesia

f.   All the above

2. True or False: There is a standardized protocol forms for research animal use (and specific regulatory requirement for an animal protocol).

3. True or False: AAALAC is an accrediting organization and has regulatory authority. AAALAC accreditation is one means by which institutions assure the PHS that they are compliant with PHS policy.

4.  There is a regulatory requirement that states:

a.  That a veterinarian or a qualified designee must be consulted in the planning of any procedure that could cause pain to animals and

b.  That pre- and postsurgical care should be “in accordance with established veterinary medical . . . procedures.”

c. (AWR 2.31,d,1,iv,B) is the regulatory requirement

d.   All the above

5.  If there are concerns regarding newly proposed procedures that are unfamiliar to the research team or are particularly invasive, sometimes the IACUC will approve it as a pilot study

a. Generally for a limited time and involving fewer animals

b.   Allow for evaluation of the skills of the research team and/or to assess any potential animal welfare concerns and their management

c.  To be monitored by a member of the veterinary team

d.  Are reviewed by the IACUC, the PI may be allowed to submit a protocol for the full study

e.   All the above

6.  Study objectives or a brief explanation of study aims and how it is important\_\_\_\_\_\_\_\_\_\_

7.  An IACUC constituted as per the requirements of the \_\_\_\_\_\_\_\_\_comprises of a wide range of experts, including one member whose primary concerns are in a nonscientific area, such as the nonscientific member and the nonaffiliated member.

8.   True or False: The purpose of explaining the rationale of the study is to provide the IACUC with a simple and straightforward overview of the proposed animal studies that can also be easily understood by all members of the committee regardless of their scientific background.

9.  True or False: IACUCs are not required to evaluate the scientific content of a protocol for quality, the benefits of the study against potential animal welfare concerns have elements of scientific merit review in them.

10. Under the protocol section title Rationale for Animal Use and Search for Alternatives, the investigator is asked to provide a rationale and purpose for use of animals to achieve study aims and to consider the 3Rs( \_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_, \_\_\_\_\_\_\_\_)

11. The overall precept of the 3Rs is that animal use in scientific research should be carried out only after \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

12. The principle of replacement will address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

13. The principle of reduction will be addressed by providing justification for the number of animals proposed. This should include an explanation of \_\_\_\_\_\_\_\_.

14. A flow chart or table is often helpful when explaining animal numbers, especially if there are several different studies combined in a single study and/or complicated breeding schemes. The IACUC will want to know:

a.  How group sizes were determined

b.   The statistical parameters used

c.  The power calculations used for achieving statistically valid results

d.   All the above

15. Refinement can be addressed by design of procedures that minimize

a.   Pain

b.  Distress

c.  Discomfort

d.   All the above

16. It is helpful to give specific examples of how the procedures have been refined to minimize pain or distress, such as use of \_\_\_\_\_\_\_\_\_.

a.   Postoperative analgesics,

b.   Noninvasive imaging procedures,

c.   Study designs that minimize the need for frequent handling or restraint of animals,

d.   Procedural training that occurs before using live animals

e.   All the above

17. Additionally, the \_\_\_\_\_\_\_ and the \_\_\_\_\_\_ require an assurance that animal activities do not unnecessarily duplicate previous studies, and also a description of the measures used for search of alternatives to painful and distressful procedures.

18. A description of the measures used for search of alternatives to painful and distressful procedures should include information such as:

a.  The databases used for the search,

b.  Date of search,

c.  The time period covered by the search, and

d.  The search strategy used.

e. All of the above

19. Species and Strain Justification includes:

a.   Justification for the choice of species and

b.   Specific animal model (genetic model, spontaneous model, etc.

c.   It is also an opportunity to explain why a species lower on the phylogenetic scale would not be equally (or more) appropriate.

d.   All the above

20. Statistical methods such as a power analysis should be used when possible to determine

21. What goes in the Description of Experimental Procedures?

a.   Complete, concise descriptions of all procedures to be employed in the study are required in this section

b.   It is important for reviewers to be able to discern the total “picture” of what will happen to animals from beginning to end to assess overall impact of the experiments on animal well-being.

c.   a and b

22. What is include in the Surgical or Invasive Procedures

a.   Indication of the type(s) of surgical procedure(s) (major vs minor, survival vs. nonsurvival) is useful here

b.  Along with information on who (personnel)

c.   Where (location, procedure room).

d.   All the above

23.  Major survival surgery is generally defined as one that \_\_\_\_.

a.   Penetrates and exposes a body cavity

b.   Produces substantial impairment of physical or physiologic functions

c.   Involves extensive tissue dissection or transection.

d.  All the above

24. Nonsurvival surgery is one in which the animal is ­­­­\_\_\_\_\_\_.

a.   Euthanized

b.   Does not recover from anesthesia.

c.  a and b

25. What is described in preoperative procedures part of the protocol?

a. Food and fluid restriction (presurgical fasting)

b.   Baseline data acquisition (e.g., body weight, blood work)

c.   Presurgical sedation if needed

d.   Acclimation to devices or jackets that might be in use after surgery

26. For description of the surgical procedure, include information such as

a.  Aseptic techniques that will be utilized,

b.  Plans for anesthesia and analgesia,

c.  Incision site and its preparation,

d.   Approximate duration of procedure,

e.   Supportive measures during procedure (fluids, ventilation),

f.   Monitoring parameters (e.g., depth of anesthesia, vital signs, oxygen saturation levels) both during and in recovery from procedures.

g.  All the above

27. For survival procedures, a detailed description of the post procedural care is required including \_\_\_.

a.   Housing and palliative care

b.  Suture removal, provision of analgesia

c.  Other postoperative medications to be administered

d.   Parameters for monitoring pain and distress during recovery

28. For survival procedures, a detailed description of the post procedural care is required including

a.   Other assessments for postoperative recovery

b. Management of potential complications

c.  Any humane endpoints in case of unrelieved pain or distress.

d.   All the above

29. True or False: Protocols should also indicate the personnel in charge of postprocedural care and assessment and regular update of records, including on weekends, after hours, and holidays

30. For anesthetics, analgesics, sedatives, or tranquilizers  part of the protocol  includes \_\_\_\_\_.

a.  The name or class of agent and dose

b.   Routes, and schedule of administration should be indicated

c.  It may be acceptable to provide a range for the dosage to allow flexibility in the procedure.

d.   All the above

31. If multiple survival surgical procedures are planned (i.e., multiple anesthetic events) information includes?

a.  A scientific justification for the multiple survival surgeries will be required

b.   Information on whether the surgeries are major or minor (as defined by your IACUC)

c.  The time period (minimum) between 2 surgeries.

d.   All above

32. True or False: Performing multiple survival surgeries on animals as a way of reducing animal numbers is not generally accepted.

33. True or False: Detailed, sequential description of all nonsurgical procedures is required.

34. Administration of substances will include:

a.   Route

b.  Frequency

c.    Volume

d.  All above

35. IACUCs blood withdrawal may have established guidelines on

a.   Blood sampling procedures such as a maximum limit of total blood collected per week

b.   Limit on the number of times a collection site is used, and

d.   Minimum recovery period between collections.

e.  All of above

36. If prolonged physical restraint is performed for any purpose, the IACUC will ask for

a.   Scientific justification and ensure that the duration of restraint is the minimum necessary for the research objectives.

b.   Information in this section should include a description of the physical restraint device

c.  A description of the acclimation procedure to the device and the prolonged restraint

d.   Measures to minimize animal distress during the prolonged restraint procedure

e.   All the above

37. Which USDA pain categories are description is accurate?

a.   Classification B: Animals being bred or held for use in research but not yet used for such purposes

b.   Classification C: Animals upon which experiments will be conducted involving no or only momentary pain, distress, or use of pain-relieving drugs

c.   Classification D: Animals upon which experiments will be conducted involving pain or distress, for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used

d.   Classification E: Animals upon which experiments will be conducted involving pain or distress but use of anesthetic, analgesic, or tranquilizing drugs will adversely affect the experiments

e.  All are correct

38. True or False: Humane endpoint criteria are established to determine when euthanasia should be performed.

ANSWERS

1. f

2. False: There are no standardized protocol forms for research animal use (and no specific regulatory requirement for an animal protocol)

3. False: It is important to understand that AAALAC is a private nonprofit accrediting organization and has no regulatory authority. However, AAALAC accreditation is one means by which institutions assure the PHS that they are compliant with PHS policy.

4. d

5. e

6. In the advancement of science or human or animal health

7. PHS Policy

8. True

9. True

10. 3Rs (replacement, reduction and refinement)

11. Exhaustively searching options for nonanimal alternatives

12. Why non-animal models (in vitro, computational) or phylogenetically lower animal models cannot be used

13. The different arms of the study, group sizes needed, time points, etc.

14. d

15. d

16. e

17. AWRs (9CFR, §2.31 (d)(1)(ii)); Guide

18. e

19. d

20. Appropriate group sizes (N) for the experiments and the total number of experimental groups stated

21. c

22. d

23. d

24. c

25. d

26. g

27. d

28. d

29. True

30. d

31. d

32. True

33. True

34. d

35. e

36. e

37. e

38. True

**Hankenson and Hallman.** [**Investigator Engagement: Somewhat Radical Considerations on Practices to Improve Animal Care Program Compliance**](https://academic.oup.com/ilarjournal/article/60/1/58/5485569)**,** **pp. 58-65**

SUMMARY: The focus of this article is to consider researchers as partners in the animal care and use program, a 4th leg of the metaphorical 3-legged stool of a program (IACUC, IO, veterinarian), in order to reduce unnecessary regulatory burden for animal users. PIs are the subject matter experts in their field of study while IACUC offices and AV designees are subject matter experts in regulations and guidelines. If these groups approach protocol development, protocol review, compliance programs, and training in a collaborative manner, it can lead to a more productive research enterprise. The first part of this proposal involves a complete orientation to the animal care program for new PIs including start up packets, informing operational managers of PI space and species needs before agreeing to provide them, protocol pre-reviews with veterinarians, and orientation to all of the support systems available to within the animal care program (i.e. vet staff, animal orders, IACUC, etc.). The second proposal is to have an introspective self-evaluation that institutes necessary compliance and post-approval monitoring measures without self-imposing unnecessarily rigid rules. This involves seeing PIs as partners in program development, making sure the IACUC is clear on its purview, creating a performance-based compliance program, and clearly communicating policies and expectations to the research community. Assisting investigators can result in both pre-approval and post-approval compliance. Suggestions include having protocol specialists or liaisons to aid in smooth protocol submission and review, holding start up meetings after protocols are reviewed but before research begins, encouraging PIs to be part of the PAM process, being transparent with PIs about what documents are used for evaluation during inspections, holding mock inspections, and inviting them to be a part of development of policies that apply to their research processes. Establishment of trust between the animal care program and research personnel is a step toward honest self-reporting of adverse events or non-compliances, and resolutions that use an objective algorithm to develop corrections that fit the classification of the offense allow the PI to understand rationale for the resolution. Lastly, authors propose that training programs be meaningful, tailored to the roles and needs of the learner, utilize multimedia and active learning techniques to engage learners, and allow flexibility based on lab staff needs and ideas.

QUESTIONS

1. According to The Guide, who is responsible for ensuring that individuals are appropriately trained in surgical procedures?

a. AV

b. IACUC

c. All of the above

d. None of the above

2. True or False: Regulations and guidelines do not provide specific guidance for how strict and formal a PAM program should be.

ANSWERS

1. c

2. True

**Cox et al.** [**Research with Agricultural Animals and Wildlife**](https://academic.oup.com/ilarjournal/article/60/1/66/5490285)**, pp. 66-73**

Domain 5: Regulatory Responsibilities

SUMMARY: Agricultural animals such as swine, sheep, goats, and cattle represented 10% of the animals used in USDA-regulated research in 2016.  Likewise, ever-increasing interactions among livestock, wildlife, and humans create situations that increase the need for research studies involving captive wildlife.  Optimum healthcare of both livestock and captive wildlife in a research setting requires proper husbandry, management, and veterinary care.  Limited peer-reviewed research on wildlife welfare, husbandry, and nutrition exists which presents unique challenges when working with them in research.

Housing or caging is one of the most important features of an animal’s environment.  A primary factor in determining the ideal housing/caging is species behavior in terms of its environment.  Wild or domestic ungulates that are social in nature should be housed in compatible groups to minimize stress.  Social behaviors of some species are seasonally variable, so special considerations may be necessary.  Housing animals for infectious disease research may require complex biocontainment facilities, whereas research on behavior, reproduction, or nutrition may be conducted in outside pens or paddocks with fewer biosecurity concerns when working with livestock and ungulate species.  Hand-rearing young animals inside an enclosure similar to containment housing may help acclimate animals to both human contact and containment.

Calm, respectful restraint and handling produces animals that are easier to work with compared with those handled roughly or disrespectfully.  Positive behavior training can be used to acclimate animals to procedures.  Equipment, methods, or attitudes typically used for handling cattle will likely result in injuries (abrasions, lacerations, fractures) or other stress-induced conditions such as capture myopathy or abomasal ulcers when handling deer.  Chemical restraint should be considered if prolonged restraint or multiple handling events over a short period of time are required.

Environmental enrichment is an important component of husbandry for both wildlife and livestock and can be categorized as social, occupational, or nutritional.  Lack of stimulation in most biocontainment settings can result in boredom and development of stereotypic behaviors, which can negatively impact research results.

Many wildlife species conceal signs of illness, making assessment of their condition difficult.  Wildlife species tend to become more excited during handling or transport than domestic species, so care must be taken during transport of wildlife to minimize stress and fractiousness that may result in injury.

Wildlife field studies are often designed to evaluate observational aspects of biology, ecological relationships, population density, behavior, reproduction, or other topics.  Other studies are more invasive, requiring capture, tagging, blood sampling, radio transmitter placement, or even surgery.  Capture and handling of a wild animal introduces measurable changes in behavior, physiology, stress, and fear, including the possibility of death.

All animals should be examined before procurement, and prior to study initiation, to avoid confounding effects caused by disease, genetics, malnutrition, parasitism, or other factors.  When acquiring both livestock and wildlife offsite, all permitting and testing requirements by appropriate agencies must be met.  When migratory birds or endangered species are to be acquired, or potentially affected in any way by the intended research, federal authorities such as the US Fish and Wildlife Service must be contacted and appropriate permits secured.  Animals reared on-site tend to be better habituated to housing, handling, and human contact, but space and feed costs, maintenance of confinement areas, and labor costs tend to be increased.  When wild-caught animals are to be used for research, a safe, secure method of capture, transport, and housing must be provided.  Housing substrates and bedding should approximate the natural environment when possible.

Investigators conducting animal research should understand that research quality is affected if animals are not well cared for, treated humanely through good handling practices, and humane endpoints used to prevent undue suffering.  Replacement refers to the use of nonsentient materials to replace living animals whenever appropriate after it has been proven that replacement will function as an accurate model for the living animal.  Reduction refers to proper design of experiments using the lowest numbers of animals necessary to still retain statistical power.  Reduction of animal numbers may not be possible due to the outbred nature of most livestock and wildlife, the study design, environmental factors, and other challenges related to wildlife field research.  Refinement terms refers to, but is not limited to, reducing stress or distress in subject animals to the lowest possible level.  Use of minimally invasive handling and sampling techniques should be considered during study design development and be included in the IACUC review process.  Good science involves obtaining the most useful information possible in the shortest time while using the fewest subjects possible.  Good sense equates to common sense in “using the right animal for the right reason” to answer the pertinent scientific questions.  Good sensibilities values empathy as a means for recognizing stress, distress, discomfort, and/or pain in research subjects.

QUESTIONS

1. Swine are naturally motivated to root with their snout and can therefore inflict serious damage to what type of flooring material?
   1. Concrete
   2. Rubberized
   3. Stainless steel
   4. Fiberglass
2. Which of the following terms refers to reducing stress or distress in subject animals to the lowest possible level?
   1. Replacement
   2. Reduction
   3. Refinement
   4. Good science
3. Which of the following terms values empathy as a means for recognizing stress, distress, discomfort, and/or pain in research subjects?
   1. Good science
   2. Refinement
   3. Good sense
   4. Good sensibilities
4. Which of the following situations would NOT require establishment of an IACUC?
   1. Institution solely conducting food/fiber research with agricultural species and without government funding
   2. Institution conducting pharmaceutical testing on sheep
   3. Institution conducting medical device testing on rats
   4. Institution conducting NIH-funded research with agricultural species

ANSWERS

1. b
2. c
3. d
4. a

**Petervary and Pullium.** [**Disaster Planning and Research Continuity in Responsible Animal Research**](https://academic.oup.com/ilarjournal/article/60/1/74/5481800)**, pp. 74-85**

Domain 4; T3

SUMMARY: Research institutions have several responsibilities in addition to research, including animal welfare, health and occupational safety, facilities management, and communication.  To ensure continued operation in the face of adverse events and disasters, a holistic approach is necessary.  Good planning involves a culture of preparedness (defined as informing and empowering individuals to obtain skills and take preparatory actions necessary to become resilient against threats/hazards), resilience (defined as capacity of adaptation to changing conditions and rapid recovery from disruptions), and understanding the interactions and partnerships with other groups.  Facilities with Public Health Service funding and AAALAC International accreditation are required to develop contingency plans for their vertebrate research animals as outlined in the Guide for the Care and Use of Laboratory Animals.  Facilities may be subject to other regulatory requirements for example, the possession, use, and transfer of select agents and storage and transport of hazardous materials.  If the facilities exist in a hospital, the Joint Commission on the Accreditation of Healthcare Organizations provides guidance.

An emergency is defined as any occasion or instance for which, in the determination of the President, Federal assistance is needed to supplement State and local efforts and capabilities.  A major emergency is defined as any natural catastrophe or regardless of cause, any fire, flood, or explosion in any part of the United States, which in determination of the President causes damage of sufficient severity and magnitude to warrant major disaster assistance.  There are 5 FEMA frameworks that address a function: 1. Prevention: avoid, prevent or stop a threat or hazard, 2. Protection: secure against acts of terrorism and natural disasters, 3. Mitigation: reduce loss of life and property, 4. Response: saving lives, property and the environment and meet basic human needs after the incident, and 5. Recovery: assistance to recover effectively.

A comprehensive disaster plan will identify risks, estimate necessary capabilities to address risks, build and sustain capabilities, plan delivery of capabilities and integrate with other institutional, community and government plans, validate capabilities, and update and revise based on changes, feedback and lessons learned.  Strategies for continuity of operations include communication strategies, alternate sites, stockpiled supplies, and offsite backups for critical documents, animal lines (such as cryopreservation at multiple locations), and cell lines.  Improving resilience can be done by practicing exercises that reinforce shared culture and values and improve communication.  A good plan will gain organizational support and appoint necessary personnel as well as assign responsibilities and authorities to a department or individual.  This can be a person in the position of chief resilience officer.  This position can appoint a committee being sure to include legal/regulatory/public affairs personnel, representation from each department, senior organizational persons, emergency management personnel and community stakeholders.  Senior research leadership involved in the planning should include the CEO and institutional official.   Development of the plan should include networking outside of the immediate organization, choosing appropriate back-ups, building in support for responders such as sleeping accommodations, food, and water, and testing of the plan.   Special considerations include animal evacuations, animal escapes, specialized life support, supplies, and technical services, and protection of confidential information.

QUESTIONS

1. Animal facilities with what type of funding or accreditation are required to develop disaster contingency plans?  For what type of animals?
2. What senior research leadership should be included in the plan development?
3. How can valuable animal lines be preserved for continuity of operations?

ANSWERS

1. Facilities with Public Health Service funding and AAALAC International accreditation are required to develop contingency plans for their vertebrate research animals as outlined in the Guide for the Care and Use of Laboratory Animals.
2. Senior research leadership involved in the planning should include the CEO and institutional official.
3. Cryopreservation at multiple locations

**Bayne and Turner.** [**Animal Welfare Standards and International Collaborations**](https://academic.oup.com/ilarjournal/article/60/1/86/5280851)**, pp. 86-94**

Domain 5: Regulatory Responsibilities

Domain 6: Education

SUMMARY:  Globalization is becoming a force that is revolutionizing biomedical enterprise, particularly that of scientific collaboration involving animals research. There is increasing interest in animal welfare worldwide, and as part of its 2001-2005 Strategic Plan the World Organization for Animal Health (OIE) identified the development of international standards on animal welfare as a priority. Authors have discussed in detail the need of harmonizing global animal welfare standards in the context of international collaboration. Further, authors discussed the role of country specific standards, OIE standards and role of various organizations such as AAALAC International in mitigating the challenges to achieve global harmonization of animal welfare standards.

 QUESTIONS

1.  Intellectual assets and scientific expertise are spread across the globe, and the world health organization (WHO) has recommended moving away from “silos” in healthcare provision. To facilitate this, in 2017, the WHO launched what program?

a. One Health Initiative

b. The Observatory Global Observatory on Health Research and development

c. CIOMS (Council for international organizations of Medical Sciences)

d. ICLAS (International council for laboratory Animal Science)

2. Factors driving international research collaborations includes \_\_\_\_?

a. Expertise and other human resources

b. Specific Animal types

c. Equipment or facility space resources

3. True or False: In the United States, the institutional official cannot overturn the IACUC’s decision.

4. True or False: In Japan, The IACUC’s decision can be overturned by the institutional official ( The IACUC has an advisory role rather than functioning as the decision-making body)

ANSWERS

1. b

2.   d

3. True

4. True

**Leland et al.** [**The Role of the IACUC in the Absence of Regulatory Guidance**](https://academic.oup.com/ilarjournal/article/60/1/95/5481802)**, pp. 95-104**

Domain 5

SUMMARY:  Institutional Animal Care and Use Committees (IACUCs) occasionally face regulatory requirements for which clear guidance may not be available. Over time, shared institutional experiences and documentation coalesce to create a general framework that provides a baseline for others to consider as templates for further policy elaboration or development.

A number of research scenarios for which clear regulatory guidance may not be available are as follow:

a.  Invertebrates

b.  Embryonated eggs

c.  Wildlife

d.   Harm-benefit analysis

e.   Reproducibility

f.    Adverse events

The article discuss potential future roles for the IACUC with regards to each issue. They attempt to provide some useful and practical perspectives to assist IACUCs to better fulfill their mission of reviewing and approving animal research while balancing the sometimes confounding goals of supporting the research and education missions against overregulation.

QUESTIONS

1.  T/F: In searching for the regulatory basis behind the HBA, neither the Animal Welfare Act (AWA) nor the Animal Welfare Regulations (AWR) mention specifically an HBA,

2.  T/F: When a scenario involves mice, the AWA and AWR do not apply.

3.  T/F: The Guide for the Care and Use of Laboratory Animals (Guide) states that during their review, IACUCs should review the impact of the proposed procedures on the animals’ well-being.

4.   T/F: For studies that may involve unrelieved pain or distress, there are special considerations for IACUC review including an obligation to weigh the objectives of the study against the potential animal welfare concerns. The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACi) has interpreted this as

5. T/F: HBA is a relatively new concept in the United States, and there remain disparate feelings as to its usefulness and whether and how to perform one.

6. A recent working group composed of members from the American Association for Laboratory Animal Science and the Federation for Laboratory Animal Science Associations defines HBA as \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

7.  The AWA and AWRs cover warm-blooded animals; however, the AWRs exempt field studies from IACUC review unless the activity involves \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ .

8.  T/F: The Guide covers all vertebrates but does not address issues specific to field and wildlife studies, although many of the principles established within the Guide are applicable to species and studies in the wild.

9.   T/F: When research is occurring outside of the laboratory and in a field situation, the IACUC must receive details about procedures that may deviate from those that would ordinarily be revealed through the standard questionnaire of most protocol templates.

10. T/F: Most existing IACUC forms are not well-suited for wildlife field research.

11. T/F: Neither the AWA, AWRs, nor PHS Policy regulate invertebrate species.

12. T/F: The Guide states, “Although formulated specifically for vertebrate species, the general principles of humane animal care as set out in the Guide may also apply to invertebrate species.

13. T/F: AAALACi also states that “All animals used…in research, teaching or testing at accreditable units are to be included and evaluated…Nontraditional animals, inclusive of invertebrate species, are also included where they are relevant to the unit’s mission.”

14. T/F: Are all animals created equal, including invertebrates?

15. Many IACUCs, as a means to manage invertebrate oversight, have drawn classifications of invertebrate species, for example, a higher classification of invertebrate animal species such as \_\_\_\_\_\_\_\_\_\_\_\_\_.

16. T/F: The IACUC has the authority to review the scientific merit and quality of a study.

17. In 2010, the United Kingdom National Centre for the Replacement, Refinement, and Reduction of Animals in Research proposed the ARRIVE guidelines (Animals in Research: Reporting In Vivo Experiments) for reporting preclinical animal research to assist with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

18. The ARRIVE guidelines were created to\_\_\_\_\_\_\_\_\_\_\_\_.

19. The journal Nature has also introduced a reproducibility checklist for submitting authors that is designed to improve \_\_\_\_\_\_\_\_\_\_\_\_.

20. The Guide defines laboratory animals as \_\_\_\_\_\_\_\_.

21. T/F: OLAW interprets the Public Health Service (PHS) Policy as applicable to their offspring only after hatching.

22. T/F: Additionally, for amphibians and fish, OLAW also states that larval forms have vertebrae and are therefore covered by the PHS Policy.

23. T/F: The AWRs do not regulate most avian species or coldblooded animals, and therefore IACUC protocol review is not required for these noncovered species.

24. T/F: Because developing chicks are not considered vertebrates by OLAW, these studies may not undergo review of the procedures performed, justification of animal numbers, identification of humane endpoints, or euthanasia methods.

25. T/F: Once hatched, chicks are considered vertebrates and the IACUC becomes immediately responsible for their care and welfare.

26. Which are correct in how an Institutions have implemented mechanisms to prepare for the use of avian eggs and to provide guidance for appropriate care and/or euthanasia of unanticipated newborn chicks.

a. Investigators may be required to complete IACUC protocols/forms based on when procedures take place relative to the length of egg incubation.

b.  Create a standard operating procedure (SOP) to cover the event of inadvertent hatching, to fulfill PHS requirements, and decrease regulatory burden for the investigator.

c. Choose to wait to create a SOP.

d. All the above

27. Breeding animals, as vertebrates, are covered under \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

28. T/F: Embryos/larvae that are used experimentally but do not survive to hatching age are not regulated and do not require protocol approval.

29. OLAW has interpreted the PHS Policy to define hatching as the developmental event that moves avian, frog, and amphibian embryos from “non-vertebrate” to vertebrate status. However, when should IACUC members be ethically concerned about these animals?

30. T/F: The CCAC Animal Care Euthanasia Guidelines includes the following statement, “There is emerging evidence that indicates precocial oviparous species are conscious at hatching and during the last few days prior to hatching.”

31. T/F: The AVMA Guidelines explicitly state that avian embryos that have attained >50% incubation (i.e., >11 days) have a developed neural tube that is sufficient for pain perception and therefore embryos should be euthanized by the same methods appropriate for avian neonates.

32. T/F :In 1997, the European Commission’s Working Group on the Euthanasia of Experimental Animals stated, “Bird embryos from the stage at which the neural tube has developed into a functional brain (>50% gestation) must be destroyed humanely as they may be capable of perceiving pain from that stage.”

33. T/F: It is important for the IACUC to complete an in-depth review of relevant literature prior to composing/revising policies and SOPs related to embryonic egg use.

34. OLAW defines an adverse event as \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

35. The \_\_\_\_\_\_\_states that the IACUC, as an institutional agent, will “review concerns involving the care and use of animals at the institution.”

36. \_\_\_\_\_\_\_outlines the role of the IACUC members in the “…establishment of a mechanism for the receipt and review of concerns involving the care and use of animals at the institution. The committee must meet as often as necessary to fulfill its responsibilities”.

37. \_\_\_\_\_\_\_\_\_do not apply to laboratory-bred mice because they are not regulated species; therefore they do not apply in this scenario.

ANSWERS

1. True (although concepts that underlie the HBA are well embedded within the AWR, including that investigators provide a rationale for using animals)

2. True

3. True

4.  The need to perform an HBA. AAALACi is most interested in how the IACUC conducts such an analysis.

5. True

6. “a transparent systematic method to gain information about harm to animals and expected benefit so that qualified decisions of approval or rejection of projects can be made.”

7. An invasive procedure, harms, or materially alters the behavior of an animal under study.

8. True

9. True

10. True

11. True

12. True

13. True

14. True

15. Octopus, squid or cuttlefish, otherwise known as cephalopods

16. True

17. The reproducibility of research

18. Improve the design, analysis and reporting of research using animals, maximizing information published and minimizing unnecessary animal studies

19. Reliability and rigor

20. “any vertebrate animal (i.e., traditional laboratory animals, agricultural animals, wildlife, and aquatic species) produced for or used in research, testing or teaching

21. True: The egg-laying adult animal is covered by the Policy. OLAW expects Assured institutions to have policies and procedures in place that address the care or euthanasia of animals that hatch unexpectedly.

22. True

23. True

24. True

25. True

26. d

27. PHS Policy, and IACUCs must approve an animal care and use protocol prior to their experimental use.

28. True

29. The exact age when embryos within eggs may perceive pain and/or distress remains unclear. Various regulatory and veterinary guidelines and scientific articles speak to the ability of chick embryos to experience pain and distress before hatching.

30. True

31. True

32. True

33. True

34. “unexpected incidents that lead to harm or endanger well-being of animals and humans at research facilities.”

35. PHS Policy

36. The Guide

37. The AWRs