

Mastering Research Administration

A Complete Guide to the
CRA[®], CPRA[®], and CFRA[®] Exams

Farin Kamangar, MD, PhD, CRA

University Distinguished Professor
Associate Vice President for Research
Morgan State University
Baltimore, MD, USA

Lulu Jiang, PhD

Program Administrator
National Transportation/SMARTER Centers
Morgan State University
Baltimore, MD, USA

Rebecca Steiner, CRA

Grants Manager
Office of Research Administration
Morgan State University
Baltimore, MD, USA

Disclaimer:

- These multiple-choice questions and the accompanying text were originally developed in 2022 and were reviewed and updated in August 2025. Grant policies, rules, and regulations may change over time. Please consult official sources for the most current information.
- While it is generally considered best practice to avoid negative phrasing and answer choices such as “all of the above” or “none of the above” in standardized multiple-choice questions, these materials were created for training purposes. In some instances, we have intentionally used such formats.

Correspondence to: farin.kamangar@morgan.edu

© 2025 Farin Kamangar. All rights reserved.

This material may not be reproduced, distributed, or sold without permission from the author.

Published: December, 2025

CHAPTER 14

Ethics in Animal Research

Table of Contents

14.1. Introduction	4
14.2. Historical Background	4
14.3. Oversight	6
14.4. Institutional Animal Care and Use Committee	6
14.5. The Three Rs of Humane Animal Research	7
14.6. Good Research Practices	8
14.7. Summary	8
14.8. Practice Questions	9
14.9. Answers to Practice Questions	13

14.1. Introduction

Animal research has long played a critical role in advancing biomedical, behavioral, and environmental sciences. Complex physiological systems in living organisms often respond differently to interventions than cell-based or computational models, making animal studies necessary in many areas of research. Federal regulations require animal testing when no validated non-animal alternatives exist. However, ethical oversight ensures that such research is conducted with respect for animal welfare and scientific integrity.

14.2. Historical Background

14.2.1. The Animal Welfare Act of 1966

Perhaps the first important law passed to ensure the ethical treatment of animals in U.S. research was the [Animal Welfare Act \(AWA\)](#) of 1966. The AWA was enacted in response to growing public concern over the mistreatment, theft, and unregulated sale of animals—particularly dogs and cats—used in research. The immediate impetus came from a series of highly publicized media investigations in the early 1960s. A highly influential investigation was the 1965 Life magazine exposé, “Concentration Camps for Dogs,” which documented filthy, overcrowded kennels, lack of food or veterinary care, and stolen family pets being sold into research. The story provoked widespread public outrage and generated tens of thousands of letters to Congress from citizens demanding federal action. In addition, researchers themselves were calling for better standards. These converging pressures led Congress to pass the AWA in 1966.

The original 1966 Animal Welfare Act had a narrow and specific scope, focused primarily on regulating the commercial sale, transport, and use of certain warm-blooded animals in research and exhibition. It covered only:

- Dogs and cats
- Nonhuman primates
- Guinea pigs, hamsters, and rabbits

Many animals were excluded, including rats, mice, and birds bred for research, and farm animals used for food or fiber.

Congress authorized the [U.S. Department of Agriculture \(USDA\)](#) to inspect animal research facilities and allowed penalties for noncompliance.

14.2.2. The 1985 Amendments to the Animal Welfare Act

The 1985 amendments to the Animal Welfare Act (AWA)—enacted as part of the Food Security Act of 1985—strengthened care for research animals. Over time, there was growing acknowledgement of the animals' psychological needs. Scientists and veterinarians increasingly recognized that animal welfare involved not only preventing physical pain but also addressing psychological well-being, especially for primates and social species. There was also a need for stronger institutional oversight. These findings, in conjunction with public demand – caused by highly publicized cases such as the 1981 Silver Spring Monkeys case, in which investigators exposed severe neglect and unapproved experimental procedures at the Institute for Behavioral Research in Maryland – led to the 1985 Amendments. This Amendment required institutions to:

- Establish an **Institutional Animal Care and Use Committee (IACUC)** to review animal use;
- Mandate exercise for dogs and psychological enrichment for primates;
- Require training for personnel who handle animals; and
- Strengthen inspection, record keeping, and enforcement.

14.2.3. The 1985 Health Research Extension Act

By the early 1980s, NIH had additional needs that went beyond USDA's mandate. The 1985 Health Research Extension Act (HREA) explicitly required Public Health Service (PHS), including NIH, to create more detailed policies.

The AWA covered only certain warm-blooded species (e.g., dogs, cats, primates, rabbits). It excluded rats, mice, and birds bred for research, which make up over 90% of research animals. It did not fully address experimental design, pain management categories, or scientific justification for animal use. NIH needed a broader, more comprehensive oversight system that applied to all vertebrate animals used in PHS-funded research.

HREA required PHS, including NIH, to:

- Establish **Institutional Animal Care and Use Committees (IACUCs)**;

- Require Animal Welfare Assurances from each funded institution;
- Provide guidance, training, and monitoring; and
- Apply policies to **all vertebrate animals**, not just AWA species.

14.3. Oversight

As a result of AWA and HREA, ethical animal research in the United States is governed by two major federal agencies:

1. The [Animal and Plant Health Inspection Service \(APHIS\)](#) under the [U.S. Department of Agriculture \(USDA\)](#) enforces the [Animal Welfare Act \(AWA\)](#).
2. The [National Institutes of Health \(NIH\)](#) under the [Department of Health and Human Services \(DHHS\)](#) provides guidance and oversight through the [Office of Laboratory Animal Welfare \(OLAW\)](#).

As a reminder, the AWA, enacted in 1966 and amended in 1985, covers dogs, cats, rabbits, guinea pigs, hamsters, nonhuman primates, marine mammals, and livestock used in nonagricultural research and teaching. It excludes birds, rats, and mice bred specifically for research, as well as cold-blooded species such as fish, reptiles, and amphibians. Whereas, NIH via [OLAW](#) expanded protection to include **all vertebrate animals** used in federally funded research, ensuring consistent standards for humane care and ethical conduct.

14.4. Institutional Animal Care and Use Committee

Each research institution utilizing animals must establish an [Institutional Animal Care and Use Committee \(IACUC\)](#) to oversee and evaluate all aspects of the institution's animal care and use program. The IACUC ensures compliance with ethical and legal standards for the humane treatment of animals.

14.4.1. Composition

The **USDA APHIS requires three (3) members**: a Chairperson, an Attending Veterinarian (AV), and one public member.

However, the **PHS OLAW IACUC requires five members**, composed of:

- A **Doctor of Veterinary Medicine** with expertise in laboratory animal care,
- A **scientist** experienced in animal research,
- A **nonscientist**, such as an ethicist or layperson,
- A **community representative** unaffiliated with the institution, and
- An additional member to fulfill institutional or federal representation requirements.

Institutions with Public Health Service (PHS) Assurance and federal funding must meet these composition requirements. Therefore, in reality, most institutions have at least five (5) members in their IACUC.

14.4.2. Functions and Responsibilities

IACUC's authority stems from the Health Research Extension Act of 1985 (OLAW) and the Animal Welfare Act Amendments of 1985 (APHIS). For both, the committee's key responsibilities include:

- Reviewing and approving all research involving live animals,
- Conducting **semiannual inspections** of animal facilities and care areas,
- Performing **programmatic reviews** of institutional animal care procedures,
- Submitting biannual reports to the Institutional Official,
- Investigating and addressing any deficiencies or concerns,
- Suspending or terminating noncompliant activities, and
- Reviewing all approved protocols at least once every **three years**.

Research involving animals must not begin before IACUC approval. Any data collected prior to approval may be invalidated, and the study may be terminated.

14.5. The Three Rs of Humane Animal Research

Ethical animal research follows the **Three R's** principle, first articulated by Russell and Burch (1959), which aims to balance scientific necessity with animal welfare:

Replacement – Use non-animal alternatives whenever possible, or substitute higher species with lower, less sentient ones (e.g., computer modeling or cell culture).

Reduction – Use the smallest number of animals necessary to achieve valid results and statistical significance.

Refinement – Improve techniques to minimize pain, distress, and discomfort (e.g., anesthesia, enriched environments, and humane endpoints).

Researchers are required to demonstrate that they have considered alternatives and applied the Three R's before seeking IACUC approval.

14.6. Good Research Practices

High ethical standards in animal research depend on active collaboration between investigators and oversight bodies.

Researchers should:

- Follow IACUC-approved protocols exactly.
- Obtain IACUC approval for any **amendments or procedural changes**.
- Conduct regular **self-audits** for compliance.
- Maintain **accurate data** on animal use, care, and outcomes; and
- Establish clear procedures for **data collection, storage, and transfer**.

Such practices ensure reproducibility, transparency, and adherence to federal guidelines.

14.7. Summary

Ethical animal research balances the pursuit of scientific discovery with the humane treatment of animals. Oversight by the **IACUC**, regulatory guidance from **NIH (OLAW)** and **USDA (APHIS)**, and adherence to the Three R's—Replacement, Reduction, and Refinement—form the foundation of responsible animal research. These measures protect animal welfare, enhance scientific quality, and uphold the ethical integrity of the research enterprise.

14.8. Practice Questions

1. Which two agencies lead oversight of laboratory animal welfare regulations?
 - a. USDA, NIH
 - b. USDA, GSA
 - c. NIH, GSA
 - d. NIH, NSF

2. After the passage of the Laboratory Animal Welfare Act of 1966, which agency was tasked with writing the corresponding regulations?
 - a. The National Institutes of Health Office of Laboratory Animal Welfare (NIH OLAW)
 - b. NIH, in collaboration with People for the Ethical Treatment of Animals (PETA)
 - c. The USDA Animal and Plant Health Inspection Service (USDA APHIS)
 - d. General Services Administration (GSA)

3. Which animals were NOT included in the 1966 Laboratory Animal Welfare Act?
 - a. Mice
 - b. Rabbits
 - c. Cats
 - d. Dogs

4. In the context of animal research, IACUC stands for:
 - a. Institutional Animal Care and Use Committee
 - b. Institutional Animal Cancer Unit Care
 - c. International Association for the Care and Use of Animals
 - d. International Association for the Condemnation of Unscrupulous Caging of Animals

5. Which statement best describes the relationship between the 1966 Animal Welfare Act (AWA) and Institutional Animal Care and Use Committees (IACUCs)?
 - a. The 1966 AWA created IACUCs and mandated their review of all animal research
 - b. The 1966 AWA regulated certain animals in research, but IACUC requirements were added later through amendments and federal policy

- c. The 1966 AWA required IACUCs only for studies involving dogs and cats
 - d. The 1966 AWA required IACUCs only in privately funded research institutions
6. According to the Animal Welfare Act, IACUC must review the animal facility program and animal facilities at least every _____ months.
- a. 1
 - b. 3
 - c. 6
 - d. 12
7. Any IACUC must have all the following members EXCEPT:
- a. A Doctor of Veterinary Medicine
 - b. A scientist practicing research with animals
 - c. A public member
 - d. A representative from the central research office
8. Which of the following is NOT a mandatory function of IACUC, per the Animal Welfare Act?
- a. Review of new animal research protocols
 - b. Review of amendments for animal research protocol
 - c. Review of the animal facility, every month
 - d. Review of ongoing projects, every 3 years
9. Which of the following must be included in animal research protocols submitted to the IACUC?
- a. The rationale for using animals
 - b. The species and the approximate number of animals to be used
 - c. A description of methods used to minimize pain in animals
 - d. All of the above
10. Which of the following led to the establishment of the NIH OLAW?
- a. The Laboratory Animal Welfare Act (1966)
 - b. Animal Welfare Act Amendments (1970)
 - c. Animal Welfare Act Amendments (1985)
 - d. Federal Health Research Extension Act (1985)

11. OLAW regulations apply to:
- a. Non-human primates, dogs, cats, rabbits
 - b. Non-human primates, dogs, cats, rabbits, hamsters, and guinea pigs
 - c. Non-human primates, dogs, cats, rabbits, hamsters, guinea pigs, and birds of prey
 - d. All vertebrate animals
12. OLAW approval of the university assurance statements is needed for:
- a. Public Health Service-funded animal research
 - b. Public Health Service-funded vertebrate animal research
 - c. All government-funded vertebrate animal research
 - d. All vertebrate animal research
13. OLAW approval of university assurances must be renewed no later than every ____ years.
- a. 2
 - b. 3
 - c. 5
 - d. 10
14. Which of the following is NOT one of the 3R principles used in humane treatment of experimental animals?
- a. Replacement
 - b. Restitution
 - c. Reduction
 - d. Refinement
15. A researcher decided to use rats for his research. A colleague informs him that high-fidelity computer simulations will give him comparable results. So, he decides to use computer simulations in lieu of rats. This is an example of:
- a. Replacement
 - b. Reduction
 - c. Refinement
 - d. Relevancy

16. In animal research, “modifications of husbandry or experimental procedures that minimize or eliminate animals’ pain and distress” is the definition for:
- Replacement
 - Reduction
 - Refinement
 - Retrenchment
17. Statistical sample size calculations show that a certain study needs to use 50 mice. However, the principal investigator decided to use 200 mice for that study. This goes against which principle?
- Replacement
 - Reduction
 - Refinement
 - Retribution
18. Which of the following is covered under OLAW rules?
- Fruit flies (*Drosophila*)
 - Roundworms (*C. elegans*)
 - Octopus
 - Zebrafish
19. The Life magazine exposé, “Concentration Camps for Dogs,” proximally led to the:
- The 1966 Animal Welfare Act (AWA)
 - The 1985 Amendments to the AWA
 - The formation of the IACUC
 - The three R’s principle, articulated by Russell and Burch
20. Which of the following practices for promoting laboratory animals’ psychological well-being became required only after the 1985 amendments to the Animal Welfare Act?
- Providing environmental enrichment for primates (e.g., toys, foraging devices, social housing)
 - Recording animal numbers in annual USDA reports
 - Using aseptic technique during survival surgeries
 - Maintaining temperature and humidity within approved ranges

14.9. Answers to Practice Questions

1. **A** **USDA and NIH** lead oversight of laboratory animal welfare regulations. USDA enforces the Animal Welfare Act through APHIS inspections, while NIH—via the Office of Laboratory Animal Welfare (OLAW)—ensures compliance for Public Health Service–funded research. Together, they safeguard humane treatment of animals in federally supported labs.
2. **C** After the 1966 Act, APHIS within USDA established standards for animal housing, care, and recordkeeping. NIH OLAW oversees policy compliance but does not write or enforce these laws.
3. **A** The Animal Welfare Act (AWA) initially covered dogs, cats, primates, guinea pigs, hamsters, and rabbits. Mice, rats, and birds used in research were excluded by regulation, though widely used in labs.
4. **A**
5. **B** The original 1966 AWA focused on the care, handling, and transport of certain animals in research, but did not establish IACUCs. The requirement for IACUC oversight came later, particularly through the 1985 AWA amendments and the Public Health Service (PHS) Policy.
6. **C** Semiannual reviews ensure humane practices, compliance, and updated oversight. Monthly or yearly reviews are not federally mandated.
7. **D** Mandatory members are a veterinarian, a scientist, and a public member unaffiliated with the institution. Like Institutional Review Boards (IRBs) for human subjects research, IACUCs, for animal use and research, mandate this diversity of expertise and affiliations to ensure that reviews are done professionally and fairly.
8. **C** IACUC must review new and ongoing protocols every 3 years and inspect facilities semiannually—but not monthly.
9. **D**

10. D The Health Research Extension Act (HREA) expanded animal research oversight, creating a formal assurance system under Public Health Service (PHS) and assigning NIH OLAW to monitor compliance.
11. D Unlike the USDA Act's narrower scope, OLAW covers all live vertebrates in PHS-supported research—mammals, birds, fish, amphibians, and reptiles.
12. B OLAW is for PHS-funded research and applies only to vertebrate animals.
13. C
14. B Refine, Reduce, and Replace are the three principles.
15. A The researcher “replaces” the use of rats with computer simulations.
16. C
17. B If a study can be done with 50 mice, there is no reason to include 200. This is against “reduction” in the number of animals used for research.
18. D Among the choices, only Zebrafish are vertebrates.
19. A The expose was published in 1965, which led to public outcry. Then, in response, Congress enacted the AWA in 1966. IACUC was mandated almost two decades later. The Three R's were proposed in 1959.
20. A The 1985 AWA amendments required research institutions to establish programs to promote the psychological well-being of nonhuman primates, including enrichment, social opportunities, and species-appropriate activities—practices not mandated before 1985.