

	Universidad Central del Caribe Standard Operating Practice (SOP)	SOP#	
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		Approval by CEO	
Institutional Animal Care and Use Committee			

I- Purpose

The purpose of this policy is to describe the mission, scope, authority, and components of the Animal Care and Use Program (ACUP or Program) for all vertebrate animals used in research, testing, and teaching at the Universidad Central del Caribe (UCC), irrespective of funding source.

II. Mission Statement

The mission of the Institutional Animal Care and Use Committee (IACUC) is to promote the proper care and use of vertebrate animals in activities conducted on behalf of the university by adhering to the Guide for the Care and Use of Laboratory Animals; Animal Welfare Act; Guide for the Care and Use of Agricultural Animals in Research and Teaching; and other applicable regulations.

III. Scope of the Animal Care and Use Program

The ACUP is defined as the research, testing, and teaching activities conducted by and at the Institution that have a direct impact on the well-being of animals, including animal and veterinary care, policies and procedures, personnel and program management and oversight, occupational health and safety, Institutional Animal Care and Use Committee (IACUC) functions, and animal facility design and management.

IV. Program Management Responsibility and Authority

Effective leadership in and collaboration among the three federally mandated components (Institutional Official (IO), Attending Veterinarian (AV), and the IACUC) are necessary. A Program that establishes a balance among these has the best chance of efficiently using resources while attaining the highest standards of animal well-being and scientific quality. Communication of activities between these components as well as other support units in the ACUP is necessary to ensure efficient ACUP operation. The following outlines the roles, authorities, and responsibilities of each component at the UCC.

A. Institutional Official (IO)

The IO for the animal care and use program of the University is the President of Universidad Central del Caribe. The IO bears the ultimate responsibility for the Program, although overall Program direction should be a shared responsibility among the IO, AV, and IACUC. The IO has the responsibility and authority for:

- Resource planning and ensuring alignment of Program goals of quality animal care and use with the institution's mission.
- Communicating the importance of animal welfare across the UCC.
- Assuming the obligations of the Assurance for the Animal Care and Use Program on behalf of the UCC.
- Supporting implementation of Program decisions and taking administrative actions to facilitate compliance.
- Allocating and distributing resources as necessary to ensure the Program's overall effectiveness.
- Appointing individuals to the IACUC and ensuring that these individuals are protected from coercion or undue influence while serving in this capacity.
- Appointing a Chair to provide leadership to the IACUC.
- Ensuring the Attending Veterinarian has the proper authority and resources to meet his/her responsibilities to the ACUP.
- Serving as a point of contact for OLAW, USDA (if applicable), and other federal agencies sponsoring and overseeing animal use and providing required ACUP reports to these agencies.
- Communicating with and advising other senior administrative officials on ACUP issues as necessary.

B. Institutional Animal Care and Use Committee

An Institutional Animal Care and Use Committee (IACUC) is required by federal regulations for most institutions that use animals in research, teaching, and testing. The IACUC has the responsibility for the assessment and oversight of the Institution's Program components and facilities. The IACUC is comprised of at least 5 members that meet specific criteria described in federal regulations, including an individual with scientific experience, a veterinarian with designated program responsibilities, a non-scientist, and a non-affiliated individual representing community interests. To fulfill its oversight responsibilities, the IACUC has the responsibility and authority to:

- Understand the laws, regulations, guidelines, and standards, as a basis for what the IACUC does.
- Review and approve, require modifications to secure approval, or disapprove proposed animal use (protocol review) and significant changes to animal use.
- Conduct regular inspections of facilities and animal use areas.
- Review the overall Program and assess animal care and use.

- Establish a mechanism for receipt and review of concerns involving the care and use of animals at the Institution.
- Evaluate ethical merit as it relates to the welfare and use of the animals.
- Suspend or terminate approval of activities not being conducted in accordance with the IACUC's requirements or that have been associated with unexpected serious harm to animals.
- Establish protocol and amendment review processes as described by federal regulations and guidance.
- Develop policies for the use of animals at the UCC.
- Solicit input from stakeholders in the ACUP regarding ACUP operations.
- Make written recommendations to the IO regarding any aspect of the Program.
- Ensure that an occupational health and safety program is in place for individuals working with or regularly exposed to animals.
- Verify that IACUC activities are compliant with regulatory requirements and UCC policies (records retention and disposal).

Note: Proposals approved by the IACUC may be subject to further appropriate review and approval by officials of the Institution. However, no officials of the institution may approve animal subjects use (i.e., authorize it to proceed) that has not been approved by the IACUC. The IACUC's decision-making must be independent from coercion or undue influence.

1- Responsibilities

The IACUC is responsible for oversight of the animal care and use program and its components as described in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)) and the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)). Its oversight functions include an ongoing assessment of animal care and use. IACUC responsibilities include:

- Review, at least semiannually, the institution's program for the humane care and use of animals;
- Inspect, at least semiannually, the institution's animal facilities (including satellite facilities);
- Prepare reports to the Institutional Official (IO) of IACUC evaluations;
- Review animal welfare concerns;
- Make recommendations to the IO on any aspect of the animal program, facilities, or personnel training;
- Review and approve those components of PHS conducted or supported activities related to the care and use of animals;
- Review and approve proposed significant changes to the use of animals in ongoing activities; and
- Be authorized to suspend an activity involving animals.

2- Membership

The IACUC membership must consist of at least 5 members and includes:

- one veterinarian with training or experience in laboratory animal science and medicine, who has direct or delegated authority and responsibility for activities involving animals at the institution;
- one practicing scientist experienced in research with animals; one member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy); and one member who is not affiliated with the institution other than as a member of the IACUC.

3- Semiannual Program Reviews and Facility Inspections

The IACUC monitors the animal care and use program by conducting thorough reviews of the program and inspections of the animal facilities. All PHS funded programs must conduct program reviews and facility inspections at least every 6 months. The standards in the *Guide* are used by the IACUC as the basis for conducting its reviews.

Facility reviews are a physical inspection of all buildings, rooms, areas, enclosures and vehicles (including satellite facilities in which animals are housed for more than 24 hours) that are used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. No member wishing to participate in an evaluation may be excluded from participating. The [Animal Welfare Act and Regulations](#) (AWAR) require animal study areas where regulated species are maintained for more than 12 hours to be included in the semiannual facility inspections.

A [Sample Semiannual Program and Facility Review Checklist](#) is available to assist IACUC's in performing this task. OLAW encourages institutions to use or modify the document to suit the institution's needs.

Inspections Dates: March and September

Ordinary Meeting Dates: March and September

4- Semiannual Report to the Institutional Official

After review and inspection, a written report (including any minority views) is compiled and provided to the IO about the status of the program including any recommendations. The report will include a description of the nature and extent of the Institution's adherence to the *Guide*, any departures from the *Guide*, identified specifically with reasons for each departure stated. The report will note any program or facility deficiencies, distinguish significant deficiencies from minor deficiencies, and include plans and schedules for correcting each deficiency. A significant deficiency is defined as one that is or may be a threat to animal health or safety.

A [sample semiannual report to the IO](#) is available to assist IACUCs in preparing this report.

Please note that semiannual reports to the IO should only be submitted to OLAW if requested, or if the institution is submitting a new or renewal Animal Welfare Assurance to OLAW. However, if serious or continuing deviations from PHS Policy are identified, they should be reported to OLAW promptly. The next section - [Reports and Recordkeeping](#) - describes PHS Policy reporting requirements in greater detail.

5- Protocol Review

The IACUC oversees the specific use of animals by formally reviewing animal use protocols and granting approval prior to the work commencing. The valid methods of protocol review are full committee (FCR) review and not by the use of alternate members. ([PHS Policy IV.C.2.](#))

FCR may only be conducted at a convened meeting with a quorum (simple majority) of members present. A majority vote of the quorum present is needed to approve, require modifications in (to secure approval), or withhold approval of a protocol. When substantive modifications are required in a protocol to secure approval, the resubmitted protocol must be reviewed.

IACUC approval of proposed animal activities or significant changes to previously approved animal activities is granted after FCR. Additionally, institutions may establish and IACUCs may approve policies (e.g., guidance documents, standard operating procedures, drug formularies) for the conduct of animal activities. These policies must be reviewed by the IACUC at appropriate intervals of no less than once every 3 years to ensure they are appropriate and accurate.

The responsibilities of the IACUC regarding review and approval of proposed significant changes to animal activities can be found in PHS Policy [IV.C.1](#). The IACUC has some discretion to define what it considers a significant change, or to establish a mechanism for determining significant changes on a case-by-case basis according to PHS Policy [IV.C.1.a-g](#). It is the IACUC's responsibility to clearly define and communicate its policy for determining significance to investigators. To learn more about what is considered a significant change to an animal activity that requires IACUC review, see NIH Guide Notice [NOT-OD-14-126](#) or [Significant Changes](#) webpage. These changes include:

- ▶ Increasing pain, distress, or invasiveness
- ▶ Animal housing/location that is not overseen by the IACUC
- ▶ Species
- ▶ Study objectives
- ▶ Principal investigator
- ▶ Impacts personnel safety

It is the PHS Policy that no IACUC member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC. Neither recused nor excluded members may contribute to the quorum necessary to conduct IACUC business. (*Lab Animal* 2010: 39(6))

The PHS Policy endorses the “U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training” ([U.S. Government Principles](#)). The IACUC is expected to include consideration of the U.S. Government Principles in its review of protocols. Protocols must conform to the institution's Assurance and meet PHS Policy requirements in section [IV.C.1.a-g](#).

The *Guide* (pp. 25-26) describes specific topic areas that should be considered in the preparation of a protocol by the PI and in the review by the IACUC.

The *Guide* (pp. 27-33) describes certain protocols that include procedures or approaches that require special consideration during the IACUC review process due to the potential for animal welfare concerns.

6- Post-approval Monitoring

Monitoring of animal care and use is required by the PHS Policy. The *Guide* (p. 33) describes methods for continuing review to include “continuing protocol review; laboratory inspections (conducted either during regular facilities inspections or separately); veterinary or IACUC observation of selected procedures; observation of animals by animal care, veterinary, and IACUC staff and members; and external regulatory inspections and assessments.”

Continuing protocol review may consist of an annual update. “Some institutions use the annual review as an opportunity for the investigator to submit proposed amendments for future procedures, to provide a description of any adverse or unanticipated events, and to provide updates on work progress.” (*Guide*, p. 34) The PHS Policy determines the maximum interval between IACUC review and approval as 3 years, i.e., a complete *de novo* review is required at least every 3 years. The review must encompass all of the criteria in the Policy at [IV.C.1.a-g](#). Animal work may not be administratively extended beyond the 3-year expiration date.

7- Addressing Animal Welfare Concerns

“The institution must develop methods for reporting and investigating animal welfare concerns, and employees should be aware of the importance of and mechanisms for reporting animal welfare concerns.” (*Guide*, p. 23).

The IACUC has a mandate to evaluate concerns regarding the care and use of animals. Concerns may be raised by staff or employees of the institution, individuals in the community, or even members of the IACUC. It is a good idea for the IACUC to develop guidelines or procedures for handling allegations of mistreatment or noncompliance

before such allegations are raised. The IACUC should also be cognizant of the rights of whistleblowers under the Animal Welfare Act (AWA), which prohibits discrimination against or reprisal for reporting violations of regulations or standards under the AWA.

8- Suspension of Animal Activities

The IACUC is empowered to suspend a project if it finds noncompliance with the PHS Policy, *Guide*, Assurance, or violations of the Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and with the suspension vote of a majority of the quorum present. Further, the IACUC must consult with the IO regarding the reasons for the suspension. The IO is required to take appropriate corrective action and report the action and the circumstances surrounding the suspension to OLAW. Because an IACUC action to suspend a project is a serious matter, the action must be reported to OLAW promptly. Additional information can be found on the [Reporting Noncompliance](#) webpage.

9- Reports and Recordkeeping

a- Annual Reports to OLAW

Each year, institutions submit a report to OLAW that includes:

- [changes in the institution's program of animal care and use or facilities](#) (PHS Policy [IV.A.1.a.-i.](#))
- changes in the Institutional Official (IO)
- changes in the Institutional Animal Care and Use Committee (IACUC) membership
- dates that the IACUC conducted its semiannual evaluations of the program and facilities
- minority views filed by members of the IACUC
- changes in the institution's accreditation status

The reporting period is the calendar year (January 1 - December 31) and the annual reports are due the end of the following month of January.

Additional information on the annual reporting requirement and a sample document can be found on the [Annual Report to OLAW](#) webpage.

Annual reports should be signed by the IO and the IACUC Chairperson and e-mailed to olawarp@mail.nih.gov.

b- Reporting Noncompliance, Guide Deviations, and Suspensions

Circumstances that must be reported to OLAW by the IO, without delay, are:

- serious or continuing noncompliance with the [PHS Policy](#);
- serious deviations from the [Guide for the Care and Use of Laboratory Animals](#); and
- IACUC suspensions.

NIH Guide Notice [NOT-OD-05-034](#) provides examples of reportable situations, situations that don't normally need to be reported, plus guidance on when and what to report.

In some cases, it may be necessary to submit a preliminary report until an investigation and corrective plan have been completed. Preliminary reports can be made by calling the Division of Compliance Oversight at 301-594-2061 or by fax to 301-480-3387 or e-mail to olawdco@mail.nih.gov.

A final report should include a detailed explanation of the situation and actions taken. Final reports must be signed by the IO and sent to the Division of Compliance Oversight by fax to 301-480-3387 or by e-mail in PDF format to olawdco@mail.nih.gov.

OLAW guidance on reporting can be on the [Reporting Noncompliance](#) webpage and under the [Topic Index](#). 301-480-3387 or by e-mail in PDF format to olawdco@mail.nih.gov.

OLAW guidance on reporting can be on the [Reporting Noncompliance](#) webpage and under the [Topic Index](#).

c- Maintaining IACUC Records

The institution is responsible for maintaining these records:

- Assurance approved by OLAW;
- minutes of IACUC meetings;
- records of IACUC attendance, activities, and deliberations;
- documentation of protocols reviewed by the IACUC and proposed significant changes to protocols, and whether approval was given or withheld;
- report of semiannual IACUC evaluations and recommendations to the IO, including minority views; and
- Accrediting body determinations.

All records are to be kept for a minimum of 3 years, with the exception of records that relate directly to protocols which must be kept for the duration of the activity and for an additional 3 years after completion of the activity.

Records documenting such activities as the provision of adequate veterinary care, training, and occupational safety, are expected to conform to the recommendations of the *Guide* and to commonly accepted professional standards.

C. Attending Veterinarian

The Attending Veterinarian (AV) is responsible for the health and well-being of all laboratory animals used at the institution. The AV is supported by additional veterinarians with expertise in the species being used and has the responsibility and authority for:

- Managing the program of veterinary care, environmental enrichment, and zoonotic disease prevention.
- Overseeing other aspects of animal care and use such as husbandry and housing to ensure that the Animal Resources Center (ARC) complies with the regulations.
- Providing guidance and oversight to surgery programs and perioperative care and assisting the IACUC in determining that personnel performing surgical procedures are appropriately qualified and trained.
- Staying abreast of current regulatory requirements as it relates to the ARC at the UCC.
- Serving as the point of authority on regulatory interpretation for veterinary and animal husbandry regulations, and animal facility inspections for external agencies including the USDA (if applicable).
- Communicating program issues, including facility problems, regulatory updates, and ARC trends to the IACUC and the IO.
- Developing and implementing training for institutional staff in the care and use of animals at the UCC.
- Assisting institutional health officials to establish and monitor an occupational health program, including biohazard control policies/procedures for ARC activities and personnel.
- Providing veterinary consultation during protocol development for procedures that may cause more than momentary or slight pain or distress to animals. Helping to ensure animals are not used for multiple major surgeries without IACUC approval.

Note: The Attending Veterinarian is *delegated program authority and responsibility for the Institution's animal care and use program including access to all animals.*

V. Principal Investigator Responsibilities

Investigators who utilize animals in their research or teaching, have the following responsibilities:

- Obtain IACUC approval prior to conducting animal use activities.
- Ensure that personnel involved in animal use are listed on the applicable IACUC protocol prior to initiating work with animals.
- Ensure that all personnel in their laboratory are trained in and familiar with the conduct of activities as described in the IACUC protocol.
- Promote proper animal care and handling of animals in their studies.

VI. Additional Components Supporting the Animal Resources Center

A. Office of the Dean of Research and Graduate School

The Office of the **Dean of Research and Graduate School (ODRGS)** provides oversight for all animal research, teaching, and testing conducted at the UCC. The ODRGS Associate Dean has responsibility for the development of overall research policies and operating procedures and for providing advice and assistance to University research administrators in the development of research programs within the University under the Bylaws.

1-Office of Responsible Research Practices

Responsible Research Practices	ODRGS	IACUC	ARC
Verifying that the principal investigator proposing the project is eligible to serve in the capacity of principal investigator and that all compliance-related requirements (e.g., COI disclosure) have been met.	✓		
Recommending full committee review of protocols to the IACUC Chair		✓	
Providing administrative support to the IACUC by keeping investigators and others informed of IACUC decisions and performing all other IACUC-related recordkeeping and administrative processing.			✓
Gathering and maintaining information related to exceptions to the Guide and AWA for inclusion in regulatory reports and advising IACUC on best practices related to regulatory requirements for IACUC administrative functions.			✓
Verifying the number of animals approved and used on IACUC approved protocols is accurate and providing this information in regulatory reports.			✓
Notifying investigators of expired/terminated/suspended protocols and facilitating transfer of animals to another approved protocol.		✓	
Facilitating post-approval monitoring, USDA inspections (if applicable), and site visits.			✓
Assisting in the IACUC's investigation of ARC findings or concerns.	✓	✓	✓
Preparing regulatory reports and agency notifications (e.g., noncompliance) per IACUC direction to appropriate institutional officials, OLAW, and other federal agencies as required.		✓	
Maintaining IACUC records per the university's "Records Retention Schedule" and arranging for inspection or provision of records as legally required.		✓	

Providing administrative support to the Institutional Biosafety Committee (IBC), which is an ancillary component of the ARC.		✓	✓
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2- Office of Research Compliance

The Office of Research Compliance supports and promotes ethical research practices at the UCC and manages the financial conflict of interest program. The ORC serves the UCC research community by coordinating institution-wide research compliance policy development and by partnering with researchers so that the university is compliant with federal, state, and local laws and regulations and university policies.

B. Dedicated ARC Housing Facilities

Dedicated animal housing facilities support the ARC by providing resources to facilitate teaching and biomedical research. These facilities have the following responsibilities:

- Managing the daily care of animals and operating the university’s animal housing facilities in compliance with regulatory requirements.
- Notifying the IACUC if facility conditions fall outside the regulatory requirements and animal health may be impacted.
- Notifying the AV staff when veterinary care is needed.
- Providing enrichment and social housing to all animals unless exempted by the IACUC.
- Ensuring that husbandry personnel comply with the requirements for protocol personnel in terms of training requirements and Occupational Risk Assessments.
- Ensure an Emergency Plan +/- Disaster Contingency Plan is in place and responsible personnel are familiar with the plan.
- Assessing the performance of environmental monitoring systems, if present, on a regular basis to ensure functionality.

C. Occupational Health and Safety Program (OHSP)

The OHSP program is jointly administered by the Human Resources Office, and Student Health Services.

OHSP is responsible for:

- Evaluation of the occupational risk for animal users as needed.
- Conducting Hazard Assessment reviews for all Principal Investigator’s using hazardous agents as part of an IACUC protocol.
- Developing hazard information forms to be posted at the lab, housing, or procedure space for the duration of the hazard.
- Assisting in the maintenance of the IACUC Occupational Health & Safety online training module as part of the animal care and use training.

The Human Resources Office is responsible for:

- Evaluation of employees whose exposure or history presents a potential occupational risk.
- Providing information on zoonotic diseases to which employees may be exposed.
- Providing ongoing care and assessments to personnel according to the "Animal Care Handler Medical SOP."

Student Health Services is responsible for:

- Evaluation of students whose exposure or history presents a potential risk and who are involved in the ARC in animal care or animal research/teaching in an unpaid position.
- Providing information on zoonotic diseases to which students may be exposed.

D. Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) is charged with ensuring that all Universidad Central del Caribe research involving recombinant DNA, regardless of funding source, is registered with the IBC and conducted in accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. The IBC is further charged with reviewing and approving research conducted with microorganisms pathogenic to humans, plants, or animals. This review is conducted pursuant to the Centers for Disease Control and Prevention/NIH publication, Biosafety in Microbiological and Biomedical Laboratories. The IBC supports the ARC by:

- Categorizing biohazard use according to CDC classifications.
- Reviewing institutional risk associated with the proposed hazardous work.
- Ensuring that appropriate animal care and use precautions are identified and communicated to investigators and the IACUC.
- Reviewing work using bio-hazardous materials in animals or genetically engineered animals prior to IACUC approval.
- Providing guidance to the UCC research community regarding proper acquisition, handling, transfer, and disposal of potentially hazardous or regulated biological materials.

E. The Radiation Safety Committee and the Radiation Safety Officer

The Radiation Safety Committee and the Radiation Safety Officer have the following responsibilities:

- Oversight of radiation generating devices (including x-rays, nuclear medicine studies, DEXA scans, CT scans).
- Oversight of and ensuring compliance with the radiation safety program.

- Establishment of university policies consistent with U.S.A. and P.R. Department of Health and federal regulations.
- Reviewing work using radioactive materials in animals prior to IACUC approval.
- Ensuring that the appropriate use of precautions is identified and communicated to investigators and the IACUC.

F. Legal Affairs

The Office of Legal Affairs can provide advice to the IACUC, the Office of Responsible Research Practices, AV, IO, and other components of the ARC, as necessary, primarily in matters related to state laws, cooperation agreements, non-compliance, conflicts of interest, and contractual issues in animal research.

G. Quality Improvement Program

The quality improvement activities include education, investigator outreach, and post approval monitoring. All components of the Animal Care and Use Program have a responsibility to ensure a quality program. Areas for improvement may be identified during the semi-annual program review and inspection, through performance problems identified by the AV or animal care staff, or as a result of specific quality improvement activities conducted by the ORRP staff. Data obtained from monitoring and compliance activities are used by the IACUC to revise existing guidance, make recommendations to the IO, and direct future educational efforts.

VIII. Compliance with Applicable Regulations

To affirm that the Animal Care and Use Program is committed to responsible animal care and use and is in compliance with applicable federal regulations and state laws, as well as institutional and academic best practices, the UCC maintains submission of its ACUP through Animal Welfare Assurance renewal every five years.

IX- Regulations and Guidance

Animal Welfare Assurance

- [Animal Welfare Assurance \(#D16-00343\)](#)

Federal Regulations

- [AVMA Guidelines for the Euthanasia of Animals: 2013 Edition](#)
- [Guidelines for the Euthanasia of Mouse and Rat Fetuses and Neonates](#)
- [Guide for the Care and Use of Agricultural Animals in Research and Teaching](#)
- [Guide for the Care and Use of Laboratory Animals: Eight Edition](#)

- [PHS Policy on Humane Care and Use of Laboratory Animals](#)
- [USDA Animal Welfare Act and Regulations](#)
- [USDA Animal Welfare Inspection Guide](#)
- <https://olaw.nih.gov/resources/tutorial/reports-records.htm>
- <http://orpr.osu.edu/files/2013/10/Animal-Care-and-Use-Program-02.pdf>

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