



INTERNATIONAL CONSORTIUM *for*
INNOVATION & QUALITY
in PHARMACEUTICAL DEVELOPMENT

Members of the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ Consortium, www.iqconsortium.org) have jointly developed the enclosed Assessment Tool with input from CRO partners.

This comprehensive questionnaire can be used in performing either a "paper-based electronic assessment" or an "onsite assessment" of a partner research organization's animal care and use program. The questionnaire may be used in its entirety or limited to select questions that are relevant to the member company's specific interests. Each section covers detailed questions that the assessor can utilize in the review of the outsourced research program of animal care and use. It is intended that the answers are provided by the contract laboratory and then affirmed by the assessor through either direct or indirect review of the institutions program of animal care and use. To make this assessment tool more user-friendly and efficient, many questions require a yes/no response. When necessary, additional evidence may be gathered by the assessors to ensure that the outsourced research program meets the requirements in question.

The following materials were prepared by the IQ Consortium for use by its members. Use of the form is voluntary and is not a requirement for IQ membership. IQ does not evaluate completed forms or provide assistance with their completion. Evaluation of responses and selection of vendors is at the discretion of the individual company.

Please use Adobe Acrobat X Pro for best results

Animal Care & Use Program Assessment Tool for Contract Research Organizations

General Information Institutional Overview (If you share a current copy of your AAALAC Program Description, some Sponsors may not require completion of the questionnaire.):

1. Briefly describe the organization and include the following:

- 1) How long have you been operating in the locations where animal research is conducted?
 - 2) A brief overview of your reporting structure?
 - 3) The size and type of facility?
 - 4) The type of rooms?
 - 5) The technical/scientific studies commonly conducted with emphasis on specialties (e.g. safety assessment, PK/PD, efficacy studies with specific expertise)?
 - 6) Is there an Internal Quality Assurance Unit for GLP Studies ? Yes No

Institutional Accreditation and Regulatory Status

1) Is the Institution accredited by AAALAC International? Yes No

If no, is accreditation a near term goal?

ANSWER The answer is 1000.

If yes, what was the date of your last site visit and what was the outcome?

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Please describe any suggestions for improvement or mandatory findings and plans for resolution. If possible, please share relevant AAALAC documentation or make it available for review at the time of an on-site audit.

2) Is the institution accredited by CCAC, if applicable? Yes No N/A

If applicable and not accredited, is accreditation a near term goal?

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If yes, what was the date of your last site visit and what was the outcome?

Please describe any suggestions for improvement or mandatory findings and plans for resolution. (If possible, please share relevant CCAC documentation or make it available for review at the time of an on-site audit.)

3) Does the institution have a USDA or National Regulatory equivalent registration? Yes No

Please indicate the type of registration. When did the national regulatory authority last inspect the institution? Please describe any citations or major deficiencies described within the last 3 years.

4) Does the institution have a PHS Assurance? Yes No N/A

5) Is the institution licensed with a local/registered animal welfare regulatory agency (e.g. state, city, or equivalent regulatory agency) if applicable?

Yes No N/A

6) Please list any other regulatory agencies that have inspected your animal care and use program within the last 5 years (e.g. FDA). Please list any recommendations from the other inspections that are related to animal welfare.

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Veterinary Care (check all that apply)

1) A veterinarian with appropriate training and/or experience is available 24/7/365(Attending Veterinarian or equivalent role)?

a) Please provide the name, credentials/board certifications and training of your Attending/Head Veterinarian.

2) A veterinarian has access to all animals and their medical records at all times.

3) A veterinarian is consulted during planning when a project requires administration of anesthetics, analgesics, and/or sedatives, or when a project involves surgical procedures (when procedures or outcomes may involve pain and/or distress or require sedation).

4) A veterinarian is involved in setting and/or approving humane endpoints.

5) A veterinarian is contacted following unexpected experimental outcomes that impact animal welfare.

6) A veterinarian has the ultimate authority to euthanize an animal when, in their professional judgment, it is in the best interest of the animal, including GLP studies.

7) A veterinarian is involved in the design and implementation of a program of veterinary care. **NOTE -** This includes having appropriate facilities, equipment, personnel and services, ability to prevent, control and diagnose diseases and injuries; daily observations of animals; timely communication of health and well-being concerns to the veterinarian; and provides guidance to investigators on the care of animals.

Health surveillance and preventative medicine program (check all that apply)

RODENTS:

1) There is a rodent sentinel monitoring program (e.g. sentinel program). If so, briefly describe.

2) There is a quarantine and /or acclimation process. If so, briefly describe.

3) Abnormal health surveillance results are reported to clients. If so, briefly describe.

4) State historical positives for certain common agents (e.g. pinworms, rodent viruses, etc.). If so, briefly describe what agents were tested positive, and what was the resolution.

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OTHER SPECIES:

- 1) There are quarantine, acclimation, health screening tests and preventative measures for other species. If so, briefly describe.

IACUC or Equivalent Ethical Review Body Questions (check all that apply)

1. The institution has an IACUC or equivalent Ethical Review Body (ERB) that meets the following criteria.

 - a) IACUC/ERB membership (research scientists, veterinarians and non-science members) is established according to relevant regulations and guidelines.
 - b) Has an actively engaged lay, community or non-affiliated member.
 - c) All members are trained to perform their IACUC or ERB functions on a routine basis and have supporting documentation.
 - d) Reviews and approves animal care and use protocols in a systematic manner that ensures oversight of all research activity using animals.
 - e) Has a defined Post-Approval Monitoring (PAM) program and PAM findings are shared with IACUC/ERB and have established resolution plans.
 - f) Significant adverse events are reported to IACUC/ERB by Attending Veterinarian/PI or other staff in a timely manner.
 - g) Performs comprehensive semiannual Program Review and inspects all animal facilities (or country specific program review) and submits all finding to the Institutional Official or equivalent.
 - h) How often does your IACUC/ERB meet?

ANSWER The answer is 1000.

Choosing appropriate endpoints in experiments (check all that apply)

- a) Guidelines for appropriate endpoints are established and implemented to ensure any actual pain, distress or suffering is minimized or alleviated.
 - b) Objective criteria (e.g. scoring, clinical) for observation are defined and utilized to assess animal's condition for endpoint determination.
 - 1) Staff is trained on these criteria and procedures for observations.
 - 2) Clinical endpoints criteria are documented in the clinical observation records. If so, briefly describe.

For more information about the study, please contact Dr. [REDACTED] at [REDACTED].

- c) The frequency of animal observations is sufficient for the level of painful procedure?
 - d) The IACUC/ERB provides appropriate oversight of endpoint determination (review, justification, monitoring, animals, euthanasia, and chain of custody?)

3Rs considerations (check all that apply)

- a) Animal studies designed and powered to utilize the appropriate number of animals to achieve statistical scientific results and control variability.
 - b) Animal studies are designed to avoid or minimize pain and distress.
 - c) Animal studies are designed to consider possible alternatives to animal use to accomplish or achieve scientific results.

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Euthanasia (check all that apply)

- a) Methods of euthanasia are consistent with AVMA Guidelines or local regulatory standards on euthanasia unless approved by the IACUC/ERB.

Please describe any methods that are used in exception to those guidelines/regulations and currently have IACUC approval.

- b) Appropriate training is provided to all staff performing euthanasia.

- c) Death is confirmed by cessation of vital signs and secondary methods (e.g. bilateral thoracotomy are used where appropriate.)

Investigating & Reporting Animal Welfare Concerns

- a) Is there a process for investigating and reporting animal welfare concerns? Yes No

- b) Are corrective actions documented and monitored? Yes No

Vendors and Animal Supplier Information (check all that apply) For suppliers of animals and animal-related materials (e.g. feed and bedding)

- a) A list of approved vendors is maintained.

- b) Vendors are qualified as acceptable.

- c) Suppliers are re-evaluated/reviewed following initial approval.

Environmental Controls

Sanitation (check all that apply)

- a) The methods and frequency of facility sanitation of animal rooms and support spaces adhere to recommendations in the Guide and to pertinent regulations.

- b) Monitoring of sanitation is done according to recommendations in the Guide or other pertinent documents.

Biosecurity Measures (check all that apply)

- a) Testing of biological materials for adventitious pathogens.

- b) Equipment and animal receipt decontamination procedures

- c) Animal separation with restricted personnel access based on animal health status

- d) Use of microisolator or ventilated caging.

- e) Use of biosafety cabinets.

Pest Control (check all that apply)

- a) Pest control program is administered and monitored by a licensed professional.

- b) Methods of pest control are consistent with recommendations in the Guide or other pertinent documents.

- c) Pest control records are maintained.

- d) There is a review and approval of the pest control strategy (e.g. veterinary staff and/or IACUC)

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Animal Housing, environment and physical plant

1) What species are housed and what is your colony average daily census?

Species Housed	Census

2) Briefly describe the primary enclosures per species

Species Housed	Enclosures

3) Briefly describe how the animal room environment is monitored. Please include a description of alarms and responses for any environmental parameters that go outside acceptable ranges.

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- 4) Briefly describe your program for socialization and enrichment of the various species.

Species	Socialization/Enrichment

- 5) Briefly describe building construction (corridors, floors, drainage, noise, vibration)

Water, Food and Bedding:

Water

- 1) How is water supplied to the animal facility?

- 2) Is the water that is provided to the animals treated? If yes, what is the treatment process? If no, what is the rationale for not treating the water?

- 3) Do you have an animal drinking water testing program? If so, briefly describe.

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Feed & Bedding:

1) From what source(s) is feed obtained?

2) Are certified laboratory diets or non-certified diets used?

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3) Is any additional analysis beyond that provided by the manufacturer conducted? If yes, briefly describe the program. (for food and bedding).

4) Is there a process for ensuring first in, first out of feed lots? Yes No

5) What type of bedding do you use for your rodents? Is it contact or non-contact bedding? Please describe actual bedding types. (corn cob, hardwood chip, etc.)

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Training & Personnel Qualifications, Record Keeping (Veterinary care/husbandry/training)

1) Is the scope and content of the training program clearly defined and documented? Yes No

2) Does the accountability for the training program reside at a governing level within the institution? If so, at what level; and with whom (role) does it reside. Yes No

3) Is there a Training Coordinator (or equivalent) to manage a program wide training program? Yes No

4) Please briefly describe the training program for technical staff, husbandry personnel and research staff (PI's, Study Directors) who have direct contact with animals or are responsible for the conduct of animal study work.

5) Is there a framework for continuing professional development/education that includes all personnel within the animal care and use program? Yes No

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6) The scope and content of the training program provides the trainee with ability to (**check all that apply**):

- a) Recognize the humane, ethical and scientific importance of the 3Rs.
- b) Recognize normal clinical condition and species-specific behavior.
- c) Identify signs or conditions that may be indicative of pain/distress or justification for unscheduled euthanasia.
- d) Respond to and alleviate pain/distress.
- e) Determine humane endpoints and euthanize animals in a competent and professional manner.
- f) Utilize literature searches and statistical analysis to reduce the number of animals used.
- g) Recognize normal and abnormal behaviors and how to implement effective enrichment strategies.
- h) Respond to or report inappropriate care or handling of an animal.

Occupational Health & Safety (OHS) of Personnel (check all that apply)

- 1) Has an established OHS program based on hazard identification and risk assessment.
- 2) The established OHS program includes the following criteria:
 - a) Program covers all personnel working in the animal facilities.
 - b) Program includes contract workers and external IACUC members.
 - c) Program is consistent with regulatory requirements.
 - d) Program includes medical evaluation, surveillance & preventative medicine.
 - e) OHS training program with documentation is in place for all personnel.
 - f) PPE required by area/function.
 - g) Procedures for use, storage & disposal of hazardous biologic, chemical and physical agents are in place.
 - h) Hearing protection is provided in noise areas.
 - i) Local medical support available.
 - j) Special precautions for personnel working with NHP's (TB screening, training, PPE, procedures for bites and scratches).
 - k) Procedure in place for reporting & handling injuries.

Security (check all that apply)

- a) Site perimeter is secure and limits public access to the grounds.
- b) Security guards or patrols are onsite (24 hours)
- c) Video surveillance exists at entry & exit points
- d) Security surveillance cameras are located within the vivarium.
- e) Policies exist prohibiting the use of cameras & cell phones in the animal areas.

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- f) Visitors to the facility are escorted at all times.
- g) Animal rooms and areas are controlled by restricted access.
- h) Employees and contractors are covered by Confidentiality Agreements.
- i) Client's information is secured and encrypted in the animal areas.
- j) Emergency disaster plans are in place.
- k) In the event of a disaster, business partners are informed.
- l) The disaster plan is periodically tested.
- m) There have been animal rights activists incidents, demonstrations, activities, or adverse publicity associated with your facility. If so, please describe.
- n) Thorough background checks are conducted on all job applicants (permanent, temporary, contractors) that will work in the vivarium to reduce activist risks. Please define parameters of the background check for animal activism.

Optional Questions (Applies to Vendors and CROs that transport research animals)

- 1) There is a selection and approval process for third party transportation companies.
- 2) We have internal vehicles.
- 3) Transportation operations (internal or third party) are evaluated against local and national regulations.
- 4) For vehicles (internal or third party) used in transport of research animals:
 - a) Internal cabins are cleaned and disinfected.
 - b) Temperatures and airflow are monitored and adjusted.
 - c) There are crisis and emergency procedures outlined.
 - d) Security procedures are in place to prevent intrusion or infiltration of shipments.
 - e) Crates and holding enclosures are constructed to ensure animal health and well-being.

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Potential program documents to review (some only requested during on-site visit):

- USDA or National Regulatory equivalent inspection reports- last 3 years
- AAALAC International or CCAC final letters of accreditation/Program description
- UDSA Annual Report
- PHS Assurance Document
- Local/Regulatory Agency Inspection reports- last 3 years
- Last 2 IACUC/ERB meeting minutes
- Last 2 Program Review/Semi Annual Inspections (or appropriate Program Review)
- Program of Veterinary Care (note: sites with full time veterinary staff are not required to have a written program of veterinary care).
- Animal health records/surgical/post-operative records
- Rodent sentinel serology reports for the past 6-12 months.
- IACUC/ERB Training Records
- Training program for animal care and research staff
- Sponsor's Reviewed and Approved Protocol's - if applicable.
- Subset of IACUC/ERB/Veterinary Guidelines and/or Policies.
 - IACUC/ERB SOP, Charter, or policy for anesthetics, analgesics, tranquilizers and paralytics.
 - IACUC/ERB SOP, Charter or policy to describe how the committee operates.
 - IACUC/ERB SOP, policy or guideline about the Post-approval monitoring program
 - IACUC/ERB SOP, policy or guideline for animal welfare concerns
 - IACUC/ERB SOP, policy or guideline for escaped animals
 - IACUC/ERB SOP, policy or guideline for animal socialization
 - IACUC/ERB SOP, policy, or guideline for humane euthanasia
- IACUC/ERB SOP, policies, or guidelines for endpoints, as applicable, for:
 - Monoclonal Antibody Production via Ascites
 - Cancer Research
 - Toxicology (acute and chronic)
 - Death as an endpoint
 - Models with specificity for pain/Pain research
 - Infectious disease
 - Other disease/surgical models with potential for high pain/distress (e.g. spinal cord injury)
- Disaster Plan
- SOP List
- Enrichment Policy
- Water Analysis
- Pest Control Program/Records
- Temperature/Humidity/Aire Reading Records