

Animal Care & Use Program Low Risk Assessment Tool for Contract Organizations



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 Low Risk Assessment Tool with input from CRO partners.

This abbreviated questionnaire can be used in performing a “paper-based, electronic assessment” of a partner research organization’s animal care and use program when the risks for animal welfare are considered to be minimal.

The questionnaire may be used in its entirety or limited to select questions that are relevant to the member company’s specific interests. 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 institution’s 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 additional sheets as necessary if your response exceeds the character limit for a question.

Please use Adobe Acrobat X Pro or higher for best results

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Animal Welfare Oversight/Regulatory (PDF of guideline or SOP can be sent in lieu of providing a response)

1) Please provide the names of personnel who are in the role of IACUC chair and Attending Veterinarian, their credentials, and the amount of time in the role within your institution.

2) What local, regional and national animal welfare regulations does the animal program comply with?

3) Has your company had a routine animal care and use audit or inspection by any governmental regulatory agency; such as the USDA, NIH or other national or regional animal welfare body? If yes, please provide agency name, and date of most recent audit or inspection.

Yes No

4) In the past 3 years, has your company received national or regional citations or direct or indirect violations of animal welfare laws or regulations, or similar follow-up report to any of the audits listed above? If yes, please list the year and provide an explanation of the findings and corrective measures instituted. Please provide documentation to support response.

Yes No

5) Please list accreditations that your organization has received for your animal program (AAALAC, CCAC). Include dates of initial and most recent accreditation visit. If applicable, please provide last AAALAC acknowledgement letter.

6) Do you have an internal animal welfare compliance oversight program (e.g. IACUC/ethics review committee)?

Yes No

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7) What is the minimum frequency of your internal animal welfare review of program/facilities. (i.e. vivarium and program/ IACUC/ or ERB)?

8) Do you have a post-approval monitoring program? If yes, please provide a basic description.

Yes No

9) If the study we are interested in contracting will rely on a sub-contracted animal lab, please describe how you will provide oversight of sub-contracted in vivo quality.

10) Direct bedding can affect animal welfare and study outcomes. Please describe the type of bedding you use for the animals that will be on study for our company (direct bedding, type of bedding).

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Standard Operating Procedures: Do you have Policies, SOP's or other controlled documents governing the following functions? Please complete table below.

Function	YES or NO	If there is no Policy, SOP or controlled document for this Function, please provide a summary of how this function is conducted and the responsible party.
<i>Veterinary medical records documentation</i>		
<i>Personnel experience and training program and documentation for animal handlers</i>		
<i>Health and safety surveillance specifically relating to animal allergens and exposures to NHP's (if applicable)</i>		
<i>Use of anesthetics, analgesics and paralytics</i>		
<i>Animal Socialization/Enrichment Program</i>		
<i>Reporting of animal welfare concerns, investigation, and resolution.</i>		
<i>Humane euthanasia</i>		
<i>Humane Endpoints</i>		
<i>Sentinel health monitoring for rodents. Please send us your last 6 months of serology reports (rodents)</i>		

Completed by:

Date Completed:

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