AAALAC International in Europe: Approaches to an Ethical Review

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Expectations for the Ethical Review

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The European Situation

- European Directive 86/609
- Currently being revised
- Follows implicitly the 3Rs but…
- No ethical review process required
- Members States (some) have implemented systems
- Variety of systems across Europe
The European Situation

• National Oversight Bodies (OB)
• Regional OBs
• Institutional OBs (IACUC-like)
• Combination of OBs
• Other official positions (AWO…)
• No OBs
• Different composition, authority, functioning
The European Situation

- Revised Directive: 3 Rs explicitly mentioned
- Permanent Ethical Review Body: Composition and Tasks
- Ethical Evaluation for Authorisation of Projects by Competent Authority: Criteria
- Harmonisation in the future?
AAALAC and the Ethical Review

• As part of the Institutional Policies and Responsibilities: Guide for the Care and Use of Laboratory Animals (Guide), NRC, 1996 and Programme Description

• There MUST be some type of Ethical Review

• Different approaches accepted

• Evaluation is performance based (focused on the outcome)

• Guide standards apply when there is no legislation in place
Expectations: Ethical Review

• Animal care and use follows the 3Rs
• Review of protocols (ethical evaluation)
• On-going review/post-approval monitoring
• Oversight of the programme of animal care and use and inspection of facilities
• Communication between OB and the Responsible person: Institutional Official/License Holder
Expectations: Oversight Body

- Appropriate composition (Veterinarian, scientists…)
- No conflict of interest
- Training
- Authority, institutional support
Characteristics of an Engaged Oversight Body

- Oversee and evaluate the entire animal care and use programme
- Ensure compliance with *applicable* Regulations
- Represent institution and community
- Serve as local oversight arm
- Foster a culture within the institution of good animal care and use practices
Characteristics of an Engaged Oversight Body

- Clearly articulate policies and procedures
  - Everyone understands expectations
- Ensure regulations are implemented using scientifically sound, performance-based standards
- Ensure effective training programmes are established
- Stimulate improvements in the programme
Potential issues

• Mandatories and Suggestions for Improvement (SFI)
• Mandatories (Must): more serious (programmatic) concerns
• SFIs (Should): up to the unit to address them
• Classification is performance-based.
• The only certain MUST: there MUST be an effective Ethical Review
Example 1: situation

- Small institution
- Institutional Ethics Committee
- Composition according to existing law
- General Manager and IO: Chair of the Committee
- Attending Veterinarian (AV) and Study Director: Secretary of the Committee
- Protocols are approved by Chair and Secretary if they think there are no ethical issues
Example 1: issues

- Conflict of interest
- No participation of the full Committee
- No evidence of deliberations
- Outcome: insufficient ethical review performed
Example 1: recommendations

• The approval of most of the studies by the Chairman of the EC, who is also the Director of the laboratory, and by the Attending Veterinarian and Animal Welfare Officer, who is also one of the main Study Directors, can present a conflict of interest. The lack of clear documentation about the expedited review process and of discussions on specific animal care and use concerns can affect the animal care and use programme. Mechanisms to ensure that all studies are more independently reviewed before the start of the experiments, and that all specific aspects of animal care and use are discussed and followed up, MUST be established.
Example 2

- Big laboratory, multi-species
- Government Committee
- AWO and AV review protocols before submission to the Committee
- AWO and AV and other specialists perform internal audits
- Outcome: ethical review well performed resulting in high level of animal care and use (no important issues)
Percent Combined Mandatory & Suggestions (2003-2008)
Combined Percent Oversight Body Mandatories & Suggestions (2003-2008)
Oversight Body/Ethical Review

• Composition and Participation
  – Conflicts of interest (study directors…)
  – Lack of members participation
  – Inadequate intensity of programme oversight
  – Only protocol review with no follow-up
Oversight Body/Ethical Review

• Protocol Issues
  – Issues of pain, distress (categorization) and humane endpoints not adequately reviewed and addressed by Committee
  – Not enough information on the form to be reviewed: nº animals, pain categories, endpoints, alternatives, safety
  – Animal research activities conducted without proper prospective ethical review