Guidelines on genetically engineered animals

CCAC National Workshop 2012

Guidelines on genetically engineered animals

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Why was this Guidelines Document Developed?


- Revision needed for
  - Animal welfare implications of advancements in genetic engineering
  - Problems associated with assigning Categories of Invasiveness
### How was this Guidelines Document Developed?

**Volunteer subcommittee**

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Draft Reviews

- Four external reviews
  - 2006 – peer review, 21 experts
  - 2008 – widespread review, 35 responses
  - 2010 – ‘final’ review, 32 responses
  - 2011 – additional widespread review, 21 responses

- Impact analysis
  - 2009-2010 – 5 group discussions
Why Single Out Genetically Engineered Animals?

- Welfare concerns for many GEAs same as for conventional animals
- Identify welfare concerns related to genetic modification early
- Particular challenges
  - Numbers of animals and procedures
  - Additional public concern
Genetically Engineered Animals Have Been Around for a Long Time

- Good practices exist for generation, care and use
- Guidelines don’t detract from good programs
- Some institutions, investigators and ACC members are less experienced in implementation of the Three Rs in this area
- Guidelines assist in ensuring necessary elements in place
Why is the Guidelines Document Inclusive of all Species?

- Focus on general principles
- Difference between institutions and types of research requires flexibility
- More specific information in implementation tools
  - best practices for procedures
  - assessment of welfare
  - documentation
Assessment of Welfare of GEAs

- Procedures should be determined by investigator and approved by ACC.
- Initial assessment may be sufficient if welfare is not compromised.
- If welfare concerns, may need more frequent monitoring and mitigation.
- Benefits animals, science and addresses public trust issues.
Welfare Status

- Refers to the animal itself (CIs refer to the procedures)

Welfare statuses:
- Standard
- Mild to moderate
- Severe

Any difference from standard should be reflected in CIs when considering the impact of procedures
Nomenclature

- Enables investigators to properly identify GEA lines
- Essential in accurately interpreting findings and in publication
- Critical to maintaining functional databases and avoiding duplication of models
Additional Reporting

- Good record keeping should be standard, if good systems in place then should be few changes
- Guidelines provide a framework, gives leeway for ACCs to use their own procedures
- Examples of how information could be captured and shared will be provided
Are Animal Passports Required?

- Term “animal passport” has been replaced by requirement to document animal information.
- Passport is an example and may be a useful reference if documentation practices not in place.
- Emphasis on ensuring an effective system is in place.
Archiving/Cryopreservation

- Investigators *should* use these technologies

- Risk assessment for catastrophic loss of line, genetic drift, fertility problems etc.
  - can the line be retrieved elsewhere
  - are controls in place to prevent loss
  - costs associated with maintaining frozen stock versus live animals
Counting Animals

- Requirement to count GEAs separately from non-GEAs in 1997 guidelines
- Assigning CI D to new lines created impression of GEAs with a high potential for pain and distress
- Reclassification did not occur in many cases
Reporting Animals

For generation and use:
- numbers of genetically engineered animals and wildtype animals reported to CCAC on AUDF

For breeding colonies:
- numbers of animals & welfare concerns reported annually to ACC