

HACKENSACK UNIVERSITY MEDICAL CENTER
Research Department Policy Manual

Name: Criteria for Using Genetically Altered (GA) Mice in Research **Policy # IACUC 121**

Effective Date: 3/2013

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GENERAL

Purpose: The welfare assessment scheme is intended to provide a framework, which can be tailored to suit each line of Genetically Altered (GA) animals. The information derived from the assessment is intended to form the basis of a “welfare profile” (see attached Mouse Welfare Profile). Implementation of these recommendations clearly requires participation from all involved in the use and care of Genetically Altered (GA) mice. It is intended that the ethical review process will play a key role in carrying out regulatory animal welfare concerns.

Administration: The Institutional Animal Care and Use Committee (IACUC) is responsible for the review and revision of this policy.

Policy: All Research Investigators working with GA mice must have a protocol approved by the IACUC and must fill out the “Mouse Welfare Profile” form (Appendix N). A Welfare Concern” form is to be filled by anyone who observes an animal welfare issue in Genetically Altered animals along with a sick report, and both should be submitted to the Clinical Veterinarian

PROCEDURE:

1: From a scientific, ethical and legal perspective, all GA mice should have in place a welfare profile, specific to the particular GA line; that can be used to identify mice with welfare concerns (indicators).

The profile would identify possible adverse effects common to the GA line in question.

2: Welfare assessments that have clearly defined limits for each GA mouse should complement the daily observations.

3: The welfare assessment should include a range of

non-invasive indicators. In the neonate - skin color, activity and presence of the milk spot; and at weaning and in the adult - appearance, size, coat condition, posture, gait, activity levels, interaction with the environment and clinical signs. The welfare assessments should be carried out using a check sheet as a prompt or guideline. (see attached Mouse Welfare Profile).

4: For any GA mice that are identified as having a welfare concern, the particular indicators that lead to this concern should be recorded and reported to the Clinical Veterinarian, Facility Manager and/or Principal Investigator (PI).

5: The welfare profile should be available in the same room as the mice in question. All records should be maintained centrally within the Facility.

6: All staff required to carry out welfare assessments should receive appropriate training and this should be regularly reviewed.

7: Whenever a new GA line is being introduced to the Facility, a Mouse Welfare Profile form (Appendix N) should be filled out in the IACUC protocol outlining any special information pertaining to husbandry, welfare issues, breeding recommendations and expected phenotypes as well as welfare concerns and limits.

8: When the GA line is being introduced after the protocol has been approved, an amendment form with the Welfare Profile appendices must be submitted to the IACUC for approval.

REFERENCES:

Profile Guidance Notes

Genetically Altered Animal Welfare Concern Form

Public Health Service Policy on Humane Care and Use of Laboratory Animals:

National Institutes of Health, Office of Laboratory Animal Welfare. Public Health Service: *Policy on Humane Care and Use of Laboratory Animals* (8/7/02).

Section IV: Implementation by Institutions. Retrieved from

<http://grants.nih.gov/grants/olaw/references/phspol.htm#AnimalWelfareAssurance>

Committee for the Update of the Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Research, Division on Earth and Life Studies, National Research Council of the National Academies. (c2011). Animal Care and Use Program. In Guide for the Care and Use of Laboratory Animals, 8th ed. (Chapter 2). Retrieved from:

<http://grants.nih.gov/grants/olaw/Guide-for-the-care-and-use-of-Laboratory-animals.pdf>

MOUSE WELFARE PROFILE

PLEASE SEND COPIES OF THIS FORM TO RELEVANT PERSONNEL IN ADVANCE OF SHIPMENT **AND** WITH THE MICE. See *guidance notes for help with completion.*

1.	Exact mouse nomenclature	
2.	Background strain	
3.	Number of backcross generations	
4.	Details of modification Include type of modification (if microinjection include copy number where known), gene affected, inheritance pattern.	
5.	References and websites (where applicable)	
6.	Contact Name (at exporting facility)	
7.	Address of contact	
8.	Email of contact	
9.	Where did the strain originate?	
10.	Genotyping method (please attach protocol) Send control DNA if possible.	
11.	Immune status	
Summary of husbandry and welfare issues		
12.	General appearance (include photograph if appropriate)	
	<ul style="list-style-type: none"> • Coat color 	
	<ul style="list-style-type: none"> • Any physical abnormalities? 	

	Is any remedial action necessary?	
13.	Behavioral traits E.G. aggression, tremor, over-grooming etc.	
	Is any remedial action necessary?	
14.	Other abnormalities: Include typical known post mortem findings.	
15.	Was a structured welfare assessment carried out for the period that adults are normally maintained? If 'yes' how long was this?	
16.	Husbandry recommendations:	
	• What diet are the mice fed on?	
	• Housing system e.g. Ventilated Racks	
	• Environmental enrichments	
17.	What is the current breeding strategy?	
	Average litter size	Pre/post-weaning mortality
18.	Growth rate (attach/include data if available)	Breeding life-span
19.	Have specific phenotypic tests been performed? (please attach results)	Yes No

Profile last updated _____ (name and date)

Profile Guidance Notes

The mouse profile is intended to provide husbandry and welfare information for establishments receiving genetically altered mice. The profile does not replace any requirements for the Department of Biological Resources or regulatory agencies.

The profile is provided for information and guidance and the originating establishment accepts no liability arising from the use of information provided in this document.

1. Details of correct strain nomenclature can be found at www.jax.org/jaxmice or Source where the animals originate from
2. Details of the original genetic background should be given.
3. Details of any subsequent breeding should be given.
4. Please give details of the transgene (and, where known, copy number if generated by pronuclear microinjection or random integration) or targeting construct and ES cell details. *If mice are genetic mutants, give details of the nature of the mutation and whether original mice were spontaneous or induced mutants.*
5. Please give details of any publications or websites that deal specifically with the strain. If substantial information is available please give the most comprehensive or recent reference.
6. Name of primary contact (e.g. facility manager, director)
7. Address of originating establishment
8. Email address of primary contact
9. This should refer to the originator of the GA mice and the contact details in order to obtain permission to use the mice. Details should include where and when the mouse was generated.
10. Please give details of the genotyping procedure. Is screening by Southern Blotting, PCR, ELISA, physical appearance or phenotypic expression? Please attach a protocol for the screening method.
11. Any known microbiological contamination? Include any information on what microorganisms were included in the screen, the length of time between each screen and the method used (e.g. sentinels or littermates).
12. General appearance should include details such as the range of coat colors to be expected, coat condition and texture (e.g. downy or fine), any problems with hair growth, any physical abnormalities (e.g. shortened tails, extra digits, shortened face, obesity, overgrown or under developed teeth). Body weight at different ages and growth rate information should be given, where available.
13. Any abnormal behavioral patterns should be noted (e.g. posture, movement, circling, tremors, aggression, submissive, over-grooming).
14. Any other abnormalities should be included.
15. Welfare assessments should be carried out for the period that adults are normally maintained for that particular line, and the limit to this should be noted.
16. Details of husbandry and advice should be provided including any special precautions that should be taken. Points to consider include:
 - What containment category does the animal fall into (1-4)?
 - Are the mice immunosuppressed?
 - What is the most appropriate housing system? For example, conventional housing, Individual Ventilated Caging, isolators, containment or quarantine.

- Type of consumables required i.e. fiber-free diet, atherogenic diet, powdered diet, irradiated, autoclaved (please state consumable supplier).
 - Are any dietary supplements required e.g. Lactated rehydration therapy? Please provide a reason as to why this may be necessary.
 - The type of bedding and / or nesting materials required.
 - Any environmental enrichment devices found to be useful or inappropriate.
 - Provide current environmental parameters including temperature, humidity and photoperiod. This is especially important if conditions differ from Department of Biological Resources or regulatory agencies guidelines.
17. Breeding recommendations: It is important to state which animals (male, female, all) carry the relevant transgene for breeding and welfare purposes. The transgenic status of the breeding colony should be stated i.e. homozygous or heterozygous, as well as details of the system used to breed mice and any comments relating to breeding management (e.g. age for first mating, pairs or harems, inbred or outbred, etc.). Also, include average litter size, average number born live / dead, pre and post-weaning losses.
18. Where available, body weight at different ages and growth rate information should be given.
19. Specific phenotypic tests include post mortem data, histology and any other analyses performed on the mice.
Please give references if applicable.

Genetically Altered Animal Welfare Concern Form

Mouse strain and line _____

Cage type _____

Date of check _____

Background strain _____

Room ID _____

Date of birth and age _____

Genotype _____

Cage ID _____

Size of litter _____

PI _____

Protocol # _____

Male/Female _____

		Question	Details of the welfare concern. Is the same seen in control animals?	If GA related – inform Source of the animal	Details of action to be taken (what, by whom, when)
NEONATE ONLY	Color of pups (for neonate only)	Do any pups show evidence of abnormal skin color (e.g. anemia, poor circulation)			
	Activity of pups (for neonate only)	Any abnormal activity, e.g. reduced wriggling?			
	Milk spot (for neonate only)	Do any pups fail to show presence of a milk spot? Any evidence of mis-mothering?			
WEANING AND ADULT	Appearance	Are there any signs of abnormal morphology (e.g. skull, tail, teeth) Any evidence of scratches or lesions?			
	Coat condition	Any piloerection, areas of hair loss, loss of whiskers, evidence of barbering?			
	Posture, gait and activity	Any abnormal gait or posture e.g. hunching, reluctance to move, rigidity or tremors, abnormal activity levels?			
	Clinical signs	Without handling – any evidence of discharge, seizures, abnormal respiratory rate? With handling – any problems with teeth, evidence of tumors?			
	Relative size	Any littermates of unusual / different size?			
	Other unexpected characteristics	e.g. excessive cage wetness, signs of aggression, signs of stereotypy			
	Any other concerns or comments? (provide details)				