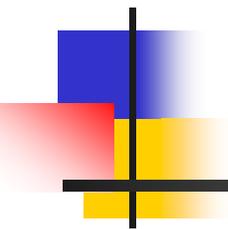
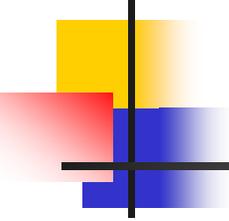


Animal Subject Coding Changes in the Grants Management Module

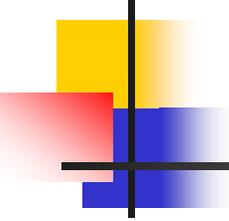


Grants Management Advisory
Committee
June 15, 2005



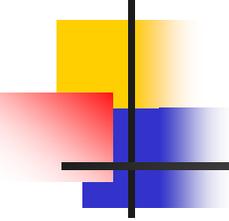
Why Change?

- More closely mirror the coding scheme of Human Subjects
- Reduce the number of Animal Subject codes from 14 to 6



When Will the Codes Change?

- Production release is scheduled for mid-June
- Many eRA modules are affected, therefore many enhancements and bug fixes are all dependent upon production release of these changes



What Will Change

- Current business rules that apply to releasing awards for research involving animal subjects do not change, but are enforced
 - No release without IACUC date or Assurance Number
 - SRG Concerns prevents award
- OLAW staff will be able to allow conditional awards

Current Animal Subject Coding

Combines info. on:

- Whether applic. involves Animal subj.
 - Ethical & Scientific assessment
 - Whether institutional assurance filed
 - Whether or not there are comments in the Summary Statement
- 10 No live vertebrate animals involved for competing appl.
 - 20 Live vertebrate animals involved
 - 30 Animals involved - no SRG comments or concerns noted
 - 32 Animals involved - SRG comments
 - 41 Animals involved - special administrative concerns
 - 44 Animals involved - SRG concerns
 - 45 Animals involved - No assurance - no SRG concerns/comments
 - 47 Animals involved - No assurance - SRG comments
 - 49 Animals involved - No assurance - SRG concerns
 - 51 Animals involved - previously coded 41 - now resolved
 - 54 Animals involved - previously coded 44 - now resolved
 - 55 HS 45 - now resolved
 - 55 Animals involved - previously coded 45 - now resolved
 - 57 Animals involved - previously coded 47 - now resolved
 - 59 Animals involved - previously coded 49 - now resolved

New Animal Subject Coding

Five separate data elements

Data Element			User
	Phase 2		
AS – ethical/scientific assessment	20	Yes	Automatically when R&R checks AS
	10	No live vertebrate animals involved for competing appl.	Peer Review, Grants Mgmt, OLAW
	30	Animals involved - no SRG concerns noted	Peer Review, Grants Mgmt, OLAW
	44	Animals involved - SRG concerns	Peer Review, OLAW
	48	Conditional award with terms & conditions	OLAW
	54	Resolved concerns, conditions removed	OLAW
AS Institutional Assur. #	Number		Peer Review, Grants Mgmt, OLAW
AS – Institutional Assurances filed?	Y	Yes – Assurances present	System when Assur.# entered
	N	No – Assurances missing	System default
	C	Conditional award with terms & conditions	OLAW
	R	Resolved concerns	OLAW
IACUC Study Date	Date		Peer Review, Grants Mgmt, OLAW
IACUC Study Certifications filed?	Y	Yes – Certifications present	System when IACUC date entered
	N	No – Certification missing	System default
	C	Conditional award with terms & conditions	OLAW
	R	Resolved concerns	OLAW

Animal Subject Coding

Comparison of current & new coding

Current AS Coding	Equivalent in Proposed AS Coding
10 No live vertebrate animals involved for competing appl.	Same. 10 No live vertebrate animals involved for competing appl.
20 Live vertebrate animals involved	Same. 20 Live vertebrate animals involved
30 Animals involved - no SRG comments or concerns noted	30 Animals involved - no SRG concerns noted. <i>Removed reference to comments</i>
32 Animals involved - SRG comments	Remove as AS Code. Add as a header reference to Summary Statements. Create addtl.checkbox item on Sum. Stmt. Preparation screen, along with biohazards, etc.
41 Animals involved - special administrative concerns	Remove as AS Code. Replaced by IACUC date and IACUC cert. filed fields.
44 Animals involved – SRG/OLAW concerns	Same. 44 Animals involved - SRG concerns
45 Animals involved - No assurance - no SRG concerns/comments	Remove. This is replaced by the Assurance # and the Assurance Filed fields. If no Assurance #, set Assurance filed to 'N' automatically. Default value is 'N'.
47 Animals involved - No assurance - SRG comments	Remove. This is replaced by the Assurance # and the Assurance Filed fields as well as the header reference to Summary Statements. If no Assurance #, set Assurance filed to 'N'.
49 Animals involved - No assurance - SRG concerns	Remove. This would be represented by '44' in Animal Subjects code and 'N' in Assurance filed field.
51 Animals involved - previously coded 41 - now resolved	Remove. This is replaced by 'R resolved' in assurance filed and IACUC cert filed fields.
54 Animals involved - previously coded 44 - now resolved 55 HS 45 - now resolved	Remove. This would be replaced by '48 IRG Concerns Resolved.' Entered by OLAW in AS code.
55 Animals involved - previously coded 45 - now resolved	Remove. This would be replaced by 'R' entered by OLAW in Assurance filed field.
57 Animals involved - previously coded 47 - now resolved	Remove. This would be replaced by 'R' entered by OLAW in Assurance filed field.
59 Animals involved - previously coded 49 - now resolved	Remove. This would be replaced by '48 IRG Concerns Resolved' entered by OLAW in AS code and 'R' entered by OLAW in Assurance filed field.

AS processing in Peer Review – Summary Statement Prep:

Adam Felsenfeld PH.D. 301-435-5539 felsenfa@mail.nih.gov	SUMMARY STATEMENT (Privileged Communication)	Release Date: 03/13/2003
RIETHMAN, HAROLD PHD WISTAR INSTITUTE 3601 SPRUCE STREET PHILADELPHIA, PA 19104		Application Number: 1 R01 HG002933-01
Review Group: GNM Genome Study Section		
Meeting Date: 02/23/2003 Council: MAY 2003 Requested Start: 07/01/2003	PCC: X3AF	
Project Title: Cloning, Mapping and Sequencing Rodent Subtelomeric DNA		
SRG Action: Priority Score: 133 Percentile: 3.4		
Human Subjects: 10-No human subjects involved		
Animal Subjects: 32-Animals involved - SRG comments		
Project Year	Direct Costs Requested	Estimated Total Cost
1	150,000	268,151
2	150,000	268,151
3	150,000	268,151
TOTAL	450,000	804,452

- Currently:
- If Peer Review has animal subject comments only without concerns, the animal subject code indicates that there are comments. This appears on the Summary Statement header which alerts the reader that there is text in the body of the Summary Statement related to these concerns.

AS processing in Peer Review – Summary Statement Prep:

SUMMARY STATEMENT
(Privileged Communication)

Walter Goldschmidts
301-443-3563
WGOLDSCH@NIH.GOV

Release Date: 03/20/2002
Revised Date: 03/27/2002

Application Number: 1 F32 MH066585-01

DANIELS, DEREK , PHD
UNIV OF PENNSYLVANIA SCH VET MED
DEPT OF ANIMAL BIOLOGY
3800 SPRUCE ST, 254E
PHILADELPHIA, PA 19104

Review Group: ZRG1 F02A (20)
Center for Scientific Review Special Emphasis Panel

Meeting Date: 03/05/2002
Council: MAY 2002
Requested Start:

PCC: TG-GRF
Dual PCC: NJP NUTR
Dual IC(s): DK

Project Title: Central melanocortin system and MAP-kinase activation

Sponsor: FLUHARTY, STEVEN J
Department: ANIMAL BIOLOGY
Organization: UNIVERSITY OF PENNSYLVANIA
City, State: PHILADELPHIA PENNSYLVANIA

Requested: 3 years

SRG Action: Priority Score: 170 Percentile: 35.8
Human Subjects: 10-No human subjects involved for competing applications
Animal Subjects: 30-Animals involved - no SRG Concerns

NOTE TO APPLICANT FOLLOWS SUMMARY STATEMENT

BIOHAZARD
Animal Subjects

AS processing in GM

Code	Description	Assurance#	Date
30	Animals involved - no SRG c	A3261-0	06/21/2002
10	No human subjects involved	FWA000	

Changes:

- GM staff can update the Animal Subject code. Only OLAW can remove a bar to resolved, to conditional, or to some other value.
- If OLAW has updated the AS field to '48' Conditional award with terms & conditions , then GM shld.incl. approp. term in NGA.
- GM staff can update Assurance # and IACUC date. Note that when GM staff keys a value in Assurance# or IACUC date, the value of 'AS Inst.Assur.filed' and/or 'AS Certif.filed' will be automatically set to 'Y'.The Assurance filed and cert.filed fields will not be directly updatable by GM staff. The default value is 'N' for these fields. Only OLAW can directly update the value of Assurance filed and IACUC cert.filed to 'C' for Conditional award with terms & conditions, or 'R' Resolved.
- When award is processed, edit check will prevent release if AS field is coded with a value '44' or Instit.Assur.field coded 'N - not filed.' or IACUC cert.filed coded 'N'. However, for foreign institutions, an IACUC cert is not required. Therefore, if assurance # starts with '5', then allow an award to go through if Cert filed? = 'N'.

AS Processing in GM J2EE

307 blocked AutoFill Options

HEALTH

User Name: SIEGERTM
[Logout](#)

Version 2.0.1

Custom Links Help

[Delete WIP](#)

Grant Status: 07 Pending Award. Non-fellowships JFF: SINGLE-CAN

PI (L,F MI): QUAN, NING Appl ID: 6867079

Inst Type: INSTITUTION OF HIGHER EDUCATIO RFA / PA:

1 - 1 out of 2 records, Page 1 out of 2 Pages

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009

005

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ON

N

[Checklist Items](#)

Filed	NF	NA		GM Checklist Status	<input type="text"/>
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Other Assurances/Certifications	Inst. Assurance filed?	<input type="text" value="N"/>
<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	Current Financial Status Report	IRB Certification filed?	<input type="text" value="N"/>
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	Interim Progress Report	Other Sup. Review ?	<input type="checkbox"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Animal Subj Inst Assurance Filed Code	IC Internal Req. Met ?	<input type="checkbox"/>
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	State Department Clearance	Expiration	<input type="text"/>
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Misconduct in Science		

As Inst Assur filed?

IACUC Cert filed?

	Code	Description	Assurance #	IA CUC/IRB Date
Animal Subjects	30	Animals involved - no SRG coi	A3261-01	06/21/2002
Human Subjects	10	No human subjects involved	FWA00006:	
Minority			Doc #	RAI059089A
Gender			PCC	I4C
Tracking Code			FOT	<input type="text"/> DSF
Child			CFDA 93	<input type="text"/>

Type 5 rollover/Shell Merge & Other Business Rules

Copy 'Institutional Assurance #' field to type 5 shell

- Copy 'Institutional Assurance filed' field to type 5 shell
- Reset 'IACUC Cert. Date' field to default to NULL in type 5 shell
- Reset 'IACUC Cert filed' field to 'N' in type 5 shell.
- If 'Institutional Assurance filed?' field is null, then set default value to 'N'.
- If 'IACUC Cert. filed?' field is null, the set default value to 'N'.
- In award release edits:
 - If animal subject code = '44', prevent release
 - If Animal Subjects code is not '10', then
 - if 'Institutional Assurance filed?' field = 'N' or NULL prevent release
 - if 'Institutional Assurance filed?' = 'Y', assurance# field must not be NULL.
 - If 'IACUC cert. filed?' = 'N' or NULL prevent release (unless Assurance # starts with 5 for a foreign institution).
 - If 'IACUC cert. filed?' = 'Y', IACUC date field must not be NULL.
- Implement new coding scheme with FY05 awards; Sweep codes retrospectively for all FY05 applications.