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 Animals involved - previously coded 45 - now resolved
- 59 Animals involved - previously coded 49 - now resolved
# New Animal Subject Coding

## Five separate data elements

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Phase 2</th>
<th>User</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS – ethical/scientific assessment</td>
<td>20 Yes</td>
<td>Automatically when R&amp;R checks AS</td>
</tr>
<tr>
<td></td>
<td>10 No</td>
<td>Peer Review, Grants Mgmt, OLAW</td>
</tr>
<tr>
<td></td>
<td>30 Yes</td>
<td>Peer Review, Grants Mgmt, OLAW</td>
</tr>
<tr>
<td></td>
<td>44 No</td>
<td>Peer Review, OLAW</td>
</tr>
<tr>
<td></td>
<td>48 Yes</td>
<td>OLAW</td>
</tr>
<tr>
<td></td>
<td>54 Yes</td>
<td>OLAW</td>
</tr>
<tr>
<td>AS – Institutional Assur. #</td>
<td>Number</td>
<td>Peer Review, Grants Mgmt, OLAW</td>
</tr>
<tr>
<td>AS – Institutional Assurances filed?</td>
<td>Y Yes</td>
<td>System when Assur.# entered</td>
</tr>
<tr>
<td></td>
<td>N No</td>
<td>System default</td>
</tr>
<tr>
<td></td>
<td>C Yes</td>
<td>OLAW</td>
</tr>
<tr>
<td></td>
<td>R Yes</td>
<td>OLAW</td>
</tr>
<tr>
<td>IACUC Study Date</td>
<td>Date</td>
<td>Peer Review, Grants Mgmt, OLAW</td>
</tr>
<tr>
<td>IACUC Study Certifications filed?</td>
<td>Y Yes</td>
<td>System when IACUC date entered</td>
</tr>
<tr>
<td></td>
<td>N No</td>
<td>System default</td>
</tr>
<tr>
<td></td>
<td>C Yes</td>
<td>OLAW</td>
</tr>
<tr>
<td></td>
<td>R Yes</td>
<td>OLAW</td>
</tr>
</tbody>
</table>
# Animal Subject Coding

## Comparison of current & new coding

<table>
<thead>
<tr>
<th>Current AS Coding</th>
<th>Equivalent in Proposed AS Coding</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 No live vertebrate animals involved for competing appl.</td>
<td>Same. 10 No live vertebrate animals involved for competing appl.</td>
</tr>
<tr>
<td>20 Live vertebrate animals involved</td>
<td>Same. 20 Live vertebrate animals involved</td>
</tr>
<tr>
<td>30 Animals involved - no SRG comments or concerns noted</td>
<td>30 Animals involved - no SRG concerns noted. Removed reference to comments</td>
</tr>
<tr>
<td>32 Animals involved - SRG comments</td>
<td>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.</td>
</tr>
<tr>
<td>41 Animals involved - special administrative concerns</td>
<td>Remove as AS Code. Replaced by IACUC date and IACUC cert filed fields.</td>
</tr>
<tr>
<td>44 Animals involved – SRG/OLAW concerns</td>
<td>Same. 44 Animals involved - SRG concerns</td>
</tr>
<tr>
<td>45 Animals involved - No assurance - no SRG concerns/comments</td>
<td>Remove. This is replaced by the Assurance # and the Assurance Filed filed fields. If no Assurance #, set Assurance filed to ‘N’ automatically. Default value is ‘N’.</td>
</tr>
<tr>
<td>47 Animals involved - No assurance - SRG comments</td>
<td>Remove. This is replaced by the Assurance # and the Assurance Filed filed fields as well as the header reference to Summary Statements. If no Assurance #, set Assurance filed to ‘N’.</td>
</tr>
<tr>
<td>49 Animals involved - No assurance - SRG concerns</td>
<td>Remove. This would be represented by ‘44’ in Animal Subjects code and ‘N’ in Assurance filed field.</td>
</tr>
<tr>
<td>51 Animals involved - previously coded 41 - now resolved</td>
<td>Remove. This is replaced by ‘R resolved’ in assurance filed and IACUC cert filed fields.</td>
</tr>
<tr>
<td>54 Animals involved - previously coded 44 - now resolved</td>
<td>Remove. This would be replaced by ‘48 IRG Concerns Resolved.’ Entered by OLAW in AS code.</td>
</tr>
<tr>
<td>55 Animals involved - previously coded 45 - now resolved</td>
<td>Remove. This would be replaced by ‘R’ entered by OLAW in Assurance filed field.</td>
</tr>
<tr>
<td>57 Animals involved - previously coded 47 - now resolved</td>
<td>Remove. This would be replaced by ‘R’ entered by OLAW in Assurance filed field.</td>
</tr>
<tr>
<td>59 Animals involved - previously coded 49 - now resolved</td>
<td>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.</td>
</tr>
</tbody>
</table>
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**

**Application Number:** 1 F32 MH066585-01

**Walter Goldschmidt**

(Privileged Communication)

**Release Date:** 03/20/2002

**Revised Date:** 03/27/2002

**W.GOLDSCH@NIH.GOV**

**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

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

**Project Title:** Central melanocortin system and MAP-kinase activation

**Sponsor:** FLUHARTY, STEVEN J

**Requested:** 3 years

**Department:** ANIMAL BIOLOGY

**Organization:** UNIVERSITY OF PENNSYLVANIA

**City, State:** PHILADELPHIA PENNSYLVANIA

**SRG Action:** Priority Score: 170 Percentile: 35.8

**Human Subjects:** 10-No human subjects involved

**Animal Subjects:** 30-Animals Involved - No SRG Concerns

NOTE TO APPLICANT FOLLOWS SUMMARY STATEMENT

**BIOHAZARD**

**Animal Subjects**
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 should include appropriate terms 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 Inst.Assur.filed 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

![Image of AS Processing in GM J2EE interface](image)

### Grant Status
- Pending: Award, Non-fellowships

### PI (Last Name, First Initial)
- GUAN, NING

### Inst Type
- INSTITUTION OF HIGHER EDUCATION

### Checklist Items
- Other Assurances/Certifications: Inst. Assurance filed? - N
- Current Financial Status Report: IRB Certification filed? - N
- Interim Progress Report
- Animal Subj Inst Assurance Filed Code: As Inst Assur filed? - Y

### Misconduct in Science

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Expiration</th>
<th>Assurance #</th>
<th>IACUC/IRB Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>Animals Involved - no SRG to</td>
<td>06/21/2002</td>
<td>A3261-01</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>No human subjects involved</td>
<td></td>
<td>FWA00000B</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Minority</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tracking Code</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Child</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### User Information
- User Name: SIEGERTM
- Logout
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.