



Congruency Review: IACUC and SPO

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Overview

- ▶ What is Congruency Review?
- ▶ Previous IACUC Congruency Review process
- ▶ New IACUC Congruency Review process
- ▶ SPO coordinates with IACUC in new process



What is Congruency Review?

- ▶ Congruence is required per the *National Institute of Health Grants Policy* Statement provides the terms and conditions that must be met to receive a grant award. Per this policy, "It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC".

How to do Congruency Review?



Perform a side-by-side comparison of the following bullet points found in both the grant(s) and animal protocol(s). For NIH grants the animal-related information can be found in the Vertebrate Animal Section (VAS) and the Research Strategy Section. For other funding agencies, the information can be found in the methods section that describes the animal work.

- ▶ General scope of work
- ▶ Experimental procedures and endpoints
- ▶ Experimental agents
- ▶ Species (strain(s) included if it represents a model)
- ▶ Approximate number of animals
- ▶ Euthanasia method(s)

Which Agencies Require Congruency Review?

U.S. Public Health Services Agencies include:

- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Services (IHS)
- National Institutes of Health (NIH)
- Office of Global Affairs (OGA)
- Office of the Assistant Secretary for Health (OASH), including
 - Office of Minority Health Resources Center (OMH)
 - Office of Population Affairs (OPA)
 - Office of Research Integrity (ORI)
 - Office of Research on Women's Health (OWH)
- Office of the Assistant Secretary for Preparedness and Response (OASPR), including
 - Biomedical Advanced Research and Development Authority (BARDA)
- Substance Abuse and Mental Health Services Administration (SAMHSA)

Non-PHS organizations which have adopted the PHS regulations:

- Alliance for Lupus Research
- American Cancer Society
- American Heart Association
- Arthritis Foundation
- CurePSP Foundation for PSP/CBD and Related Brain Diseases
- Juvenile Diabetes Research Foundation
- Susan G. Komen for the Cure

In addition:

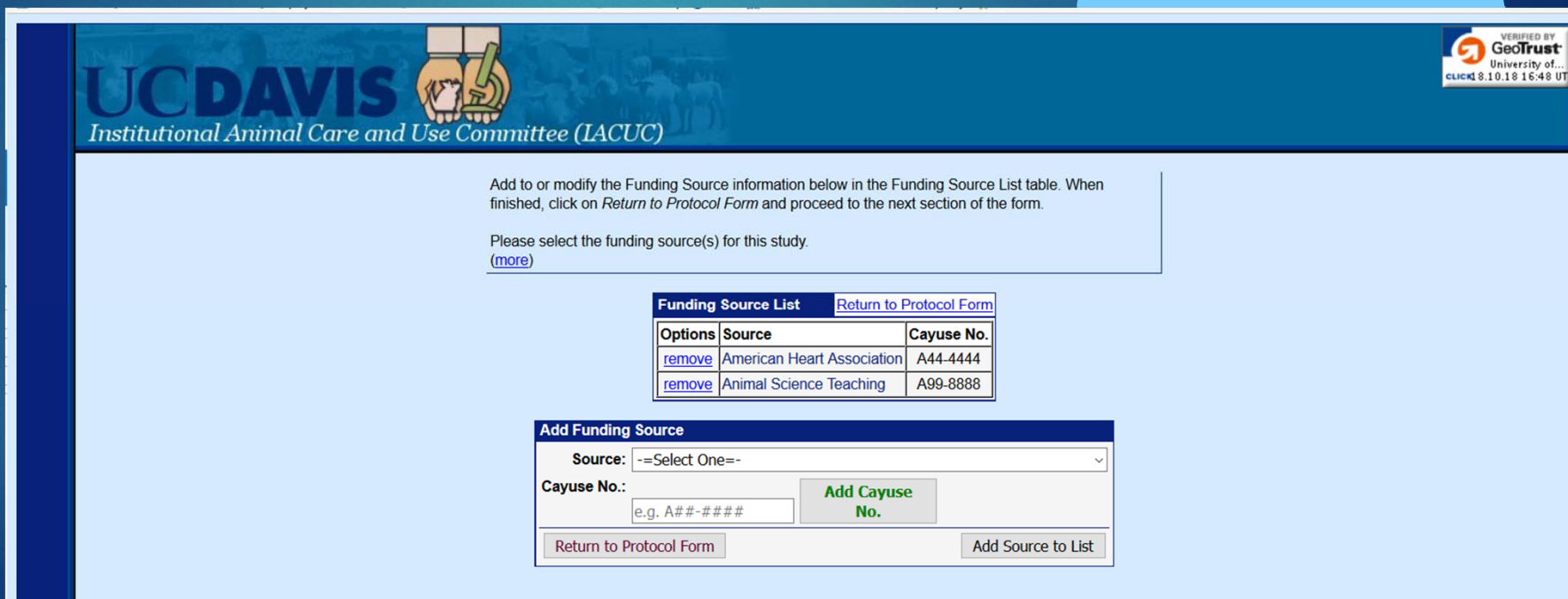
Veterans Administration
Department of Defense (DOD)
UCOP

IACUC Previous Congruency Review Process

- ▶ Congruency was performed by the IACUC staff only when a protocol or amendment was submitted listing a newly submitted or funded NIH grant
- ▶ Reasons for a new process
 - ▶ Not all funding agencies that require congruency reviews were being identified
 - ▶ IACUC staff does not have the staffing to perform congruency reviews for all required agencies
 - ▶ IACUC staff members are not best situated to evaluate the grant on a scientific level
 - ▶ The PI is the content expert on both their grants and IACUC protocols

IACUC New Congruency Review Process

- ▶ Grant congruency will be the responsibility of the PI
- ▶ New Process
 - ▶ Complete section 10 of the IACUC protocol and enter Cayuse number for the grant



The screenshot displays the UC Davis Institutional Animal Care and Use Committee (IACUC) web portal. At the top left is the UC Davis logo and the IACUC name. At the top right is a GeoTrust verification badge. The main content area contains instructions for adding or modifying funding sources, a table of existing funding sources, and a form to add a new funding source.

Add to or modify the Funding Source information below in the Funding Source List table. When finished, click on *Return to Protocol Form* and proceed to the next section of the form.

Please select the funding source(s) for this study.
[\(more\)](#)

Options	Source	Cayuse No.
remove	American Heart Association	A44-4444
remove	Animal Science Teaching	A99-8888

Add Funding Source

Source:

Cayuse No.:

IACUC New Congruency Review Process

- ▶ PI Complete the SPO Protocol Certification Form following IACUC approval of new protocols or amendments to add a funding source and send to SPO

SPONSORED PROGRAMS PROTOCOL CERTIFICATION FORM

Cayuse SP Proposal #: _____

Cayuse SP Project #: _____

PI Last Name:	PI First Name:
Phone #:	Email:
Department:	
Title:	
<div style="border: 1px solid black; height: 30px; width: 100%;"></div>	
Project Period From: _____ Through: _____ Sponsor: _____	

Does this project involve Vertebrate Animals? Yes No

Associated IACUC Protocols:	Approval Date:	Expiration Date:	Notes:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<div style="border: 1px solid black; height: 80px; width: 100%;"></div>
<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>	

Principal Investigator- Certification: I certify the protocols listed above are approved by the UC Davis Institutional Animal Care and Use Committee (IACUC) for vertebrate animal research, these protocols are congruent with this project's scope of work, and no additional protocols are pending or anticipated for this project. I further certify that I will notify the IACUC of changes to this project that affect these protocols.

Signature, Principal Investigator

Date

Does this project involve Human Subjects? Yes No

Associated IRB Protocols:	Approval Date:	Expiration Date:	Notes:
<input type="text"/>	<input type="text"/>	<input type="text"/>	<div style="border: 1px solid black; height: 80px; width: 100%;"></div>
<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>	

Principal Investigator- Certification: I certify the protocols listed above are approved by the UC Davis Institutional Review Board (IRB) for this specific project and no additional protocols are pending or anticipated for this project. I further certify that I will notify the IRB of any changes to this project that affect these protocols.

Signature, Principal Investigator

Date

IACUC New Congruency Review Process

- ▶ Situations when the PI will have to fill out the new SPO Protocol Certification form for IACUC purposes
 - ▶ After a new IACUC protocol for a new project is approved
 - ▶ After an amendment to add a funding agency to an existing IACUC protocol is approved
- ***It is highly suggested that an IACUC protocol is submitted when a priority score is received that indicates that the grant will likely be funded***
- ▶ PI will submit the SPO Protocol Certification form to SPO
 - ▶ Download the form from the UC Davis SPO/Forms webpage

When SPO checks that Congruency Review is Completed

SPO analysts will check via a synched website that the IACUC protocol number corresponds with the awarded grant (listed by Cayuse number), and that the PI has certified congruency (by Protocol Certification Form)

- ▶ When new funding is received – a New Award
- ▶ When supplemental funding is received on an existing award – a Supplement
- ▶ When a grant amendment is received that amends the Scope of Work – Grant Amendment
- ▶ ***In all of these cases, please check to determine if the IACUC protocol needs to be amended in any way.***

IACUC Process for Congruency Review Explained to PI

- ▶ IACUC has prepared an SOP that outlines how a PI should perform a congruency review
- ▶ The SOP can be found in the protocol instructions for Section 10 (Funding Source) of the IACUC Protocol and on the IACUC homepage

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