

William S. Middleton Memorial Veterans Hospital  
IACUC Policy #10-13

## **Changes of Protocol for Animal Component of Research Protocol (ACORP)**

**Policy:** All changes in existing protocols must be requested on specific forms prior to IACUC review. These forms include:

- Change of Protocol form
- Notice of Change in Personnel form or
- Temporary Change of Protocol form for Short-term Personnel (less than 3 months).

These forms appear at the end of this policy. They may be obtained electronically by e-mailing the IACUC Coordinator.

**In addition**, (except for “Temporary Change of Protocol for Short-term Personnel”) the Principal Investigator shall incorporate all changes into their previously approved Animal Component of Research Protocol (ACORP) form. Additions to the ACORP should be marked by **highlighting**, and deletions should be marked by ~~striketrough~~.

Minor changes DO NOT require full IACUC Review. They will be reviewed and approved administratively through the Research Office either by the VMC, the Chair of the IACUC, or the AO of Research. Significant changes require full Animal Research Committee review.

### **Definitions:**

Temporary Change. *Temporary Changes ONLY APPLY to short-term personnel additions (e.g., summer employees or employees who work under the protocol for less than 3 months).* A Temporary Change of Protocol may be reviewed and approved administratively.

The PI must complete the Temporary Change of Protocol Form (Short-term Employees). The PI does NOT need to revise his/her full protocol. Temporary Changes of Protocol are reviewed and approved *administratively*.

Minor Change. A Minor Change is any change that is *administrative* in nature and does not affect the experimental design approved. A Notice of Change in Personnel form can replace the Change of Protocol form for adding personnel who will work over 3 months. Contact the IACUC Coordinator in the Research Office to request the form.

Examples of Minor Changes include:

- change in funding source
- change of vendor
- changes in after-hours phone contact numbers
- mistakes (such as typographical errors) in previously approved protocols
- change in any procedural location
- change in housing locations
- increase in animal numbers if less than 5%
- change in animal strain provided the new strain does not have additional health concerns

- changes of personnel who will have contact with animals\*\*

NOTE: The approving officials for minor changes (AO, IACUC Chair, or VMC) may determine that a change submitted as "Minor" should be reviewed by the full committee.

Significant Change: A significant change is any change that is *substantive* in nature and involves a change in the experimental design approved.

Examples include:

- increase in animal numbers if greater than 5%
- changes in methods of anesthesia or euthanasia
- addition of new test substances, new procedures, surgeries, or models
- extension of animal housing or survival periods
- change in type of caging
- change in specimen collection before euthanasia
- change in endpoint criteria, etc.

NOTE: If you are unsure whether your proposed change of protocol meets "Minor" or "Significant" criteria, please contact the IACUC Coordinator in the Research Office or the VMC.

## **Responsibilities:**

### **1. Role of the Investigator**

The Principal Investigator is responsible for notifying the IACUC of all changes of protocol before implementing the proposed change(s). Proceeding with studies proposed under the change of protocol without IACUC approval is a violation of the protocol and must be reported to the IACUC.

Temporary Change: The Principal Investigator must complete and submit a Temporary Change of Protocol form for Short-term Employees. The PI does NOT need to revise their current protocol.

Minor Change: The Principal Investigator completes and submits a Minor Change of Protocol form (see definitions above to determine if your change meets "Minor" criteria), a Notice of Change in Personnel form (used in cases where the PI will add or delete personnel who have worked for over 3 months), or a Temporary Change of Protocol form for Short-term Personnel to the IACUC Coordinator.

Significant Change: The PI completes and submits a Change in protocol form and submits to the IACUC coordinator.

The PI will be notified of the administrative approval or disapproval via e-mail and will be sent a paper copy of the IACUC approval memo and approved protocol. **Animal work cannot begin until PI receives approval from the VA R&D committee, RSC (if applicable), as well as the UW IACUC if the protocol is funded by the NIH and/or housing is in a UW facility or any live animals are taken to a UW lab.**

**Questions:** Any questions on this policy may be directed to the A.O. (280-7222).

**References:**

- Policies of the UW Research Animal Resources Center
- Policies of the UW Office of Biological Safety
- Notice NOT-OD-03-046; release date June 6, 2003; “Office of Extramural Research Revised Guidance Regarding IACUC Approval of Changes in Personnel Involved in Animal Activities”

**Effective date:** This policy was approved at the ARC meeting on September 15, 2003, and updated at the ARC meeting on July 11, 2005. The revision was approved at: 9/12/2005, 7/07/2008, 9/08/2008, 5/11/2009, and the 6/28/2010, 9/13/2010, 3/07/2011, 7/11/12, 9/11/13 IACUC meetings.

File Source: VA Research Office, ARC Coordinator's Network Folder, ARC Files, ARC Policies revised

# EXAMPLE

## Obtain electronic copy from IACUC Coordinator

### Notice of Change in Animal Research Personnel (for Temporary Employees - 3 months or less)

*Directions: Return this completed form to the VA ARC Coordinator. PIs will receive notice of ARC Approval via Memo. Please **BOLD** your responses to the questions below.*

Protocol Title and No.:

Principal Investigator:

Added Personnel:

Time Period Employed:

1. List all specific procedures from the protocol that new personnel will perform (*including euthanasia, administration of anesthesia, specific surgical procedures, monitoring of animals after surgery, administration of substances, etc.*):
  
2. List prior education, training, and/or experience **relevant** to the procedures listed above:
  
3. If no prior training or experience with said procedures, how will new personnel be trained and by whom?
  
4. Required Animal User Training below **MUST** be completed before new personnel are approved to work under the animal use protocol. Items b) and c) may not be applicable, in which case please type “**N/A**” in bold below the paragraph. Copies of certificates of completion of the appropriate courses below should be sent to the ARC Coordinator at VA Research, Room C-3127 or can be faxed to her attention at 280-7244 (or 1-7244 from within the VA):
  - a) UW RARC On-line Animal User Orientation Seminar Certification (<http://www.rarc.wisc.edu/training/cert.html>)
  - b) For those completing the Animal User Orientation for the first time, the following course is also required: UW RARC Basic Bi methodology Course(s) for the species with which an individual will work under an approved animal use protocol. Registration information can be found at <http://www.rarc.wisc.edu/training/mouse.html> for mice and <http://www.rarc.wisc.edu/training/rat.html> for rats.
  - c) For those completing the Animal User Orientation for the first time and for those who will perform surgery on animals, the following 1 day course is also required: *UW RARC Lab Animal Surgery*. Registration information can be found at: <http://www.rarc.wisc.edu/training/las.html>
  - d) UW Occupational Health and Safety Class (1 hour). Registration information can be found at: <http://www.rarc.wisc.edu/training/ocsafety.html>

- e) If personnel will be working in BSL-2 conditions, they must take the VA's BSL-2 training. Please contact the VA Research Safety Coordinator to set-up a BSL-2 training session.

**Responsibility of the Principal Investigator:**

As the Principal Investigator of the study cited above, I take full responsibility for ensuring that any personnel I add to my research staff has had or will receive adequate training/experience with the specific procedures the personnel is assigned to perform. I also ensure that new personnel WILL NOT perform any of the aforementioned procedures until this completed form has been approved by the VA Research Services administration.

*PI Signature:*

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***Admin Only:*** Certification that new personnel have completed the appropriate training courses

- UW RARC On-line Animal User Certification Seminar
- N/A or UW RARC Biotechnology of Mouse and/or Rat Course
- N/A or UW RARC Lab Animal Surgery Course
- N/A or VA BSL-2 Training
- UW Occupational Health and Safety Program (includes Health and Immunization Questionnaire)
  
- WOC (Without Compensation) Paperwork Completed (**Required for Non-VA Employees only**)  
*(Paperwork available at the VA Research Office, C-3127)*

**Approval Signature:**

*AO Research*

*Date*

## EXAMPLE

# Obtain electronic copy from IACUC Coordinator

Department of  
Veterans Affairs

Memorandum

William S. Middleton Memorial VA Hospital  
Madison, WI

Date:

From: IACUC Coordinator

Subj: Annual Review of Animal Use

To:

1. Annual review of the animal use component of your research Protocol **Title(#)** is scheduled for the next meeting of the Animal Research Committee. Continued use of animal subjects in these projects requires annual review and approval before the anniversary date of the original approval.
2. Request for Continued Approval of Animal Use form is attached. **Please answer each item under Protocol Status and return all forms to me by X Date. The PI (not lab personnel) can send back the form electronically by checking the box under signature line.**
3. Should your answers to items 2 or 3 under Protocol Status require that you submit a Change of Protocol Form and a revised version of your ACORP, please underline or highlight your changes. For the most recent version of your ACORP and the most recent version of the Change of Protocol form (version 19), please contact me at the address listed below. You are reminded that **any changes or new procedures described in such forms may not be performed until approved by the VA Animal Research Committee.**
4. Your protocol involves a procedure or housing method that is an exception to *The Guide*. Please comment (on the renewal form) the alternatives you have researched in the past year to try to refrain from using this technique. It is AAALAC's expectation that PI's and Animal Care & Use Committees periodically review such practices to determine if new alternatives may be available.
5. Item 5 deals with the current personnel on this protocol. Please review and be sure this is correct. These listed personnel must complete annual Citiprogram.org training by XXX date. If this does not happen by XXX (date) the protocol will not be renewed. The listed personnel below will receive information regarding this training in an email.

Thank you,

*IACUC Coordinator*

Research Office, C-3127  
608-256-1901

Inter D Mail address: VA Research Service, C-3127

**Request for Continued Approval of Animal Use**  
**William S. Middleton Memorial VA Hospital**  
**Madison, WI**

Principal Investigator:

Date of Notice:

Protocol No.:

Protocol Expiration Date:

Protocol Title:

Approved Animal Species:

Type of Review:

1. Protocol Status (*Check **ALL** that apply*):

- Protocol is active and animal subjects are being used.
- Protocol is active with NO animals currently being used, BUT animals were used within the past year.
- Protocol is active but animal use has not started.
- Protocol is nearing its expiration date: to continue my study, I will be submitting a new ACORP for ARC review before the current protocol expires.
- Protocol has ended.
- Protocol will end on its expiration date (please check this item **only** if your protocol is up for 3-year renewal)
- Other; EXPLAIN STATUS OF PROTOCOL:

## 2. Animal use within the past year has been in accordance with the approved protocol.

*If answer is "No," briefly describe the changes that will be made to the ACORP in the space below Item 3 and submit a new Protocol form along with a Change of Protocol form ASAP.*

- Yes
- No
- N/A

## 3. Changes in animal use are anticipated during the upcoming year.

*If answer is "Yes," briefly describe the changes in the space below and submit a new Protocol form along with a Change of Protocol form **before you implement the change(s)**.*

- Yes
- No
- N/A

4. Your protocol includes an exception to the animal care and use practices that are recommended by *The Guide*: List exception(s) here. Please comment on alternatives that you have researched within the past year that may or may not have worked to try to eliminate this procedure that is an exception to *The Guide*.

## 5. Below is the list of current personnel on the protocol. If this is incorrect and you need to either add or delete personnel, please fill out a change of personnel form and return to the ARC Coordinator. Listed personnel must complete training by XXX date.

Jane Doe, James Doe

*I am aware that all research activity that uses animals must be approved by the Animal Research Committee (ARC) before it is initiated, that any change in animal use requires similar approval, that continuation of approval requires annual review, that animal use in projects not reviewed and approved is prohibited, and that records of animal use-related matters must be retained by the PI for three years after the study has ended. This form, together with any requested additional information, is submitted in compliance with these requirements.*

Investigator's Signature

Date

- By checking this box, I am electronically signing this renewal form.

## Notice of Change(s) in Animal Research Personnel

Wm. S. Middleton Memorial Veterans Hospital

### Directions:

**Return this completed form plus an electronic copy of your revised ACORP to the ARC Coordinator at arccoordinator@va.gov at the Research Office C-3127. PIs will receive notice of IACUC Approval via Memo. Please BOLD your responses to the questions below.**

Protocol Title and No.:

Principal Investigator:

	Yes	No	
Adding Personnel	<input type="checkbox"/>	<input type="checkbox"/>	Name(s):
Deleting Personnel	<input type="checkbox"/>	<input type="checkbox"/>	Name(s):

1. List all specific procedures from the protocol that new personnel will perform (*including euthanasia, administration of anesthesia, specific surgical procedures, monitoring of animals after surgery, administration of substances, etc.*):
  
2. List prior education, training, and/or experience **relevant** to the procedures listed above:
  
3. If no prior training or experience with stated procedures, how will new personnel be trained and by whom?
  
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  - d) UW Occupational Health and Safety Class (1 hour). Registration information can be found at: <http://www.rarc.wisc.edu/training/ocsafety.html>
  - e) If personnel will be working in BSL-2 conditions in VA lab space or within the ARF, they must take the VA's BSL-2 training. Please contact Randy Wolff (randal.wolff@va.gov) to set-up BSL-2 training.

**Responsibility of the Principal Investigator:**

As the Principal Investigator of the study cited above, I take full responsibility for ensuring that any personnel I add to my research staff has had or will receive adequate training/experience with the specific procedures the personnel is assigned to perform. I also ensure that new personnel WILL NOT perform any of the aforementioned procedures until this completed form has been approved by the VA Research Services administration.

*PI Signature:*

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***Admin Only:*** Certification that new personnel have completed the appropriate training courses

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- N/A or VA BSL-2 Training
- UW Occupational Health and Safety Program (includes Health and Immunization Questionnaire)
- WOC (Without Compensation) Paperwork Completed (Required for Non-VA Employees only)**  
(Paperwork available at the VA Research Office, C-3127)

**Approval Signature:**

*AO Research*

*Date*