

# University at Buffalo Institutional Animal Care and Use Program

## Policy on Amendment Submission During “Click Blackout Zones”

### Introduction

In accordance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, all activities with live vertebrate animals must be covered under an active approval by the Institutional Animal Care and Use Committee (IACUC). Federal regulations (USDA Animal Welfare Regulations and PHS Policy) require that the IACUC at each institution “review and approve, required modifications (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities.” The same federal regulations define the responsibilities of the IACUC regarding the review and approval of such changes, a process referred to as **amending a protocol**. Policies pertaining to the amendment review processes must be IACUC approved before implementation.

For significant changes to animal activities previously approved by the IACUC, the IACUC usually uses a combination of Full Committee Review (FCR) and Designated Member Review (DMR) to review amendments. Currently, **there are times when the electronic protocol software system (Click) does not allow submission of amendments. Times during which PIs are unable to submit amendments to approved protocols are acting as “blackout zones” that prevent seeking approval for protocol changes in a timely fashion.** This has been found to cause unnecessary research delays and could result in increased noncompliance if not addressed. It is caused entirely by computer programming deficits realized by use of Click!

The UB IACUC has developed an alternative method for submission of amendments during these blackout zones. The policy explains the process which will still utilize a combination of FCR and DMR.

### Definitions

**Full Committee Review (FCR):** Per federal mandate, FCR occurs when a quorum of IACUC members meets to discuss and vote on research or teaching protocols/amendments and any related IACUC business. IACUC meetings allowing FCR occur monthly at UB.

**Designated Member Review (DMR):** Protocol/amendment review is assigned to select IACUC members outside of an official IACUC meeting. At UB, amendments and revisions of protocols already reviewed via FCR are assigned to designated reviewers by the IACUC Chair. Designated reviewers may always recommend FCR if complicated issues are noted.

**“Click Blackout Zones”:** Times during which PIs are unable to submit amendments to approved protocols utilizing the currently programmed submission options. These include:

- The time period after a triennial renewal is created and/or submitted extending from day of creation/submission until final approval of the protocol.
- Whenever another amendment on the same protocol is under review. Click is not programmed to allow for review of more than one amendment at a time.

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Revised:--

## Policy

This policy outlines the requirements and steps for submitting UB IACUC Protocol Amendments during “Click Blackout Zones.”

1. “Blackout Zone Amendments” are **NOT** to be placed:
  - a. When a “regular” amendment may be submitted electronically within Click
  - b. When an IACUC Protocol has lapsed (expired)
  - c. If such an amendment would contradict an amendment from the same protocol that is already under review
  
2. “Blackout Zone Amendments” **ARE** encouraged during these circumstances:
  - a. Triennial review of the protocol has been created and/or submitted blocking the submission of further amendments to what is still an approved protocol
  - b. Another non-contradictory amendment is pending for the same approved protocol
  
3. The **procedure for amending an approved protocol during a “Click Blackout Zone”** is as follows:
  - a. Complete a **Blackout Zone Amendment Form**, and attach it to your IACUC Protocol via a non-private comment.
  - b. **Send an email to [iacuc@research.buffalo.edu](mailto:iacuc@research.buffalo.edu)** to notify the IACUC Office that you have submitted this form. Be mindful that after-hours/weekend requests may not be reviewed until the next business day.
  - c. If an amendment submitted in this fashion conflicts with another pending amendment, you will be notified that the amendment cannot be approved in this fashion.
  
4. Following receipt of a Blackout Zone Amendment Form, the IACUC Office Staff takes the following actions:
  - a. Email the Blackout Zone Amendment Form to all IACUC Committee Members as an attachment (exclude members if the amendment pertains to a protocol in which they are an active member).
  - b. IACUC Members are given 3 business days for FCR per standard policies.
  - c. Following FCR, the amendment will be assigned to selected members for DMR.
  - d. Reviewer comments resulting from FCR and DMR will be formally relayed to the PI in a letter drafted by the IACUC Office and attached to the Protocol History in Click.
  - e. The PI shall make any required edits to the Blackout Zone Amendment Form based on reviewer comments and resubmit by attaching to the protocol via non-private comment (and notifying the IACUC Office via email).
  - f. The IACUC Office shall once again assign DMR. Once members assigned to DMR have approved the amendment, the IACUC Office will formally notify the PI by sending an Approval of Submission Letter, visible on the Protocol History in Click per standard amendment approval policies.

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Revised:--

5. Following approval of changes via Blackout Zone Amendments:
  - a. Approved changes may begin immediately following receipt of IACUC's Approval of Submission Letter.
  - b. PIs will be given 90 days to file a follow up amendment in Click to establish congruency between the changes made by the Blackout Zone Amendment and the visible approved protocol in Click.
  - c. Allowance for changes made via Blackout Zone Amendments expire after 90 days.
  - d. Any changes made via Blackout Zone Amendments will be noted in the next IACUC meeting agenda so that the IACUC is aware of the amendments approved this way.


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University at Buffalo Institutional Animal Care and Use Committee (IACUC)


# BLACKOUT ZONE AMENDMENT FORM, Page 1

<b>Principal Investigator:</b>	
<b>IACUC Project Number:</b>	
<b>Reason for Blackout Zone Amendment:</b> <i>Delete whichever reason does NOT apply!</i>	<ul style="list-style-type: none"> <li>▶ A Triennial Review of this approved protocol has been created or submitted (and the approved protocol has NOT yet lapsed).</li> <li>▶ Another amendment is currently pending, and its content is not contradictory to this amendment in any way</li> </ul>

**NATURE OF CHANGE:** Please check all that apply.

<b>Type of Changes Proposed in Amendment-Check gray columns for any changes that apply!</b>			
	<p><b>Addition of Animal Numbers:</b> ____  <i>Add number!</i></p> <p><i>Scientifically justify the requested number of animals below.</i></p>		<p><b>Changes in Experiments and Procedures</b></p> <p><i>Fully explain all changes below.</i></p>
	<p><b>Change in Personnel</b></p> <p><i>List name(s) in space below. Indicate which procedures they will be performing in the approved protocol.</i></p> <p><i>NOTE: All new personnel must enroll into the OHMP (Occupational Health Monitoring Program) and take all required trainings.</i></p>		<p><b>Change in Animal Housing</b></p> <p><i>Add new vivarium locations, new specialty housing (examples: High Level Barrier, ABSL-2) and non-vivarium locations (example: lab testing spaces). Included building names and room numbers. Add all changes below.</i></p>

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<b>Use of Hazardous Agents</b>	<b>Other Changes</b>
<p><i>Check this box if any change involves the use of a hazardous agent (examples: human cells, infectious agents, chemicals, toxins, carcinogens, radiation, laser, recombinants, nanoparticles, etc.). This will prompt review by Environment, Health and Safety Staff.</i></p>	<p><i>Please specify <b>HERE</b> if changes made fall into any other category.</i></p> 

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## **BLACKOUT ZONE AMENDMENT FORM, Page 2**

In the space below, provide details AND reasons for proposed changes/additions. Proposed changes must be clearly identified and contrasted with the approved protocol.

### **Required Attestations:**

1. I hereby attest that I also understand that changes approved via Blackout Zone Amendments will expire within 90 days of approval UNLESS an official protocol amendment is made and approved.
2. I have fully reviewed and understand the UB IACUC Policy on Amendment Submission During Click Blackout Zones.

Signature of Principal Investigator:	Date:
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