**Create a Concern**



**Work Instructions:**

Anyone possessing an IACUC user role (*Study staff*, *IACUC Coordinators*, *Directors*, *Committee Members*, etc.) can enter a concern or report of non-compliance about the research facilities or personnel involved in the care and use of animals. Concerns can arise because of facility inspections, IACUC program reviews, or audits of approved protocols. Additionally, a user can submit a concern at any time that is not related to a specific IACUC event (ad hoc).

The workflow starts with a Click IACUC user entering a concern into the system. The user will either complete a short or long version of the concern form depending on their role.

* Short form:
For *Principal Investigators*, *Ancillary Reviewers*, *Veterinarians*, and any other user that is not part of the IACUC to enter basic concern information.
* Long form:
For IACUC staff (*Coordinators* and *Directors*), *Committee Members*, *Inspection Officers*, and *Post-Approval Monitoring (PAM) Coordinators* to enter additional information such as the source of the concern (facility inspection, program review, etc.) and any deficiency details.

**Work Instructions: Create a Concern – Short Form**

1. Log into the Click Portal and click on the **IACUC** tab in the top navigation menu.
2. Click the **Create Concern** button.
3. Complete the **SmartForm**, and then click **OK**. **Note:** *Required fields are marked with an asterisk (\*).*
4. Click **Submit**. Select a **Committee** to review the **Concern**, and enter **Comments** and/or **Supporting Documents** as needed. Click the **OK** button; the concern moves to the **Pre-Review** state*.*
 **Note:** *Only IACUC Coordinators, Directors, and PAM Coordinators can submit a Concern started with the short form. If you do not hold one of those roles, your Concern will appear in the IACUC Coordinator’s Inbox, and they will submit the Concern on your behalf.*

**Work Instructions: Create a Concern – Long Form**

1. Log into the Click Portal and click on the **IACUC** tab in the top navigation menu.
2. Click the **Create Concern** button.
3. Complete the **SmartForms**, paying special attention to the fields listed below. Click the **Continue** button to save your work and move between pages.

**Note:** *Required fields are marked with an asterisk (\*).*

 **Basic Information**

**Question 2 - Select the category**The choices are Administration or Animal Welfare.

**Question 3 - Select the source**The choices are Ad Hoc, Concern Investigation, Facility Inspection, PAM Audit, Program Review, or Other.

**Question 4 - Is this a deficiency?**Select either Yes or No. Refer to your institution’s policies for determining if a Concern is actually a Deficiency. If you select Yes, a Deficiency Details page is added to the SmartForm.

 **Identification**

**Question 1 - Describe the Concern**Provide specific and verifiable details that will help the IACUC investigate your Concern. Include the following information if available: personnel involved, protocol details, location and time of concern, and animal affected.

**Question 2. Identify any associated Principal Investigators**Click the Add button to search for and select the *PI*.

**Question 3 - Identify any related IACUC research protocols**Click the Add button to search for and select the appropriate protocol(s).

**Deficiency Details**

**Question 4 - Add related concerns**Click the Add button to search for and select the appropriate Concern(s).

**Regulatory Context**

**Question 1. Add any associated departures from the Guide**If you click Add, the Add Departure SmartForm opens. Complete the SmartForm, and then click OK. Click OK and Add Another if there are multiple Departures to be added.

1. Click the **Finish** button to return to the workspace.
2. Click **Submit**. Select a **Committee** to review the **Concern**, and enter **Comments** and/or **Supporting Documents** as needed. Click the **OK** button; the concern moves to the **Pre-Review** state*.*

