



Protocol Flowchart – Submission Guidelines

Every animal protocol must include a protocol flowchart that provides a comprehensive overview of the experimental procedures to be used. The protocol flowchart should be designed to be a stand-alone document. Someone not at all familiar with your protocol should be able, using the chart, to know exactly what is happening to the animals involved in your study (what, when, how, to which animal). Similarly, your protocol flowchart should be used as a guide for your research team; members of your team can quickly refer to the current approved version of the flowchart to confirm which procedures may be conducted under the terms of the approved protocol.

Your protocol flowchart is considered a component of your overall animal protocol. It will be reviewed and approved by the IACUC as such. Please be careful to ensure that all of the elements included in your protocol application are captured accurately and appropriately within the flowchart. The IACUC committee will not approve your protocol unless the flowchart is accurate. You are responsible for rectifying discrepancies between the flow chart and the written part of the protocol. Only those activities specifically designated in the **flowchart** will be considered approved activity for your protocol.

Protocol amendments will require a revised protocol flowchart. The amended flowchart must reflect the overall flow of experimental procedures in your protocol including the changes approved in the amendment. Your amended flowchart should clearly designate an amendment number and date so outdated versions can quickly be identified and replaced.

It may be helpful to print your flowchart on colored paper; each newly amended and approved flowchart should be printed on a new color which will serve as a visual aid in ensuring that all members of your research team are using the correct, updated flowchart.

A copy of the most current approved version of your protocol flowchart should be included in your study documentation and at the front of each active medical record being used in your study. Protocol flowcharts should be readily available for review by your research team, veterinary staff, animal staff, and inspectors reviewing your protocols.

Required Elements in a Protocol Flowchart:

- **Identifiers:** Protocol Name, PI name, Date, Amendment Number
- **Flow:** A sequential flow and brief but concise description of each procedure (minor or major) being conducted on animals

- **Experimental vs. Control:** Delineate procedures for experimental vs. control groups
- **Numbers:** Indicate number of animals being used in each arm of the study (i.e. n=8, etc. per group) with total number for study so designated (i.e. total = 100, 25/group, 4 groups). Please be specific about the number of animals at each experimental endpoint.
- **Timepoints and Intervals between events:** Indicate specific time points for each procedure noted in flowchart. If there are gaps between procedures (e.g. arrival and surgery, or surgery and euthanasia) the chart should state the interval or range of possible intervals between procedures.
- **Exceptions:** Routine, standard care for animals need not be mentioned (e.g. care that is not considered specific to experimental process, routine animal husbandry). Exceptions from standards of care **do** need to be noted (e.g. special diet or medications or toxins administered).
- **Procedure detail:** In case of surgical intervention or biopsy, more detailed information must be provided, for each intervention, in a brief narrative following the flowchart. The information must include the following:
 - **Anatomical markers:** Indicate the pertinent anatomic location of the surgery or biopsy.
 - **Anesthesia:** When anesthesia of any kind is being used, indicate whether sedation, local anesthesia, general anesthesia, then drugs and dosage. Indicate approximate time animal will be under anesthesia.
 - **Analgesia:** State type of analgesia (drugs and dosage), how often given, interval between administration and duration of administration.
 - **Monitoring:** Indicate monitoring plan, including how often animals will be monitored and duration of monitoring.