GUIDELINES ON REPORTING ADVERSE EVENTS

PURPOSE:

To establish and define the system for reporting adverse events regarding IACUC protocols.

GUIDELINES:

The following guidelines serve to outline the process for reporting adverse events on an animal use protocol.

WHAT IS AN "ADVERSE EVENT"?

The Liberty University IACUC has defined an adverse event as any event that is not expected or is not specifically included in the approved IACUC protocol that occurs on a protocol.

EXAMPLES OF REPORTABLE ADVERSE EVENTS

- Unexpected death of a study animal
- Unexpected clinical signs of pain, discomfort, or illness
- Unauthorized access to study animals or facilities
- Escaped animals
- Facility issues (flooding, power outages, temperature extremes, HVAC interruptions)
- Administration of unapproved substances
- Administration of substances beyond the approved range
- Unapproved procedures performed
- Excess samples collected (beyond approved amount or occurrences)
- Unapproved euthanasia performed or failure to confirm death

REPORTING PROCESS

1. Immediately contact the attending veterinarian, dcmguirt@liberty.edu or 434-582-2485, if an event is ongoing or has the potential to impact the health and welfare of animals or personnel.
2. All adverse events must be reported to the IACUC within 48 hours of the event by emailing iacuc@liberty.edu with a completed Adverse Event Report Form.
    a. If appropriate for the health and well-being of the laboratory animals, consult a veterinarian regarding their care.
3. The Principle Investigator (PI) is solely responsible for reporting adverse events.
4. Once the IACUC receives the report, it will be reviewed in its entirety, and additional information may be requested.
5. The attending veterinarian along with the IACUC chair will determine any necessary actions to take.
6. The IACUC will relay any required actions to the PI and work to ensure tasks are accomplished in a timely fashion.
7. The PI will be informed in writing once no further action is required.