# UTHSCSA IACUC Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td><strong>A</strong></td>
<td><strong>Adulteration</strong> Addition of a substance that is used as an addition to another substance (does not imply impure, cheap, or unnecessary ingredient).</td>
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<td><strong>B</strong></td>
<td><strong>Biologic</strong> Section 351 of the Public Health Service (PHS) Act defines a biological product as a “virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, … applicable to the prevention, treatment, or cure of a disease or condition of human beings.” FDA regulations and policies have established that biological products include blood-derived products, vaccines, in vivo diagnostic allergenic products, immunoglobulin products, products containing cells or microorganisms, and most protein products. Biological products subject to the PHS Act also meet the definition of drugs under the Federal Food, Drug and Cosmetic Act (FDC Act). Note that hormones such as insulin, glucagon, and human growth hormone are regulated as drugs under the FDC Act, not biological products under the PHS Act.</td>
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<tr>
<td><strong>Biopsy</strong></td>
<td>The removal of a piece of tissue from a live animal.</td>
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<td>If the collection of tissue involves entering a body cavity, then the biopsy shall be considered a <strong>major surgery</strong> (e.g. liver wedge biopsy). The exception is the use of transcutaneous Tru-cut® biopsy needles, fine needle aspirates, or similar techniques of collection samples of organs within a body cavity.</td>
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<td>If the collection of superficial tissue (e.g. skin) is large relative to the animal size, then the biopsy shall be considered a <strong>minor surgery</strong>.</td>
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<td>The collection of a superficial biopsy may not necessarily require general anesthesia and may only require subcutaneous instillation of a local anesthetic (e.g. bupivacaine). If appropriate wound care to prevent infection, biopsies may be allowed to heal by “second intention”, i.e. wound closure may not be necessary with appropriate and frequent cleaning of the area. Principal Investigators will consult with LAR veterinarians regarding the best possible anesthesia and wound care for the specific biopsy technique.</td>
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<tr>
<td><strong>Body cavity</strong></td>
<td>Is defined as the abdominal, thoracic, cranial, synovial, or bone marrow cavities, i.e. those chambers not immediately associated with the outside world.</td>
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### Clinical Use/Purpose
(Also referred to as Therapeutic Use/Purpose)

Manipulations or interventions used for:
- the clinical prevention or treatment of illness, disease or injury (such as health assessment, veterinary medical care, or emergency medications)
- to prevent or reduce/eliminate animal pain or distress (such as anesthesia or analgesia)
- euthanasia

### *DLAR Managed Areas*

The IACUC has established criteria to define animal use or housing areas that are the responsibility of the Department of Laboratory Animal Resources (DLAR). In these areas, DLAR:
1. approves the species to be housed in the area, no matter whether the University has assigned the space to DLAR or a non-DLAR department,
2. charges per diem or technical fee for vertebrate species,
3. is financially responsible for minor maintenance and repairs,
4. is responsible for daily oversight of the animals when the area is actively in use (note that DLAR may delegate aspects of husbandry— including documentation of daily observation),
5. controls access to the area, and
6. approves any renovations, new construction, major HVAC changes, etc. to any part of the area prior to the start of the project. DLAR management must approve the use of a room prior to occupancy.

### Death as an Endpoint

When mortality is an experimental endpoint.

### *Department Managed Procedure Room*

The IACUC allows Departments or Institutes to manage animal use areas that are the responsibility of the Department or Institute Chair. This is a location outside of the DLAR managed vivarium that does not meet the minimum criteria for an animal housing area and the animals will held in the area for less than 12 hours and not overnight; must comply with IACUC Policy

### *Deviation*

Deviations are one type of violation and include any variance in the research practices from originally approved proposals that adversely affect animal welfare.

### *Deficiency*

Deficiencies are one type of violation and include any condition of animal care or treatment that is not in compliance with the Animal Welfare Act (or its regulations and standards); or established by assurance, regulation, policy / procedure with other applicable entities.

Deficiencies are distinguished as either significant deficiencies or minor deficiencies.

A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals.

Deficiencies involving the research facility’s program for humane care and use of animals or the animal facilities including animal study areas must contain a reasonable and specific plan and schedule with dates for correcting each deficiency.

### Drug

A substance recognized by an official pharmacopoeia or formulary.

A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

A substance (other than food) intended to affect the structure or any function of the body.

A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.

Biological products are included within this definition and are generally covered by the same laws.
and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process).

### E

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<th><strong>Euthanasia</strong></th>
<th>the humane destruction of an animal accomplished by a method that produces rapid unconsciousness and subsequent death without evidence of pain or distress, or a method that utilizes anesthesia produced by an agent that causes painless loss of consciousness and subsequent death (AWR)</th>
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### Expired Medical Materials

Materials such as drugs, fluids, or sutures that have exceeded the “to be used by” date or “expiration” date.

### Experimental Endpoints

The scientific aims and objectives of the study. Experimental endpoints are used to determine when animals have completed the study, and can be transferred or euthanized.

### F

| **Freund’s Adjuvant** | Complete - is a water in oil emulsion containing dried Mycobacterium butyricum which is used to enhance antigenicity and a greater immune response. *(may be abbreviated as either: CFA or FCA)*  
Incomplete - has the same oil/surfactant mixture as FCA but does not contain any mycobacteria. It is frequently used to boost animals that received a primary antigen injection in FCA, but it can be used as the adjuvant for the primary injection as well. *(may be abbreviated as either: IFA or FIA)* |
| --- | --- |

### H

| **Housing Room** | Any location were vertebrate animals are maintained for more than 12 hours or overnight.  
The Guide defines minimum specifications including acceptable temperature and humidity ranges, appropriate light cycles, required security, sanitizable room surfaces, and HVAC requirements. |
| --- | --- |

### Humane Endpoints

Criteria used to end experimental studies before all experimental endpoints have been met in order to avoid or terminate unrelieved pain and/or distress in animals. An important feature of humane endpoints is that they should be set with the goal of meeting the key study objectives even though the study is ended at an earlier point. Ideally, humane endpoints are sought that can be used to end studies before the onset of pain and distress. Humane endpoints are used to determine when animals can be removed from the study, treated, or euthanized.

### I

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<tr>
<th><strong>Investigational Use/Purpose</strong></th>
<th>see Research Use/Purpose</th>
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### M

| **Major survival surgery** | Both the Animal Welfare Act and the Guide of the Care and Use of Laboratory Animals state that a "major surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function."  
The Guide goes on to include: “involves extensive tissue dissection or transection  
Examples of a major surgery include, but are not limited to:  
  - Laparotomy, including laparoscopy**.  
  - Thoracotomy. |
| --- | --- |
- Craniotomy.
- Thyroidectomy
- Arthrotomy and joint replacement, excluding arthroscopy.
- Orthopedic procedures (e.g. limb amputation).
- Injury models (e.g. head trauma)
- Nerve/muscle transection.
- Eye surgery with corneal incision.
- Significant soft tissue transection.

**Laparoscopic procedures - If the IACUC, after thorough review, determines that the surgical procedure only penetrates but does not expose a body cavity and that the procedure does not produce substantial impairment, the IACUC may conclude that it is not a major operative procedure.**

Major surgeries require appropriate anesthesia, analgesia, sterile technique, wound closure (sutures, staples, tissue glue, and/or bandaging), postoperative wound care, and more extensive postoperative monitoring of the animal until healed and/or achieved a normal health status. The IACUC protocol or amendment must be clear in regards to who is directly responsible for post-operative care, e.g. appropriately trained laboratory personnel or DLAR clinical staff.

### Minor survival surgery

The *Guide* states that a “minor survival surgery does not expose a body cavity and causes little or no physical impairment; this category includes … any procedure routinely done on an “outpatient” basis in veterinary clinical practice).”

Other examples of minor surgical procedures include, but are not limited to:
- Peripheral vessel cannulation (e.g., percutaneous or vascular cut-down approach to an artery or vein (jugular or femoral).
- Tissue biopsy not involving surgical exposure of a body cavity (e.g. skin, muscle, via endoscopy).
- Superficial biopsy involving a scientifically justified area large relative to animal size
- Skin or subcutaneous implants
- Surgical repair of a superficial injury
- Arthroscopy
- Oral surgery and tooth extractions not involving bone
- Closed castrations
- Tooth extraction
- Wound suturing

Minor surgeries require appropriate anesthesia, analgesia, sterile technique, wound closure (if applicable, to include sutures, staples, tissue glue, and/or bandaging), postoperative wound care, and frequent postoperative monitoring of the animal until healed and/or achieved a normal health status. If post-operative care is necessary, the IACUC protocol or amendment must be clear in regards to who is directly responsible for post-operative care, e.g. appropriately trained laboratory personnel or DLAR clinical staff.
**Moribund Condition**

When an animal is “in the state of dying,” or “at the point of death.” Moribund animals may experience pain and distress during progression to a moribund condition.

A moribund condition may be an appropriate humane experimental endpoint for some studies where there is the induction of severe disease states and high rates of mortality. Pre-emptive euthanasia of moribund animals can prevent further pain and distress.

**Non-surgical procedure**

all non-invasive procedures or invasive procedures limited to entering a preexisting orifice that does not involve cutting with a scalpel, scissors, biopsy forceps, punch biopsy, laser, cautery, direct tissue damage by cold (liquid nitrogen) or any comparable device or technique.

**Non-survival surgery**

(also referred to as a Terminal Procedure)

any surgical intervention in which the animal will not recover from anesthesia (euthanized before waking).

**Noncompliance**

Conducting research in a manner that 1) disregards or violates federal regulations or institutional policies and procedures applicable to use of animals, or 2) failure to follow the research practices listed in the IACUC-approved proposal.

Noncompliance is characterized by severity of the event (i.e., serious or not serious) and the pattern of like or similar events (continuing or not continuing). Noncompliance that is determined by the IACUC to adversely affect animal welfare is also considered a deviation.

**Pharmaceutical grade compound**

Any active or inactive drug, biologic, reagent, etcetera, which is approved by the FDA for which a chemical purity standard has been written or established by any recognized pharmacopeia, which is a book or a compendia, such as the US Pharmacopeia [USP], the National Formulary [NF], the British Pharmacopoeia [BP], the Pharmacopoeia of the Council of Europe [EP]. Note that both the USP and the NF have combined their standards into one compendia [http://www.usp.org/usp-nf].

**Principal Investigator**

This title identifies the individual responsible for the conduct of the project (event when the project does not involve research). This responsibility includes the intellectual conduct of the project, fiscal accountability, administrative aspects, and the project's adherence to relevant policies and regulations.

**Procedures that are expected to or may cause more than momentary pain or distress**

1. Physical or Chemical restraint lasting more than 4 hours
2. Diagnostic procedures such as laparoscopy or needle biopsies
3. **Surgical** procedures (e.g., biopsy, laparoscopy, etc.)
4. Ocular blood collection in mice
5. Terminal cardiac blood collection
6. Ascites tumors for monoclonal antibody production
7. Complete Freund’s Adjuvant
8. Tumor growth
9. Research that requires continuation until clinical symptoms are evident or death occurs

10. Ocular or skin irritancy testing

11. Food or water deprivation beyond that necessary for ordinary pre-surgical preparation

12. Application of noxious stimuli such as electrical shock if the animal cannot avoid/escape the stimuli and/or it is severe enough to cause injury or more than momentary pain or distress

13. Tail snip if more than 5mm or if done after weaning (21 days old in rats or mice)

14. Toe clip if done after 12 days old

| *Procedure Room | The entire room meets the minimum specifications for an animal procedure room but does not meet specifications for animal housing room. |

| R | Reduction | Involves strategies for obtaining comparable levels of information from the use of fewer animals or for maximizing the information obtained from a given number of animals (without increasing the pain or distress) so that in the long run fewer animals are needed to acquire the same scientific information. |

| | Refinement | Refers to modifications of husbandry or experimental procedures to enhance animal well-being and minimize or eliminate pain and distress. |

| | Replacement | Refers to methods that avoid using animals. Including: |
| | | - Absolute replacement (i.e., replacing animals with inanimate systems such as computer programs) |
| | | - Relative replacement (i.e., replacing animals such as vertebrates with animals that are lower on the phylogenic scale) |

| Research Use/Purpose | Manipulations or interventions used to accomplish the scientific aims of the study. (Examples include breeding, performing a procedure, administering a test article, etc) |

| Restraint | Physical (manual or mechanical) or chemical (anesthetic or tranquilizer not used in conjunction with surgery) means to limit some or all of an animal’s normal movement or behavior. |

| S | *Significant Deficiency | See definition of Deficiency |
**Substantial impairment of physical or physiologic function**

the circumstance where the animal is not expected to be normal after a reasonable postoperative recovery period. Examples include, but are not be limited to those procedures permanently and significantly affecting ambulation, physiology, the immune system, and mentation.

**“Survival surgery”**

means that the animal recovers from anesthesia following a surgical procedure. In accordance with the AWARs and the Guide all survival surgeries require aseptic technique.

**“Surgery”**

creation of a novel opening in the body or of a pre-existing orifice that involves cutting with a scalpel, scissors, biopsy forceps, punch biopsy, laser, electrocautery, or direct tissue damage by cold (liquid nitrogen) or any comparable device or technique.

**“Terminal Procedure”**

(also referred to as a non-survival procedure)

any procedure in which the animal is under anesthesia and will be euthanized before waking.

**Therapeutic Use/Purpose**

See Clinical Use/Purpose

**USDA-covered Species**

(Also referred to as regulated species)

USDA regulations pertain to all vertebrates except the following:

- Birds bred for use in research
- Rats of the genus Rattus bred for use in research
- Mice of the genus Mus bred for use in research
- Horses not used for research purposes

**“Violation”**

A violation of the standards promulgated by the AWA or assurances required by federal agencies.