Performance Standard: Duke believes that reuse, refinement, and reduction should be balanced on a case-by-case basis. Duke encourages reuse of animals which meets the needs of research, assures the principles of the 4 R’s, and engages effective animal welfare coping strategies.

Background: The Animal Welfare Act/Regulations (2.31(d)(1)(x)), USDA AC Policy #14, USDA Animal Welfare Inspection Guide (7-26 and 7-38), and The Guide for the Care and Use of Laboratory Animals (Guide), 8th Edition (page 5 and 30), discuss animal re-use. When assuring necessary animal welfare provisions, animal reuse may serve as an appropriate experimental refinement and reduction strategy. The goals of animal reuse must assessed on a case-by-case basis. Key considerations in the decision making process to reuse animals includes:

- Reduction should not be a rationale for reusing an animal or animals that have already undergone experimental procedures, especially if the well-being of the animals would be compromised (The Guide, pg. 5).
- Whether a procedure is major or minor should be evaluated on a case-by-case basis (The Guide pg. 30).
- Regardless of classification, multiple major surgical procedures on a single animal should be evaluated to determine their impact on the animal’s well-being. Multiple major surgical procedures on a single animal are acceptable only if they are (1) included in and essential components of a single research project or protocol, (2) scientifically justified by the investigator, or (3) necessary for clinical reasons (The Guide pg. 30).
- Conservation of scarce animal resources may justify the conduct of multiple major surgeries on a single animal, but the application of such a practice on a single animal used in separate protocols is discouraged and should be reviewed critically by the IACUC (The Guide pg. 30).
- Cost savings alone is not an adequate reason for performing multiple major survival surgical procedures (The Guide pg. 30).
- No USDA-covered species will be used in more than one major operative procedure from which it is allowed to recover, unless (AWR 2.31(d)(1)(x), AC Policy #14, USDA Inspection Guide pg. 7-26 and 7-38):
  - Justified for scientific reasons by the principal investigator, in writing, described in one protocol, and approved by the IACUC;
  - Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian (spaying, neutering, descenting, or an emergency major operative procedure for health reasons); or
  - Exemption approval by the APHIS Administrator for individual animal use in two separate protocols with major operative survival procedures.
- Facilities should track USDA-covered species to ensure that they are not used for another survival surgery, unless approved by the IACUC or APHIS. Tracking must include written documentation to prevent their use in an unapproved second survival.
surgery, examples include: health records, individual animal records, cage cards, surgery records, and investigator logs. (USDA Inspection Guide pg. 7-26 and 7-38 and AC Policy #14)

**APPLICABILITY:** This policy applies to reuse of animals on different Duke Protocols form the protocol to which the animal was originally assigned. Other animal disposition modalities are outlined in the policy “Disposition of Research and Teaching Animals.”

**ROLES:**
- **DLAR/DLC:** will review and approve request for animal reuse as described in this policy.
- **OAWA:** will facilitate processing of protocols and amendments which may be related to animal reuse as outlined in this policy.
- **IACUC:** will review protocols and amendments which may be related to animal reuse as outlined in this policy; and determine disposition of the animal under consideration (includes reuse and final disposition).

**DEFINITIONS:**
- **Used:** Animals that are used are counted against the protocol as described in the policy “Counting Animals.”
- **Survival surgical procedure or non-surgical procedures:** in general are animals that are determined to be in a pain and distress category C, D, or E as outlined by the policy “Categories of Potential Pain or Potential Distress (The Duke Animal Program Definition).” If animals are used in procedures (pain and distress category C, D, or E) this policy applies, unless otherwise described.
- **Situations for which this policy does not apply:** There are two potential categories of ‘not used:
  1. Animals that are determined to be in a pain and distress category B as outlined by the policy “Categories of Potential Pain or Potential Distress (The Duke Animal Program Definition).”
  2. Animals that undergo routine a veterinary procedure, or animals that receive a procedure to protect the health or well-being of the animal as determined by the attending veterinarian, or designee.

**POLICY:** Approval for reuse of an animal occurs as follows:

**IACUC Protocol**
- **Section B8** outlines the source of animals to be used in the described activity.
  - If the PI knows that animals will be transferred from another Duke protocol, the name and protocol number of the transferring PI is required. This allows OAWA veterinary reviewers and IACUC members the opportunity to confirm ‘transfer’ as a disposition option of the source protocol, ask additional questions regarding the use of these animals, and approve this source.
  - If the PI does not indicate animal transfer from another Duke protocol at the time of initial protocol submission, the steps for transfer approval outlined in this policy apply.
Amendments can be submitted, if required, to update Section B8.

- **Section E2. Final Disposition of Animals**
  - As a default on all protocol, live animals may be transferred to other approved Duke protocols to facilitate collaborative interactions and reduce overall animal usage and undue wastage. All transfers must be coordinated through DLAR (or DLC for lemurs), unless otherwise specified in the approved protocols.
  - Other disposition options are also captured in Section E2.
  - Amendments can be submitted, if required, to update Section E2.

**NOTE:** This policy applies to all animal transfers regardless of the response to section B8 or E2 on the protocol application.

**Transfer Request Approval**

- **DLAR**
  - DLAR has an established process for animal transfer request. The request is made by the PI, or a representative to transfer the animal. The PI must identify the species and if the animals requested for transfer have been used (or scheduled for use) on the source protocol.
  - Not used animals: Transfer of experimentally naïve animals (i.e., not used on the source protocol) does not require further review.
  - Animals that have undergone a **Survival surgical procedure or non-surgical procedures**: Transfer of ALL animals that have undergone a survival surgical procedure or non-surgical procedures on the source protocol requires DLAR veterinary approval prior to transfer approval.
    - For USDA-covered species: a notification is sent to OAWA, IACUC, and DLAR leadership, with transfer and use details, for consideration prior to approval. Protocol amendments may be required by the DLAR veterinarian reviewing the request or OAWA, IACUC, and DLAR leadership, prior to approval.
    - Approval of a transfer request is based on appropriate experimental refinement and reduction alternative(s) to meet scientific needs, as well as considering the welfare of the animals involved.
    - A transfer request can be denied by any reviewer and does not require IACUC action. In this case, the PI would have to receive IACUC approval of an amendment detailing their request and scientific justification for transfer.
    - **NOTE:** Reuse of USDA covered species that has undergone or has the potential to undergo more than one major survival surgery, as determined by the veterinarian reviewer or OAWA, IACUC, or DLAR leadership: MUST be described and approved in the IACUC protocol. In addition, approval MUST be in accordance with the AWA/AWR/AC Policies and related regulatory documents.
DLC
- Lemurs maintained at the Duke Lemur Center are only used for minimally invasive procedures; the DLC Research Committee approves all proposed DLC lemur use & reuse activities.

Tracking
- **IACUC Protocol:** If known at the time of protocol submission, Section B8 and E2 of the protocol template will outline the PI/protocol number of the animals transferred from another Duke protocol and/or special animal disposition request. Additionally information may be captured in a protocol amendment.
  - **DLAR:**
    - Animal transfer request and information on used animals are tracked by the animal management database.
    - Written records outlining major survival surgeries are maintained in one or more of the following locations: health records, individual animal records, cage cards, surgery records, or investigator logs.
- **DLC:**
  - The DLC Research manager tracks all animal use.
  - Written records outlining major survival surgeries are maintained in the health records or individual animal records.

Veterinary care
- Any procedures (major or minor) performed on an animal as part of routine veterinary care or to protect the health or well-being of the animal as determined by the attending veterinarian, or designee, do not count as animal reuse. Examples: spaying, neutering, de-scenting, or an emergency major operative procedure for health reasons.

Tissue sharing with the Duke Research Community
- The IACUC Protocol Template (Section E4) does allow for tissue sharing of post-euthanized animals. IACUC approval for tissue sharing is determined on a case-by-case bases as outlined in the policy "When an Animal Use Protocol is Required (or when a protocol is not required)."