The University of Pennsylvania Institutional Animal Care and Use Committee (IACUC) has developed the following policy to provide guidance to Principal Investigators (PI) regarding the requirements for establishing and the best practices for maintaining “core” protocols and facilities.

**Animal Core Protocol** is a protocol that describes all procedures that are performed as a service by the Animal Core Facility and includes a list of personnel authorized to perform the procedures. The Core Protocol must also include a justification why the establishment of a “core” is necessary.

**Animal Core Facility** is a facility/laboratory that provides services to the research community pertaining specifically to animal care and use procedures. This may include breeding, tissue harvest, surgery, behavioral testing, or other procedures.

**IACUC REVIEW AND APPROVAL OF A CORE PROTOCOL**
A “core protocol” is reviewed as any other animal research protocol, but there are special considerations that the PI should address when designing and writing a core protocol.

- **Pain and/or distress categories** of the core protocol should be listed as the highest level for any procedure listed on the core protocol. Additionally, if an “affected” animal transferred to the core protocols is considered to be categorized as having an elevated pain and/or distress level, then the core protocol must also be listed at that elevated category. For instance, the transfer of a severely paralyzed animal (“Category C”) to the core protocol will require the core protocol to be approved as a “Category C” protocol prior to transfer. Please see Assigning Pain and Distress Levels to Animal Use Protocols for guidance.

- **Animal use procedures** are the hallmark of core protocols. Descriptions should be clear and concise, with specific reference to the phenotype (if relevant) of the animals to be used, how the animals will be manipulated or tested, the duration of the procedures, and the experimental time points and humane endpoints to the procedure. The qualifications of core personnel to the core procedure should be clearly described.

- **Core SOPs for procedures** relevant to animal care and use (e.g. should be attached to core protocols and to the protocol submission of core users. This practice may minimize delays in the protocol review process.

- **Animal numbers must be listed and justified** in the core protocol submission. Animal numbers may represent a reasonable estimation from previous year or protocol period. If cage capacity of the facility or personnel is the determining factor of the animal numbers, then the description should include plans to limit workload or to delineate expansion through either addition of core personnel, facility cage space, or other resources. Animal to be tested and those used in a breeding colony should be described separately.

- **Breeding cores** should reference the protocols that they will supply and describe a plan to document the transfer of the specific animal numbers used on other protocols. Not doing so may lead to duplication of animal numbers. An estimation of the total size of the breeding colony is required. Animal to be tested and those used in a breeding colony should be described separately.
ANIMAL CORE PROTOCOLS AND FACILITIES

• **Specific contact information** for the core facility must be provided to the IACUC either directly or with the protocol submission. Required information includes the website of the core facility and the “Director” if that person is not the PI on the core protocol.

PERFORMING CORE PROCEDURES

A “core facility” may operate in various ways and still maintain the requirement that only procedures approved on a protocol may be performed on animals on that protocol (OLAW) by trained personnel also listed on that protocol (PHS Policy).

• **Procedures are performed on the animal core protocol.** Another PI may transfer his/her animals to the core protocol, via an official ULAR “Request to Transfer Animal Form”. If transport between facilities is required, then an animal re-location request form must be submitted.

  - For rodents moving between animal housing facilities, re-locations request should be sent to ULAR Diagnostic Services. Pinworm testing is required for all inter-facility moves. Rodents that are to re-locate from a conventional housing facility to a barrier-maintained facility must first be quarantined and undergo comprehensive testing for infectious agents.

  - Specific requirements may be found in “Quarantine Requirements for Mice Relocated on the University of Pennsylvania Campus” (ULAR website, Policies and SOPS), “Importation of Rodents from Non-Approved Sources for Acute Use” (pending ULAR SOP), and “Relocation of Rodents between Rooms, Suites, and Facilities in the School of Medicine”.

  - Once the animals are officially transferred to the core protocol, the procedures described in the core protocol may be conducted. If the animals are to be returned to the original PI, they must be officially transferred from the core protocol back to the original PI. The inter-facility movement process described above is not required for rodents being released from the Transgenic and Chimeric Mouse [Core] Facility.

• **Procedures are performed on the original protocol.** The PI may choose to include the description of the procedures which will be conducted in the animal core facility on his/her own “original” protocol. The IACUC suggests acquiring relevant standard operating procedures from the core facility for inclusion in the protocol. The PI should also include core facility personnel who will be doing the procedures, if they are not his/her own personnel. If transport between facilities is required, then movement of personnel between UPenn facilities must adhere to ULAR SOP 5.0 “Movement of Clinical Care, Diagnostic Services, Animal Care and Research Personnel through Rodent Holding Areas” (ULAR website, Policies and SOPS).

• **Other options may be submitted to the IACUC for approval**, with consultation with ULAR Procurement and ULAR Diagnostic Services where appropriate.

  *Any procedure performed on an animal must be described in the IACUC-approved protocol to which the animal is assigned and only appropriately trained personnel listed on that approved protocol may perform those procedures.*

PRINCIPAL INVESTIGATOR RESPONSIBILITIES
ANIMAL CORE PROTOCOLS AND FACILITIES

1. PIs of the “original protocol” using the services of an Animal Core Facility must ensure that the animals are on a protocol which describes the procedures being performed and includes the personnel who will be performing it.

2. The PI of the core protocol shares the responsibility to assure that the approved animal use procedures are performed on the appropriate protocol.

3. If the PI is transferring animals to the Animal Core Protocol, official transfer paperwork must be submitted and approved by ULAR Procurement prior to moving animals and performing the core procedures.

4. Personnel physically moving animals between the original facility and the core facility must strictly adhere to “Relocation of Rodents between Rooms, Suites, and Facilities in the School of Medicine” and ULAR SOP 5.0 “Movement of Clinical Care, Diagnostic Services, Animal Care and Research Personnel through Rodent Holding Areas” describing animal movement and personnel movement between facilities.

5. While animals are on the animal core protocol, no procedures described in the original PI’s protocol may be performed unless they are also specifically described in the core protocol.

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