

## **Guidelines for Institute/Center Collaborations involving Animal Activities Performed inside NIH Laboratories, Core or Shared Facilities**

This Guideline delineates the lines of accountability between an investigator and a collaborating core facility or laboratory. It is the goal of this Guideline to facilitate collaborations by:

- Establishing lines of accountability for collaborations which permit an investigator's animal to move to a core facility or collaborator's laboratory for a procedure without having to transfer ownership of the animal;
- Ensuring that all animal procedures on an Animal Study Proposal (ASP) are approved by the responsible Animal Care and Use Committee (ACUC);
- Ensuring consistent NIH ACUC review by ensuring that changes to ACUC approved animal procedures are not required of the collaborating core facility or laboratory to conduct the collaboration; and
- Ensuring that essential information on the nature of the collaboration, procedures to be conducted, etc. are present in an investigator's ASP prior to beginning a collaboration.

**Three (3) possible mechanisms exist for a Principal Investigator (PI) to conduct animal related collaborations with another NIH investigator, an established core (i.e. IC Centralized Transgenic Core, etc.) or shared facility (e.g. NIH Mouse Imaging Facility, etc.) facility:**

### **1) Transfer of Ownership:**

#### Considerations:

- Best used for "one-way", permanent animal transfers.
- Receiving collaborator must have an approved Animal Study Protocol (ASP) or ACUC approved SOPs (Core and Shared Facilities Only) and the animals received must be in accordance with the animal requirements and study objectives outlined in the approved ASP or SOPs.
- Animal transfer must be orchestrated through both IC's Animal Care and Use Committee administrative offices and both the shipping and receiving animal holding facilities. Additional transfer requirements (i.e. MTA, etc.) may be required depending on the animals transferred and programs involved;
- All animal transfers require the review and approval of the receiving Institute/Center's (IC) ACUC, as well as the receiving animal holding facility (i.e. pathogen status, space availability, etc.) prior to the transfer of the animals;
- Additional information can be found at ([http://oacu.od.nih.gov/ARAC/FinalATA607\\_fill.doc](http://oacu.od.nih.gov/ARAC/FinalATA607_fill.doc)).

#### Pros:

- Once ownership has been transferred, the PI transferring ownership has no accountability for the transferred animal(s) once the receiving collaborator and/or their program has accepted the animals.

Cons:

- Multiple short term transfers have resulted in the erosion of animal identification and cage card data;
- Multiple transfers can adversely impact the approved animal numbers on an ASP and IC USDA reporting numbers.

**2) Non-Transfer of Ownership with One Investigator Accountability:**

Considerations:

- Best used when all procedures can be conducted within the PI's laboratory and animal holding area;
- The approved ASP must include the names of the collaborator(s), their training, the procedures to be conducted under collaboration including a detailed description of the procedure(s) (i.e. methodology, restraint, anesthesia, euthanasia, endpoints, etc.), and other information not already included in the approved ASP (e.g. holding locations, procedure sites, final disposition of the animal(s), pain and distress categorization, use of hazardous agents, etc);
- **The PI and his or her IC ACUC must have access and oversight of all animal procedure and holding locations identified on their ASP;**
- **All animal procedure and holding locations must be included in the PI's IC's semi-annual program evaluation.**

Pros:

- No animal transfers required;
- PI maintains ownership and control of all animals at all times.

Cons:

- PI assumes **all** accountability for the collaborator, the animals and procedural outcomes;
- PI **must** ensure that all work conducted under collaboration is conducted as delineated on their approved ASP;
- Collaborator **must** conduct all animal work as approved on the PI's approved ASP;
- The PI and his or her IC ACUC may not have access and oversight authority for the procedure and/or holding locations used by the collaborator.

**3) Non-Transfer of Ownership with Two Investigator Accountability:**

Considerations:

- Ideal for multiple collaborations and "two-way" animal transfers;
- The PI requesting to collaborate with another investigator, core or shared facility **must** include the name and affiliation (IC and Lab/Branch/Section/Unit) of the collaborating investigator or core facility; the number and title of the collaborating investigator's ASP or core/shared facility's SOP which states the manner in which procedures will be conducted; a list of the procedures to be conducted; the animal procedure location(s); any special post-procedural care required by the animals to be provided by the PI; the individual(s) responsible for the provision of the PI provided post-procedural care; and the appropriate USDA column listing for the procedure(s) to be conducted under collaboration.

- The PI's ASP must include the animals to be used under collaboration in the numbers reflected in Section B of his or her approved ASP.
- The collaborating investigator's ASP must clearly state that approved procedures will be offered under collaboration to other investigators. In addition, the procedures to be offered under collaboration should be clearly delineated. The animals used in procedures conducted under collaboration should not be included in Section B of the collaborator's approved ASP.
- ***The USDA tracking of the animals used is the responsibility of the PI's ACUC and not that of the collaborating IC.***
- When animals are being held in a collaborator's animal holding space for an approved procedure under the collaborator's ASP, the originating cage card from the PI can be maintained, **but** should be supplemented with a cage card indicating the name of the collaborator, the collaborator's ASP number under which the animals are being tested and the projected dates that the animals will be housed in the collaborator's animal holding space. In addition, the facility must be provided with a copy of the "Emergency Treatment and Care Form" of the originating PI who maintains ownership the animal(s). This form must clearly identify contraindicated treatments and the final disposition of the animal(s) in the event of its death.
- Once the PI's ASP has been approved by his or her ACUC, a copy of the approved ASP should be submitted to the collaborator's IC ACUC (Figure 1). It is the collaborating IC ACUC's responsibility to review the PI's approved ASP to ensure that the above required information is present prior to the conduct of any collaborative procedures. ***The review process can be conducted by an IC's ACUC designated agent of the collaborating IC's ACUC and does not constitute a second approval of the PI's ASP. It is the responsibility of the collaborating investigator or core facility to ensure that this has occurred prior to beginning any work under collaboration.***
- The PI's ACUC may request a copy of the collaborating investigator's approved ASP or core/shared facility's SOP(s) which further delineate the procedures to be conducted, but the PI's ACUC may not make changes to the collaborating investigator's approved ASP or core/shared facility's SOP. Only the IC ACUC responsible for the ASP or SOP(s) can approve changes in the documents. In exceptional cases where the PI's ACUC believes that changes should be made to a collaborating ASP or SOP, the PIs ACUC can make a recommendation to be considered by the collaborating investigator's or facility's ACUC. Alternatively, the PI's ACUC can choose not to approve the collaboration.
- It is important to ensure that both ICs are aware of their responsibilities for the locations, procedures, activities and services conducted under an approved collaboration;
- If animal movement between different holding facilities is required, the prior review and approval of the receiving facility is required to ensure appropriate pathogen status, space availability, etc. It is strongly recommended that animal movement of this nature only be arranged through the involved animal facilities.
- The ASP modifications and procedures as outlined above constitute a formal written understanding between the PI, collaborator and the involved ICs.

Pros:

- Ownership of the animal(s) is never transferred;
- Animal numbers, justifications and USDA reporting is clear and uncomplicated;

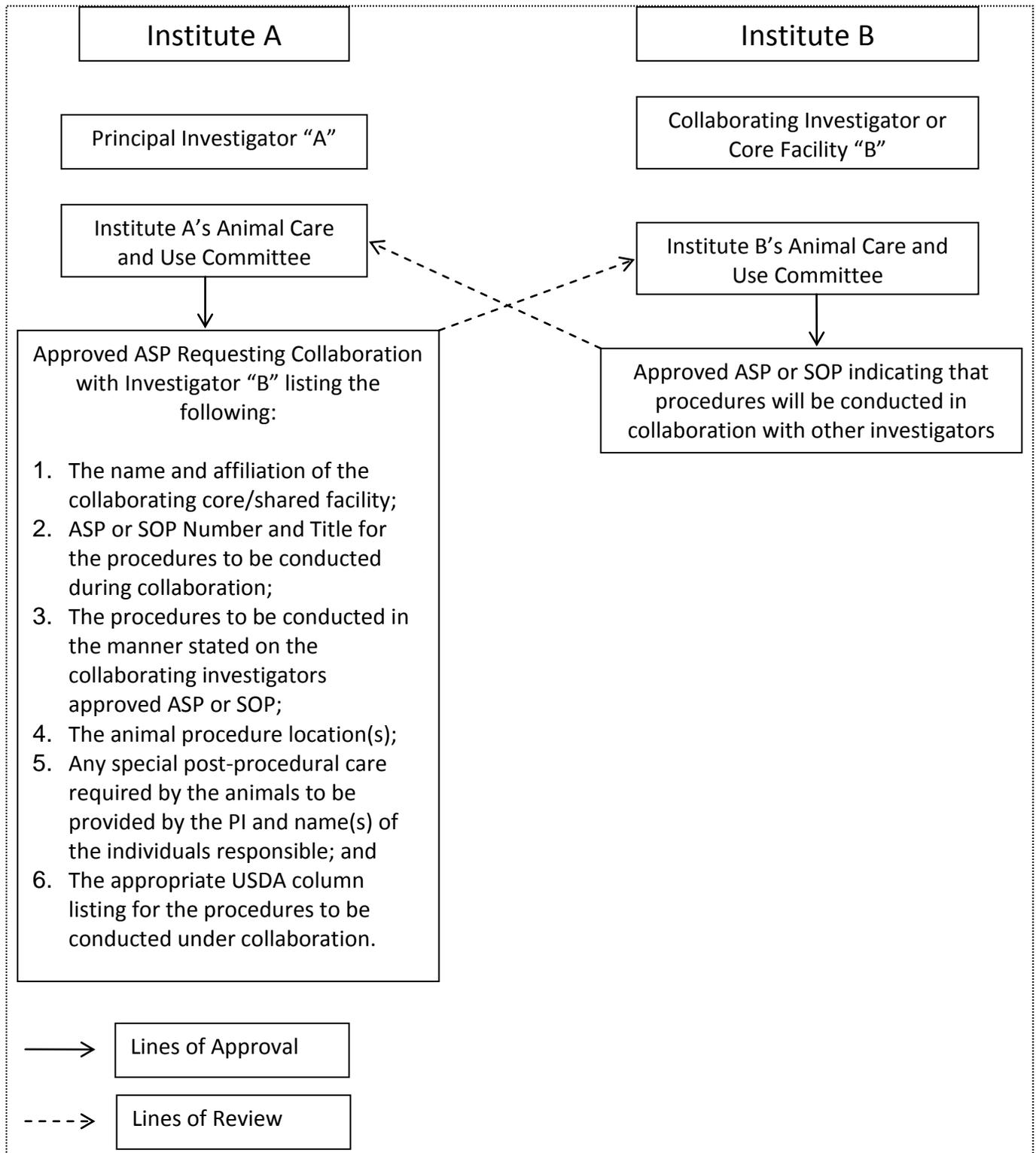
- Once a collaborative structure is established in both the PI's and collaborator's ASP each scientist only has accountability for the animal when it is in their possession;
- Collaborator conducts animal work as detailed on their approved ASP;
- Each PI and his or her respective IC ACUC is only accountable for the laboratories, procedure and animal holding locations already under their oversight.
- Since the originating cage cards and information are preserved throughout the collaboration, there is no erosion of animal identification and cage card data.

Cons:

- Requires prior establishment of a collaborative structure between the PI, collaborator and their respective ACUCs;
- Communication must be maintained at all times between all parties, including the animal facility(s) housing the animals.

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**Figure 1 – Flow Chart of Review Process\***



\*The ACUC coordinators will facilitate the exchange of the ASPs and/or SOP between the ACUCs, but the PI and collaborator are responsible to ensure the process has been completed prior to beginning the work.