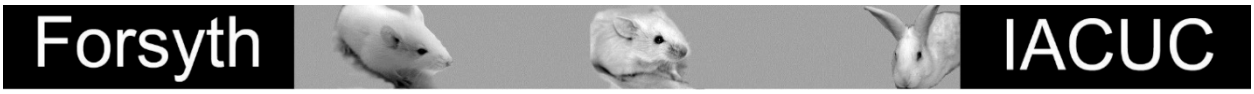

Animal Program Policy

Title: **Humane End Points**
Date Created: **4/26/2012**
Date Reviewed: **9/30/2015; 9/26/2018**

The Forsyth Institute recognizes that the use of animals in research has the potential of subjecting some of the animals to certain levels of pain and/or distress. The ethics of involvement of animals in research dictates that such conditions must be minimized in both intensity and frequency in justifying the use of animals. Commonly, pain and/or distress can be minimized using appropriate sedation, analgesics, and anesthetics. However, there are some situations in which it becomes unjustifiable to continue the involvement of a given animal in the research if the pain and/or distress cannot be relieved, the animal experiencing such a situation cannot add valid data to the on-going study, and/or the condition producing the pain and/or distress is irreversible. The objective is to establish endpoints that are a humane balance between minimal stress to the animal and maximal ability of the Investigator to detect a significant impact of the experimental treatment.

In developing any protocol for review by the IACUC, the Principal Investigator must consider carefully the potentials for animals involved in the study to experience unjustifiable pain and/or distress. Such conditions may include the:

- experimental procedures themselves,
- conditions arising from some genetic characteristic of the animal apart from any actual experimental procedure
- side effects (anticipated or not) from the animal's involvement in the study (pain from unintended infection, unresolved healing, etc.)

At some point the pain and/or distress experienced by any given animal is ethically unjustifiable, and consideration must be given to euthanizing the animal.

Humane endpoints, those characteristics of an experimental animal that would indicate the need to euthanize the animal rather than subjecting the animal to continued experimental participation, for each protocol must be considered and identified by the Principal Investigator at the time the protocol is developed. The protocol must state what the humane endpoint(s) will be, how they will be measured/monitored, what the decision parameters will be concerning any such identified animal, and the euthanasia process that will be used. Identification of such a process must be distinguished from the process that will be used by the Principal Investigator to determine when an animal (or a group of animals) will receive pain/distress-reducing analgesics.

The IACUC, too, must review all protocols keeping in mind the need for a "humane endpoint" segment in any given study. The IACUC, as part of the review and subsequent communications with the Principal Investigator, may:

- require the Principal Investigator to develop a humane endpoints segment of the protocol if, in the opinion of the IACUC the Principal Investigator did not recognize the potential for unrelieved pain and/or distress,
- require the Principal Investigator to expand on the details of the humane endpoints for the study as presented, or
- impose specific humane endpoint requirements into the protocol that the IACUC feels are more appropriate in managing the potential,
- Disapprove the study if the potential for unresolved pain and/or distress is inappropriate for the scientific justification for the study,
- Approve the study that contains a proposal for unresolved pain and/or distress if the Committee feels the benefits of the field justify the purposeful allowance of such pain and/or distress. (It is the contention of the IACUC at the outset that such protocols are very rare indeed, and such a decision will not be taken lightly by the Committee.)

All Principal Investigators are bound to abide by the provisions of their protocol as modified in discussions with the IACUC. Thus, the humane endpoint issue as addressed in the final approved protocol mist be a focused component of the execution of the protocol by the Principal Investigator and all his/her supporting technical staff.

In addition, the animal facility staff, the assigned protocol personnel, and the Consulting Veterinarian are directed to monitor each animal in the animal facility and take steps to implement any corrective actions necessary if a condition of unresolved pain and/or distress is identified in any animal.