BLANKET PROTOCOLS (FOR TRAINING GRANTS)

PERFORMANCE STANDARD: All animal activities performed by recipients of federal funds are covered by IACUC-approved protocols.

BACKGROUND: The IACUC has the responsibility to assure all animal use activity meets federal law mandates, Public Health Service policy, and accreditation expectations. This policy specifically addresses certification of IACUC approval for grants where animal procedures may potentially be performed by grant-supported personnel, but there are no funds for purchase of animals or for animal procedures issued from the grant.

ROLES:
1. Researcher: The investigator should work with the IACUC to assure grants are processed in a timely manner.
2. OAWA: Assure the review and processing is timely and consistent with this policy.

PROTECTION POSTURES REQUIRED: None

DEFINITIONS:
Blanket protocol: An administrative tool that facilitates grant management processes by associating several protocols under which trainee(s) will / may work under a single blanket protocol registry number that is provided to grant management system. This tool is most commonly used for training grants (or trainee grants) that provide salary support but do not provide funding for specific animal use activities.

NOTE: Blanket protocols do not describe any animal use activities. Those activities are described in the IACUC-approved protocol(s) that reside under the blanket.

POLICY:
1. When notified of a funding agency request for confirmation of IACUC protocol approval for training grants or other grants that meet the above definition, a Duke Sponsor will prepare and submit a Blanket Protocol application. This application requires a listing of all IACUC protocols under which grant-supported personnel work may use animals for research, teaching, or testing.
2. The Duke Sponsor will usually be the PI of the training grant for which certification of IACUC approval is requested. The Duke Sponsor should be faculty or staff of Duke University, but it is not required that they meet all requirements outlined in the Principal Investigator (Definition, Obligations, and Signatures).
3. The institution where the animal activities are being performed shall be responsible for the IACUC-approved protocol(s) covering that animal work.

4. The Duke IACUC may require written confirmation of an approved protocol at any non-Duke institution where personnel supported by the training grant are participating in animal activities.

5. The blanket protocol will be approved by the IACUC Leadership Review process. Once approved, a letter documenting approval will be issued by OAWA.

6. Each blanket protocol will be approved for not more than 12 months from the approval date. No extensions are allowed.

Amendments to a Blanket Protocol:

1. Since blanket protocols are umbrella protocols for already approved protocols and have no direct implication on animal care, use, or welfare, any amendment to a blanket protocol will be considered a minor amendment. Example of such amendments would be the addition of another approved protocol to the blanket protocol list of approved protocols, change of one approved protocol for a second approved protocol, or change of principal investigator or Duke Sponsor.