

# Boilerplate Language for Human Subject and Vertebrate Animals Sections of Competitive NIH Training Grant Applications

GCO's boilerplate language for the human subject and vertebrate animal sections of the training program plan in competitive NIH training grants is intended for applications where 1) research involving human subjects and or animals is solely part of other research projects and 2) no portion of the training grant award will be used to support the research.

Please review the excerpt from <u>NIH's Training Grant Instructions</u> (T.420 10. Human Subjects / 12. Vertebrate Animals) below and use GCO's suggested language if applicable.

## **Human Subjects**

#### **NIH Instructions:**

If trainee participation in research involving human subjects is solely as part of other research projects and no portion of the Training Grant Award will be used to support this research, describe how the institution will ensure that trainees only participate in (a) exempt human subjects research or (b) non-exempt human subjects research that has IRB approval.

## GCO Suggested Language:

Trainees that participate in research involving human subjects do so as part of other approved research projects. No portion of the training grant award will be used to support human subject research. Any activity involving non exempt human subject research cannot commence without IRB approval and exempt activities can only commence after a determination of exemption has been made by the IRB. Mount Sinai's Program for the Protection of Human Subjects (PPHS), comprised of five Institutional Review Boards (IRBs), assures the ethical conduct of research and compliance with federal, state and institutional regulations. The PPHS' accreditation by the Association for Accreditation of Human Research Protection Programs (AAHRPP) is an affirmation of the overall excellence of Mount Sinai's human research protection program and demonstrates its pursuit of the highest ethical practices and principles.

#### **Vertebrate Animals**

### **NIH Instructions:**

Describe how the institution will ensure that trainees only participate in IACUC approved vertebrate animal research when: the training program uses live vertebrate animals only as part of other research project grants, and the Training Grant Award does not support the purchase, use, or husbandry of live vertebrate animals for this research.

### GCO Suggested Language:

Trainees that participate in research involving the use of live vertebrate animals do so as part of other research projects. No portion of the training grant award will be used to support the vertebrate animal research. Any activity involving of the use of live vertebrate animals in biomedical research, training, or teaching cannot commence without IACUC approval. The mandate of the IACUC is to ensure that all activities involving the use of vertebrate animals are conducted ethically, humanely and in accordance with federal regulations and the guidelines contained in the *Animal Welfare Act Regulations*, *Public Health Service Policy* and the National Research Council *Guide for the Care and Use of Laboratory Animals Guide*.