



September 11, 2020

To: Addressees
From: Deputy Director for Intramural Research, NIH
Subject: Scientific Merit Review for the Use of Nonhuman Primates

The NIH program for the scientific merit review of Animal Study Proposals (ASPs) involving the use of nonhuman primates was established by the NIH Scientific and Clinical Directors in 2015. In accordance with this program, each NIH Institute/Center (IC) must conduct a scientific merit review of all new ASPs and major modifications involving nonhuman primates in addition to the review performed by the IC Animal Care and Use Committee (ACUC). An “acceptable” scientific merit rating is required prior to ACUC approval.

A description of the scientific merit review program is attached.

Please direct questions or comments regarding the intent or contents of this memorandum to me or to the Director, Office of Animal Care and Use.

Michael M. Gottesman, M.D.

Attachment

Addressees:

IC Directors and Scientific Directors
IC Lab/Branch Chiefs
IC ACUC Members and Animal Program Directors
NIH IRP Principal Investigators

Description of the NIH Program for the Scientific Merit Review of Animal Study Proposals Involving Nonhuman Primates

The NIH program for the scientific merit review of animal study proposals (ASPs) involving nonhuman primates was established by the NIH Scientific and Clinical Directors (SD/CDs) in 2015. As of 2015, all new ASPs and their major modifications [as defined by the Institute/Center (IC)] involving nonhuman primates continue to be reviewed by the IC Scientific Merit Review Committee (SMRC).

The program is applicable to all NIH IC Intramural Research Programs (IRP) using nonhuman primates in research studies and experiments. It is not applicable to ASPs exclusively addressing nonhuman primate husbandry, transportation, and breeding activities.

An 'Acceptable' rating from the SMRC is required prior to IC Animal Care and Use Committee (ACUC) approval of the ASP or modification.

Responsibilities and procedures of the nonhuman primate scientific merit review program:

- The IC Office of the SD/CD appoints the SMRC. The SMRC can be a standing or ad hoc committee. The SMRC is composed of at least three individuals:
 - One individual is designated as the SMRC Chair
 - At least one individual must be from outside the IC
 - The Principal Investigator (PI) submitting the ASP and their research team members cannot serve on the SMRC
- The Department Head or PI submits their ASPs and modifications to their IC's Office of the SD/CD to arrange its review.
- The SMRC reviews the submission with respect to the following criteria:
 - The proposed research is scientifically significant;
 - The proposed research is expected to provide knowledge that will improve human and/or animal health;
 - The proposed experiments are well designed to address the study objective(s);
 - The proposed nonhuman primate species is the appropriate experimental model for the study; and
 - The number of nonhuman primates requested for use in the study is appropriate.
- The SMRC rates the submission's scientific merit as: 'Acceptable' or 'Unacceptable'
- The SMRC Chair reports the committee's ASP rating to the PI, IC ACUC Chair, and IC Office of the SD/CD.