



February 14, 2023

To: Addressees

From: Deputy Director for Intramural Research, NIH

Subject: Scientific Merit Review for the Use of Nonhuman Primates

The NIH/IRP program for the scientific merit review (SMR) of Animal Study Proposals (ASPs) involving the use of nonhuman primates (NHPs) 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 (SMR) of all new NHP ASPs and all amendments to NHP ASPs proposing a change in species or a change in study objectives resulting in a modified experimental design. This review is in addition to the review performed by the IC Animal Care and Use Committee (ACUC). The IC ACUC review and SMR can occur concurrently, but final IC ACUC approval cannot be granted until the SMR Committee (SMRC) determines the ASP, or the ASP amendment receives a SMR rating of *acceptable*.

A description of the SMR program is attached.

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

Nina. F. Schor, M.D., Ph.D.

Attachment

Addressees:

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

## **Attachment 1. Description of the NIH/IRP Program for the Scientific Merit Review of Animal Study Proposals Involving Nonhuman Primates**

The NIH program for the scientific merit review (SMR) of Animal Study Proposals (ASPs) involving nonhuman primates (NHPs) is applicable to all NIH Intramural Research Program (IRP) Institutes/Centers (ICs) using NHPs in research studies and experiments. It is not applicable to ASPs exclusively addressing NHP husbandry, transportation, breeding activities, or training in support of veterinary care, husbandry, transportation, or breeding activities.

A Board of Scientific Counselors (BSC) review of an existing study or project involving the use of NHPs and its associated ASPs involving NHPs active at the time of the BSC review is equivalent to the SMR conducted by a SMR committee (SMRC) for new ASPs. Therefore, the BSC review process provides an ongoing program of SMR for studies using NHPs.

In summary, review by a SMRC is required for the following:

- A NHP ASP that was not active at the time of the Principal Investigator's (PIs) last BSC review.
- A NHP ASP amendment that proposes a change in species.
- A NHP ASP amendment that proposes a change in study objectives resulting in a modified experimental design.

ICs may define other NHP ASP amendments that require review by the SMRC in addition to the two described above. An acceptable SMRC rating does not replace or guarantee IC ACUC approval of the ASP. Both an acceptable SMRC rating and IC ACUC approval are required prior to initiation of animal activities.

The NHP SMRC program procedures and responsibilities include the following:

- The IC Office of the SD/CD appoints the NHP SMRC, which can be a standing or *ad hoc* committee. The SMRC is composed of at least three individuals from NIH, with the following conditions:
  - One individual is designated as the SMRC Chair.
  - At least one individual shall not be a member of the IC submitting the ASP or amendment.
  - The PI and research team members cannot serve on the SMRC reviewing their own submission.
- The PI (or designee) submits the ASP or amendment through their IC ACUC Coordinator to their IC's Office of the SD/CD to arrange a SMR (submission process may vary by IC).
- The SMRC reviews the submission with respect to the following criteria:
  - The proposed research is scientifically meritorious.
  - 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 NHP species is the appropriate experimental model for the study.
- The SMRC rates the submission's scientific merit as: *Acceptable* or *Unacceptable*.
- The SMRC Chair reports the evaluation and rating to the IC Office of the SD/CD.
- The IC SD/CD reviews and signs the report indicating agreement.
- The IC Office of the SD/CD forwards the report to the PI and IC ACUC Chair/Coordinator.