



OREGON NATIONAL PRIMATE Research Center

PROGRAM ANNOUNCEMENT: 2024 ONPRC New Approach Methodology (NAM) Pilot Grant Research Program

Key Dates:

Letter of intent (LOI) deadline	September 19, 2024
Full application deadline (if invited)	November 7, 2024
Earliest funding start date	January 1, 2025

BACKGROUND AND PURPOSE

The Oregon National Primate Research Center (ONPRC) is soliciting proposals for a new pilot grant research program focused on new approach methodologies (NAMs). The purpose of this funding mechanism is to encourage activities related to developing complementary methods to the use of nonhuman primates (NHPs) for biomedical research. The term “new approach methodology” encompasses *in vitro*, *in silico*, and *in chemico* technologies and approaches that can be used to complement NHP studies or reduce reliance on NHPs in biomedical research. While the technologies developed for NAMs have improved significantly over the past decade, for many areas of discovery NAMs still cannot replicate a living organism. These approaches complement NHP research, for example, by providing additional insight into human physiology or disease. Complementary approaches may improve animal welfare and reduce reliance on NHPs, which can be achieved by substituting alternative models or decreasing the number of NHPs used in research. NAMs developed using NHP cells and tissues will be an increasingly important area of research since, in many cases, the development of strategies for prevention and therapeutic agent testing will move from NAMs to limited NHP testing to human trials. NHP cell and tissue-based NAMS will allow comparison of results of NAMS testing to *in vivo* NHP work.

NIH is planning to invest significant funds in the development of NAMs. A recent report from the Working Group on Catalyzing the Development and Use of Novel Alternative Methods to the NIH Advisory Committee to the Director recommended seven high-priority needs which are listed below. The Working Group also emphasized that animal models will continue to be essential for biomedical research, including the development of NAMs.

Recommendation 1: Prioritize the development and use of combinatorial NAMs (including studies with animal models)

Recommendation 2: Establish resources, infrastructure, and collaborations to promote the use of interoperable, reliable, and well-curated/high-quality datasets produced from research using NAMs

Recommendation 3: Promote effective dissemination and interconnection of NAMs technologies

Recommendation 4: Invest in comprehensive training to bolster continuous advances in NAMs development and use

Recommendation 5: Facilitate multidisciplinary teams with expertise across technologies and the lifecycle of NAMs development and use

Recommendation 6: Promote social responsibility in both the creation and deployment of NAMs across the research lifecycle

Recommendation 7: Support and maintain coordinated infrastructure to catalyze effective and responsible NAMs development and use

We anticipate that projects chosen for funding through this pilot mechanism will address one or more of these recommendations.

Pilot research should be developmental or high-risk and, in the case of biomedical research proposals, should be used to generate preliminary data in support of applications for further project support, such as NIH and other federal or foundation grants. We encourage proposals from external applicants, early-stage investigators, and researchers new to NHP research. One of the areas of focus in the development and refinement of NAMs is the establishment of collaborations between investigators working in NAMs and those using *in vivo* animal models. This collaboration allows the transfer of data between these groups to inform and validate NAMS development. Collaborative efforts that include validation of NAMs with an *in vivo* physiological standard through comprehensive “omics” approaches (spatial transcriptomics and proteomics, single cell transcriptomics, proteomics) are also encouraged. One of the goals of the NAMs Pilot Program is to encourage and foster these collaborations.

Due to increased demand for the limited NHP resource, applicants are encouraged to utilize study animals or samples from ongoing studies or biobanks whenever possible.

PILOT RESEARCH PROGRAM GUIDELINES

1. All activities related to the use of NHPs must be conducted on-site at ONPRC. Other activities can be performed at other sites, depending on the nature of the pilot project. If relevant, a subcontracting mechanism within the pilot project can be used to support a component of the pilot project performed outside of ONPRC.
2. Pilot research funds may not be used to provide interim support for established projects or for investigations funded from other sources to conduct similar or overlapping work. This solicitation is for one-year projects at a maximum budget of \$75,000. All work must be completed by one year from the funding start date.
3. Pilot grant applicants need not be ONPRC core scientists; however, if a non-core scientist is the PI, an ONPRC core scientist must be involved in the planning, execution, and supervision and must assume responsibility for overall project management, coordination, and progress reports. The core scientist’s role must be specifically addressed in the application. Inquiries from other NPRC investigators or PIs at other institutions can be directed to Dr. Jon Hennebold (henneboj@ohsu.edu). As pilot funds are designed to facilitate subsequent grant proposals that will expand the research topic of the pilot proposal, PIs must be faculty rank and be eligible to serve as PIs on NIH R-type and similar grants.
4. Funds for the project may be used for the following purposes:
 - Personnel, excluding salary support for PIs/core scientists.
 - Supplies.
 - Animals and animal care costs.
 - Items of equipment costing less than \$5,000. Equipment costing more than \$5,000 must be approved prior to beginning the pilot project.

- Consultants and other special services, including ONPRC core services such as surgery, pathology, assays, or clinical services.
- This solicitation is for one-year projects at a maximum budget of \$75,000 (total cost).

APPLICATION INSTRUCTIONS

A. LETTER OF INTENT (1-page maximum)

Letters of intent must address the following points:

- Project title with names and affiliations of key personnel, including affiliated ONPRC core scientist
- Brief summary of the scientific plan.
- Why is this a “pilot” application, and how will the data generated be applied to future funding applications?
- How does the proposed project differ from the PI’s current research?
- How can the proposed research be accomplished in 1 year at the requested budget?

B. FULL APPLICATION (11-pt Arial, single-spaced, ½-inch margins; 6-page maximum)

- Title, PI names and affiliations, and abstract that includes specific aims (1/2 page)
- Significance and innovation (up to 1 page)
- Approach (up to 3 pages)
- References cited (1/2 page)
- Summary budget and justification (up to 1 page). Applicants will be directed to contact appropriate ONPRC Business Office personnel immediately upon notification of the request for a full proposal.
- Vertebrate Animals Section (NIH format; not included in page limit)
- Biosketches for PI and Key Personnel (NIH format; not included in page limit)

C. SUBMISSION

Letters of intent should be submitted through CAP at no later than 11:59 PM on **September 19, 2024**. Revisions or additions to the application will not be accepted after the due date. Submissions that do not follow the formatting guidelines will not be reviewed.

D. REVIEW PROCESS

- The ONPRC Research Advisory Committee (RAC) will review and prioritize LOIs, with the most meritorious invited to submit full proposals. Summaries of the review of the LOIs will be provided to all applicants.
- Full proposals will be evaluated by expert external reviewers. Each reviewer will assign a score, based on the NIH grant review scale, to each proposal, and mean scores will be calculated for each application. Reviews of full proposals will be provided to all applicants.
- Final funding decisions will be made by ONPRC leadership based on recommendations from the RAC.

E. AWARDEE RESPONSIBILITIES

- Funds are restricted to supporting the research project as described in the application submitted and as approved by the RAC.
- IRB and IACUC approval (if needed) are required prior to the release of funds.
- Submit reports describing project accomplishments when requested for P51 core grant annual progress reports and 5-year renewal. ONPRC is evaluated by the NIH on the effectiveness of its Pilot Programs in stimulating new research findings and

publications. Important metrics for the success of Pilot Projects include new funding, publications, licenses, and patents. ONPRC may approach investigators for additional details related to the success of Pilot Projects. Awardees are expected to submit a manuscript to a peer-reviewed, scientific journal and/or submit a grant application to one or more external agencies as part of the successful execution of the pilot project.

- All publications that result from ONPRC support (funding and/or infrastructure services) must include the following acknowledgment: *This publication was made possible with Pilot Program support from program development funds from the Oregon National Primate Research Center, and infrastructure and operations support through P51 OD011092.*

F. FURTHER INFORMATION

Please direct all questions to Dr. Jon Hennebold at henneboj@ohsu.edu