

**Expert Panel's Recommendations
for the Regional Primate Research Centers Program**

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1. INTRODUCTION

Nonhuman primates are critical to many aspects of biomedical research. These animals often represent the best or only living model for studying human conditions or diseases such as AIDS, menopause, aging, neurological disorders, and heart disease. Recognizing the importance of these laboratory animals to biomedical investigations, the National Institutes of Health (NIH) established a network of seven Regional Primate Research Centers (RPRCs) in the 1960s to enable development of improved primate models for examining human health problems. These original RPRCs, each affiliated with a major academic research institution, today collectively house more than 16,000 nonhuman primates, representing about 30 different species. More than 1,000 investigators—including RPRC staff scientists, collaborators, and visiting scientists from other institutions—currently rely on the Centers' animals to study AIDS, disorders of the nervous system such as Alzheimer's or Parkinson's disease, the potential of embryonic stem cells, and many other issues related to human health. The RPRCs also include specialized facilities for animal housing, research laboratories, and an extensive inventory of equipment and other research-related items. Whereas the original RPRC grants were devoted entirely to research, today the grants are used primarily to support Center infrastructure, including buildings, animals, and portions of the research of core staff scientists.

The RPRC Program is administered by the Comparative Medicine area of the National Center for Research Resources (NCRR), a component of NIH. In 1994, as part of a strategic planning process, NCRR was directed to evaluate all of its constituent programs, including the RPRCs, which had not undergone a comprehensive evaluation since 1979.

The current full-scale evaluation of the RPRC program was launched in 1998 to examine the following major questions:

1. Are the individual Centers succeeding in meeting RPRC Program objectives?
2. How effectively is the RPRC Program contributing to the advancement of the biomedical and behavioral sciences?
3. What major changes, if any, in policies, operations, or management are needed to enhance the overall quality and/or effectiveness of the RPRC Program?

A more detailed listing of the questions outlined in NCRR's Statement of Work (Contract No.

N01-OD-7-2115 awarded to James Bell Associates, Arlington, VA) can be found in Appendix 2.

An Expert Panel—comprising 11 researchers of varied backgrounds, varied research experiences with nonhuman primates, and varied expertise—attended site visits and advised and oversaw the evaluation conducted by James Bell Associates, an independent contractor. The evaluation included a comprehensive analysis of each Center's research resources, including animals, facilities, instrumentation, personnel, funding, and expenditures. All seven of the original RPRCs participated in the evaluation. A new RPRC at the Southwest Foundation for Biomedical Research was established in 1999, after the evaluation was already under way, and so was excluded from the study.

The evaluation culminated in a two-day meeting, held June 29-30, 2000, in Bethesda, Maryland. At the meeting, James Bell Associates presented its final report to the Expert Panel, who reviewed the findings of the evaluation and issued the recommendations described in this document.

2. EXECUTIVE SUMMARY

After examining the final report on the full-scale evaluation of the RPRC Program, the Expert Panel concluded that the original seven Centers enable the conduct of high-quality biomedical research; have expert, well-qualified staff; and are a critical component of the nation's biomedical research infrastructure. The Panel also agreed that the Centers are meeting all objectives outlined in the current RPRC Program Guidelines, issued in 1992, save one: That of serving as a national and regional resource to the community of NIH-sponsored investigators who conduct nonhuman primate research. The overarching goal of RPRCs is the expansion and dissemination of knowledge. The breeding and rearing of nonhuman primates provides a resource that is distinct from research objectives. However, the scientific demand for nonhuman primates has risen steadily since the discovery that the simian immunodeficiency virus (SIV) is an ideal model for studying AIDS; other biomedical disciplines are finding the animals to be similarly useful for understanding additional aspects of human health. Although 1992 Program Guidelines do not require the Centers to satisfy requests for nonhuman primates outside of their own institutions, the Panel proposes that the Centers are ideally equipped to assist in fulfilling this national need. However, Panel members vary in opinion as to the extent to which Centers should participate in the production of research animals.

Several of the Panel's recommendations, therefore, aim to enhance outside use of Center resources. Since the RPRCs were established nearly 40 years ago, each of the seven Centers has operated with considerable autonomy, and each has evolved unique areas of expertise, resource characteristics, and modes of operation. Although the diverse expertise and resources of the RPRCs is a notable strength, having made possible a broader range of biomedical discoveries, the Panel finds that the lack of standardized procedures for keeping track of animal availability and other research assets across Centers probably impedes outside use of RPRC resources. In addition, the lack of standardization hinders evaluation of Center resources, operation, and performance.

The Panel also found that the quality of the research performed by RPRC-participating investigators, as judged by publication record, is comparable to that of investigators who conduct nonhuman primate research outside of the RPRCs. However, considering the substantial national

investment in the RPRC Program over its nearly 40-year history, the Panel had hoped to see exceptional research emanating from the Centers; that is, these facilities should be national “Centers of Excellence” in primate research.

To address many of the concerns described above, the Panel issued a series of recommendations that serve to address four larger goals:

- (1) To have the RPRC Program serve as a truly national resource,
- (2) To enhance and streamline the investigator’s access to Center resources,
- (3) To enhance the quality and effectiveness of the RPRC Program, and
- (4) To consider directions for future improvements once the Panel’s recommendations are put in place.

In addition to these recommendations, the Panel reviewed a proposed revision to the RPRC Program Guidelines drawn up by NCRR’s Comparative Medicine area (see Appendix 3). The Panel agreed with the concepts expressed in this revision. The Panel also considered whether the RPRCs were allocating resources and research to the study of AIDS in proportion to the level of funding they received for AIDS research. The Panel agreed, based on a available data, that the RPRCs were achieving an appropriate balance in accommodating AIDS research. However, additional special nonhuman primate needs for AIDS studies may require alternative funding mechanisms outside of the RPRC Program.

Finally, the Panel reviewed the original questions issued in NCRR’s Statement of Work for the Full-Scale Evaluation of the RPRC Program (see Appendix 2). Although the final report on the evaluation provided extensive data, the Panel found that the information in the report was not sufficient to address all of the questions. The Panel also concluded that meaningful estimates of total infrastructure cost could not be calculated due to the complexity of the interactions among the core and research functions at each Center; therefore, the Panel did not issue a recommendation as to what percentage of the RPRC core grant should be devoted to infrastructure rather than research.

Overall, the Panel agreed that the RPRC Program is an essential national treasure that should be supported and strengthened.

3. RECOMMENDATIONS

1. Serve as a truly national resource. As a top priority, the RPRC Program must be responsive to national needs for nonhuman primates and related resources essential to the conduct of NIH-funded research. This is a fundamental shift in emphasis for the RPRC Program. Under current guidelines, the Centers are required only to meet the needs of RPRC host institutions, and then preferentially to NIH-funded researchers. However, the Panel recognizes an impending increase in the demand for nonhuman primates, especially genetically characterized, specific-pathogen-free (SPF) animals, which have become an increasingly valuable commodity essential to the study of AIDS, neurobiology, cardiology, and other aspects of human health.

1. Survey the demand for nonhuman primate research resources throughout the NIH-funded community of scientists who use nonhuman primates. The Panel perceives a continuing problem with supply and demand for nonhuman primates, but the magnitude of the problem has not been quantified. The Panel finds that the Centers generally meet their own needs for nonhuman primates and related resources, but do not have the capacity to satisfy the needs of outside investigators. Additional capacity has been supported by other funding mechanisms. A survey is required to place the RPRC evaluation into a context of user community needs and should solicit input from current nonhuman primate users. Before significant changes are made to Center and other NIH-supported breeding operations, the magnitude of demand and the nature of shortages in the supply of nonhuman primates must be assessed.
2. Meet needs for specially bred, well-characterized nonhuman primates. As nonhuman primates become increasingly critical to the study of AIDS, other immunological disorders, and other areas, the Panel anticipates an increased demand for SPF and genetically characterized, but not necessarily homogeneous, animals. No other animal model can so closely parallel human HIV infection, and evaluation of potential AIDS vaccines in nonhuman primates is an irreplaceable

step between the basic sciences and phase 1 clinical trials. Unfortunately, rapid changes in research directions make it difficult to project the future need for specific research animals, and breeding programs have inherently slow capabilities that often lag behind demand by 3 to 5 years for the most commonly used nonhuman primates.

Although there were questions as to the lowest cost source for nonhuman primates, most Panel members agreed that the *quality* of the animals—especially their documented history, health status, and genetic makeup—takes primacy over cost issues when conducting critical studies related to AIDS and other complex diseases. The RPRCs, with their wealth of expertise, experience, and animal resources, have a well-deserved reputation for producing high-quality SPF and other specially characterized animals.

The Panel endorses NCRR's current efforts to enhance breeding of SPF-rhesus macaques and encourages additional efforts to characterize MHC profiles, improve directed reproduction (e.g., in vitro fertilization and cloning), and standardize breeding guidelines, provided demand is demonstrated. The Panel suggests that RPRCs, with their knowledgeable and experienced staff, are in an optimal position to assist investigators in identifying specifications. While RPRCs, with their specialized animal resources, may be positioned to develop competitive applications to produce such animals, additional capacity and alternative sources of nonhuman primates should be sought to meet the national needs of the NIH-funded research community. The funding and utilization of such alternatives has proven successful and allows market forces to operate to the benefit of investigators and funding agencies.

3. Change name to National Primate Research Centers (NPRC) to reflect the proposed broader scope of the Centers' mission. The NPRCs will be a truly national resource open and accessible to the NIH-funded research community.

2. Enhance accessibility to Center resources. The Panel finds that variability in procedural operations in each of the seven evaluated Centers can prove daunting to potential users—both within and outside the host institution. Because the Centers do not adhere to a uniform structure for pricing animals and support services, potential users have difficulty comparing projected costs across Centers. And because each Center has a unique system for tracking, identifying, and characterizing animals, there is no simple way to assess the availability of animals and related resources. The panel recommends that NCRRL require a minimal level of standardization across the Centers and develop a variety of user-friendly strategies to encourage outside use of RPRCs.

4. Establish a standardized central data repository that provides information on animals and protocols utilizing nonhuman primates. The lack of a centralized database can be bewildering to potential users trying to identify appropriate sources for animals and also makes it difficult for NIH decision-makers to assess utilization of resources. At a minimum, the data repository should:
 - Identify each animal by a unique ID number
 - Indicate the animal's utilization status (i.e., whether it is available to potential users, already assigned, or unassignable because it is a protected species, involved in breeding activities, or for other reasons)
 - Identify the protocol for each research animal, including venture-pilot studies
 - Provide information on sources of investigator support (i.e., whether core or non-core scientists, NIH-funded, or supported by private industry)
 - Develop a system for monitoring formal inquiries from NIH-funded investigators. A monitoring system will help NCRRL more accurately track supply-demand relationships for nonhuman primates in federally funded biomedical research.

Additional data might include each animal's genotype, medical history, and other characteristics. Information on specialized instrumentation, facilities, and other research resources might also be included. The data repository might even be expanded to include data on NIH-supported nonhuman primates that are not Center animals, the Panel suggests. However, before moving ahead, NCRR should determine how best to institute and maintain a useful database efficiently with respect to the investment of time and money.

5. Establish a Primate Resources Coordinating Center to oversee operation of the centralized data repository. The Coordinating Center might be responsible for identifying NIH-sponsored sources of animals, setting guidelines, and providing quality assurance standards for animals and procedures. The Coordinating Center might be located at one of the RPRCs or might be at an unrelated entity. The Coordinating Center should incorporate representatives and mechanisms for obtaining suggestions from all of the RPRCs.
6. Adopt a uniform pricing structure for protocol-support services, as well as uniform pricing structures for all categories of charged services, including animal use fees and per diem rates. Dollar values need not be identical across Centers, but Centers should present charges the same way, so potential users can make informed decisions. The complexities of the current system are prohibitive to potential users.
7. Expand laboratory facilities to accommodate outside users. Laboratory and research space is at a premium at the Centers and may not accommodate the proposed expansion of the user community. The Panel recommends that additional facility enhancement funds be made available to improve or expand capabilities of research resources to meet additional demands.
8. Enhance funding of venture-pilot studies to outside investigators. Funding of pilot programs is currently limited to a total of \$100,000 per year for each Center, with the maximum allowable per project set at \$30,000. The Panel recommends raising the ceiling on these funds, possibly to a maximum of \$300,000 per Center, and \$50,000 per project. As an incentive for providing pilot funding to non-core, non-

host-institution scientists, the Panel recommends creating a matching funds mechanisms for RPRCs to accommodate special projects. For each venture project conducted with RPRC support by non-host-institution investigators, the RPRC will receive additional matching funds from NCR. Such a mechanism might provide an incentive for host-institution or core scientists to solicit collaborations with scientists that are not affiliated with the host institution. A database would also be established to track the outcome of venture studies to identify the proportion leading to R01-type funding.

9. Increase the ceiling on R21 funding to \$150,000 per year in direct costs. The R21 mechanism provides 2-year grants for exploratory research. The maximum allowable R21 award at the Centers is currently set at \$100,000 per year (direct cost).
 10. Communicate the improved availability and accessibility of these resources to NIH-funded investigators, especially through the NIH Guide. The Panel noted that the community of potential RPRC users is not generally aware of the Centers' available resources. The Panel urges NCR and the Centers themselves to step up communications efforts to broadcast the availability of these critical resources, perhaps utilizing examples from other government funding agencies (such as the National Aeronautics and Space Administration).
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3. Enhance the quality and effectiveness of the RPRC Program. The Panel found that the RPRCs are conducting top-notch research, but the quality of the studies is not clearly superior to primate research conducted outside the Centers. Because of the Nation's significant investment in these Centers over the past 40 years, the Panel would like to ensure that nonhuman primate studies conducted at the Centers are of the highest possible quality. To improve the effectiveness of the Program overall, the Panel urges NCR to consider mechanisms that standardize and centralize certain aspects of the Centers. A level of autonomy should also be fostered that would allow the development of superior and unique primate research resources at each of the individual centers.

11. Establish measures of productivity and performance. Performance measures might include, but are not limited to, (1) the quality and impact of the research publication record, and (2) the number of research protocols initiated by non-core investigators (i.e., those not receiving salary support from the Center core grant). The Panel agreed that the concept of “leveraging” as a performance measure is misleading when applied to the RPRC Program. Because the Program necessarily has high costs, involving year-round housing and care of large-animal colonies, leveraging of the RPRC Program cannot be usefully compared to the leveraging of other programs, especially since it is not possible to attribute a specific proportion of support to infrastructure. Rather, to assess RPRC performance it would be more informative to identify measures that gauge how well or how often the Centers enable the nation’s highest quality research involving primates.
12. Standardize categories of data compilation across Centers to acquire data that are more meaningful to decision-makers. Centers have disparate methods of accounting and vary greatly in the categories they use for their reference (full-time-equivalent employees, square footage, etc.) as the allocation base for indirect costs, making it difficult to determine which instruments, space, and other infrastructure are part of a Center.

The Panel found that the diversity and inadequacy of data collected and provided by Centers create difficulties for comparing Centers, assessing their productivity, and evaluating how capacity is being utilized. In addition to contributing uniform data to the centralized animal database described above, the Panel recommends that the Centers adhere to a standardized system for managing and collecting data. At the same time, the Panel cautions NCRR not to make these requirements cumbersome by requiring extraneous information, lest compliance be compromised.

13. Promote unique Centers of Excellence—for example, in the neurobiology, reproduction, or cardiovascular health of primates—to heighten the impact of research conducted at the RPRCs. Concentrating such specializations at specific Centers could help to avoid duplication of expensive instrumentation and expertise at the Centers. Centers with specialized equipment needs for nonhuman primate research might take advantage of potential collaborations with neighboring General Clinical Research Centers, host-institutional centers, or Shared Instrumentation Grant recipients.
 14. Strengthen host–RPRC affiliations by arranging Center scientist joint appointments and by encouraging resource sharing. The Panel commented that RPRC core scientists sometimes have difficulty attaining faculty positions at host institutions, which may lead to attrition of expertise at the Centers.
4. Consider directions for future improvements. After the Panel’s recommendations are put in place and the user survey is completed, NCCR should reassess the Program’s effectiveness in meeting the needs of the biomedical community.
15. **Analyze the effectiveness of the entire set of recommendations**, perhaps three years after they are put in place. The Panel recommends that NCCR periodically examine the accomplishments of each of the new programs and activities established as a result of this Report. If there is insufficient evidence that the efforts are achieving their intended goals, NCCR might consider altering or eliminating certain activities.
 16. Consider changing the funding mechanism. NCCR might consider modifying the base grant award mechanism to be a cooperative agreement, which might provide more intensive national leadership to the Program. A cohesive, more uniform effort under a cooperative agreement might be better able to respond to the national needs of the NIH-funded primate research community. However, the panel cautions NCCR to carefully consider the potential risks of such a drastic change, and prefers that reorganization of the Program be “evolutionary” rather

than “revolutionary.”

17. Consider consolidating breeding operations where justified at certain centers, possibly emphasizing conventional breeding at specific centers and specialized breeding at others. NCRR might investigate whether it would be more cost-effective and productive to centralize the expertise and equipment for different types of breeding at different Centers.
18. Assess need for RPRC support for currently underutilized species. Consider whether RPRCs should continue to support maintenance of special nonhuman primate species not currently in demand for biomedical research. These species—including sooty mangabeys, marmosets, and Formosan macaques—are consuming Center resources but are seldom studied to advance biomedical science. Such colonies should be consolidated, divested, or further developed as models for human research. For instance, the marmoset—a small, short-lived primate now housed and used at two RPRCs—is increasingly used in studies by the pharmaceutical industry and might also be further developed for additional use in RPRC investigations. Other primate species that are endangered or protected might prove useful in observational studies or be recommended for funding by non-RPRC program sources.

4. APPENDICES

Appendix 1: Roster of Expert Panel Workgroup
Full-Scale Evaluation of the Regional Primate Research Centers
June 29-30, 2000

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***Due to time constraints, Dr. Eisen resigned from the
RPRC Expert Panel in October 2000, before the
Recommendations were finalized.**

Yvonne Paterson, Ph.D.

**Appendix 2: Questions from Statement of Work
Contract No. N01-OD-7-2115
awarded to James Bell Associates, Arlington, VA**

1. Are the individual Center programs succeeding in meeting NCCR objectives? Are specific recommendations needed to help improve the quality and/or effectiveness of their efforts?
2. Research Performance: How effectively is the RPRC Program contributing to the advancement of the biomedical and behavioral sciences?
 1. By examining their publications, how well are the RPRC research programs advancing knowledge in their scientific disciplines compared to non-RPRC nonhuman primate research programs? What evidence is there of strengths or weaknesses in the individual RPRCs or across the entire program?
 2. Is research being conducted by the various categories of users of the facilities comparable in effectiveness? If not, what types of programmatic changes are indicated?
 3. In which scientific areas or disciplines are RPRC researchers achieving most recognition? Should these areas receive greater emphasis, or what kinds of changes are needed to improve areas of research that are currently less effective?
 4. How extensive and effective is venture pilot research in the RPRCs? What kinds of changes might lead to improvement in this area? If the availability of funds is a factor, what steps should be taken to improve opportunities in this area?
 5. Is there evidence that participants in RPRC research are, or are not, achieving recognition in their host academic institutions that is commensurate with their contributions?
3. Infrastructure: What major changes, if any, in policies, operations, or management are needed to enhance the quality and/or effectiveness of the RPRC Program?
 1. How cost-effective are the RPRCs? What is the optimal operational model for the RPRCs to ensure cost-effectiveness?
 2. What common definition of infrastructure can be applied to all the RPRCs, and once identified, what do these elements of infrastructure cost?
 3. What funds are available to support research at the RPRCs?
 4. What accounts for the differences in costs to different types of investigators?

Appendix 3: RPRC Guideline Revisions Proposed by NCRR Prior to Final Expert Panel Meeting

In September 1998, NCRR's Comparative Medicine area developed draft revised Guidelines (Fifth Edition)¹ for the Regional Primate Research Centers Program. The most significant of the proposed changes would:

- Elevate the Program's specific objective "to provide regional and national resources" to number one among six specific objectives.
- Define the infrastructure of an RPRC as the composite of a variety of critical resources and resource-related items and support functions that are required to provide a firm foundation for the efficient conduct of biomedical research using nonhuman primate models. Under the RPRC grant, the Center may include budget requests for items needed to provide administrative support, partial salaries for designated core staff scientists, pilot research projects, laboratory equipment, animal housing, animal care, primate breeding, nonhuman primate colony maintenance, and specialized support services for the Center's ongoing core and collaborative research programs.
- Emphasize that "all Centers are expected to obtain funding from other sources for the conduct of biomedical research of categorical diseases."
- Stipulate that with the exception of "pilot" and "resource-related" projects, base grant funds will not support the research projects of staff scientists.
- Emphasize that core staff scientists' responsibilities include "research on... nonhuman primates" (i.e., are resource-related).
- Establish the minimum proportion of effort that core staff scientists must spend on nonhuman primate research at 50 percent (of their base grant-supported time).
- Establish a cap of 20 percent above the final non-competing year's budget level for competing renewal applications (recommended by NARRC).
- Eliminate base grant support for "special colonies not in demand for biomedical research purposes."
- Require timely submission of information on non-base grant applications of Center staff scientists to the Program.

¹ Approved by NCRR's National Advisory Research Resources Council (NARRC) and commented upon by the RPRC Directors