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Nonhuman Primate Evaluation and Analysis

Part 1: Analysis of Future Demand and Supply

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Summary

Nonhuman primates (NHPs) serve as critical animal models for many research areas, including infectious diseases; social, cognitive and behavioral research; reproductive biology; regenerative medicine; aging and neuroscience research. The National Institutes of Health (NIH) provides support for NHP breeding colonies, facilities, and other research resources to facilitate the effective use of NHPs by NIH grantees as well as intramural scientists. This support is provided through grants and cooperative agreements administered by the Office of Research Infrastructure Programs (ORIP) within the Office of the Director as well as through other grants, cooperative agreements, and contracts administered by individual institutes. ORIP programs currently include the seven National Primate Research Centers (NPRCs); the Caribbean Primate Research Center; and baboon, African green (vervet) monkey, and squirrel monkey colonies located at various academic institutions.

Ensuring an adequate supply of NHPs to sustain research progress has been an ongoing challenge, with periodic shortages and surpluses being experienced at various times over the past several years. The NHP Evaluation and Analysis was conducted to provide the NIH and the research community with an improved understanding of the demand for and supply of NHPs within the United States, with particular emphasis on the NPRCs and other NHP centers supported by the ORIP, which support research across the NIH Institutes, Centers, and Offices. The results will also aid the NIH in determining the best strategy to pursue with regard to NHP research resources in order to facilitate execution of NIH's research programs. The study was comprised of an initial phase (described in the present report) to collect and evaluate quantitative and qualitative data on supply and demand, followed by a second phase employing an expert panel to assess future needs (described in the companion to this report). Part 1 of the study was designed to use multiple methods to evaluate future demand and supply owing to the uncertainties associated with any single method and was comprised of four distinct components:

- A review of the capabilities of major U.S. NHP service providers
- An analysis of trends in historical NHP use by NIH awardees and others
- An analysis of historical NHP use data and forecasts of future demand for NHPs reported by major NHP service providers, and definition of their operational characteristics
- Conduct of a survey of NIH-sponsored NHP users to characterize consumer demand

Capabilities of Major U.S. NHP Service Providers

Twenty-one facilities were evaluated that, together, provide the majority of NHPs available in the U.S. to NIH-sponsored investigators. Within these facilities, a total of 15 different NHP species were identified as used in medical research. Eleven of these species are currently being bred in the U.S., with rhesus macaques being the most commonly bred species. In terms of research capabilities, the NPRCs appear to provide a much more diverse portfolio of services than those available from commercial providers and most other universities included in the analysis. In particular, the veterinary medical support procedures available at NPRCs are much more extensive than those at other organizations that were reviewed.

Trends in Historical NHP Use by NIH Awardees and Others

Historical NHP use was evaluated in NIH new and renewal grant and cooperative agreement awards for project-driven research awarded from fiscal years 2013-2017 (FY13-FY17); data on NIH contracts were not available for evaluation. Within these awards, rhesus macaques comprised 65% of all planned NHP use, followed by cynomolgus macaques (15%), baboons (5.5%), and marmosets (3.1%). There appears to be a generally increasing trend in use of NHPs since FY13, driven largely by increasing use of rhesus and cynomolgus macaques. Use patterns for other species were more variable, such that

clear trends were not evident. In the case of rhesus macaques, a particularly large increase in proposed use occurred in FY16 awards. The FY16 surge in planned rhesus macaque use was due to a large increase in planned use of this species for HIV/AIDS research (sponsored by the National Institute of Allergy and Infectious Diseases [NIAID]) and, to a lesser extent, behavioral and systems neuroscience studies sponsored by both the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) and the National Institute of Mental Health (NIMH). Although rhesus macaque use proposed in FY17 awards declined substantially from that seen in FY16, use for HIV/AIDS research remained above that in FY15 and it appears that use of this species in HIV/AIDS research is on an upward trend. In the case of behavioral and systems neuroscience, there also appears to be a gradual increasing trend in use of NHPs, but unlike the case with HIV/AIDS research, the trend is driven by smaller increases across several species.

Limited data on annual use of NHPs by intramural NIH investigators showed some similarity to the national aggregated award data, with a large increase in acquisition of rhesus macaques in FY16, followed by FY17 acquisitions returning to levels similar to pre-FY16 levels. Most of these animals were used for infectious disease research. Data on imported rhesus macaques showed no increase in FY16 and no major upward or downward trend.

Data on the sex and ages of animals used in NIH awards was incomplete. However, based on the limited available data, overall use of males and females appeared to be similar, although in certain research areas, there appeared to be some preferences for one sex or the other for reasons that are not always apparent. In the case of age, an increased emphasis in recent years on studies of juvenile animals was seen, particularly in rhesus macaques, although the reasons for this increase are not known.

Historical NHP Use, Forecasts, and Operating Information from Major NHP Service Providers

Historical trends reported by several NIH-sponsored NHP centers, as well as quantitative forecasts and qualitative predictions of these centers and other major academic and commercial NHP service providers point to an increase in researchers' demand for rhesus macaques and marmosets over the coming 5 years, a prediction supported by supply shortages that are currently being experienced at several centers. There is significant uncertainty as to the ability of the rhesus macaque colonies at the seven NPRCs and the Caribbean Primate Research Center to meet the predicted increase in demand for rhesus macaques in the near term. This is due to infrastructure limitations as well as the inherent long lead times involved in increasing colony production and the availability of sufficiently mature animals for study. While there may exist some additional capacity to address the predicted increase in demand within academic centers or commercial organizations not presently supported by the NIH, it is unclear whether these organizations will be able to produce sufficient numbers of animals and also be willing and able to address all the needs of the academic community, since many of these organizations focus on commercial or Federal customers and operate under a different paradigm from the more academic-focused NIH-sponsored NHP centers.

Characterization of Demand by NIH-Sponsored NHP Investigators

Among the respondents to a survey of NIH-sponsored NHP investigators, just over half indicated that their NHP studies would be performed at an NIH-sponsored facility, either an NPRC or another center that included an NIH-sponsored breeding colony. However, these respondents accounted for 71% of all animals estimated to be used from calendar years 2018-2022. Many of these investigators are already located at an organization that hosts an NPRC or another NIH-sponsored breeding colony and in general, most investigators who had an NHP facility within their own organization planned to use the facilities of their own organization for their studies.

Among the factors that may influence an investigators' selection of an NHP study site, the most important factor for the majority of investigators was the availability of NHPs of the appropriate species, age, and sex. Access to specialized equipment or facilities, relevant animal models, and specialized expertise were all considered important, but none of these factors clearly differentiated those who chose to have work performed in their own institution from those who chose to use an NIH-sponsored or other external NHP service provider. Maintaining local access to animals was a significantly more important factor to individuals who planned to use the facilities of their own organization as compared with those who planned to use an external organization for their studies.

Among investigators who have NHP-capable facilities within their own organization, those who use large numbers of animals (more than 30 per year) were somewhat more likely than smaller users to choose an external organization to perform their NHP studies. However, there was no apparent impact of the number of animals used on the choice of the type of external organization that was planned; about 50% to 60% of respondents planned to have their studies performed at an NPRC and the remainder planned to use a mix of other academic centers, commercial research organizations, or other sites. A similar pattern was seen across all survey respondents who did not have an NHP-capable facility within their own organization, and therefore would have to rely on external service providers.

A large number of critical research capabilities were identified by survey respondents, with the most frequently mentioned requirements pertaining to imaging, behavioral testing capabilities, general veterinary support and veterinary surgical capabilities, specialized housing, and biological containment. In general, investigators performing studies in NIH-sponsored facilities expressed similar needs to those whose studies were being performed in other facilities, and only a few capabilities were limited to one or the other of these two groups.

Estimates provided by surveyed investigators of their planned annual use were relatively constant from 2018 to 2022 for most species, and the planned use of males and females was also relatively balanced for most species. An upward trend in the estimated use of marmosets was seen across all years, although this increase was estimated to occur at facilities other than those sponsored by NIH. The use of baboons at NPRCs was also predicted to surge from 2019-2021, but this trend was not seen at other locations. Due to a lack of directly comparable historical data, the uncertainties inherent in estimating future animal use, and the possibility that the investigators who responded to the survey do not fully represent all NHP users, the estimates are likely not absolute predictions of future demand. However, the direction of trends seen within the data may nevertheless be indicative of future trends.

Half of all surveyed investigators reported having problems within the past 2 years, either in obtaining NHPs or in obtaining related research services, that delayed their research, altered their experimental design, or influenced how they performed their research. The most common problem was delays in obtaining NHPs of the required species, sex, and/or age, or with other specific characteristics. Problems of this type were reported with rhesus macaques and baboons, and were especially prevalent among marmoset users. Programmatic barriers to NHP research were also noted and included concerns with peer review processes, concerns over the impact of direct funding caps on the number of animals that can be used and their impact on statistical power of the studies, and concerns over cuts to award budgets that may be made by NIH Institute or Center (IC) Advisory Councils. Significant concerns were expressed by many respondents regarding the increased cost of purchasing NHPs. In several cases this was related to the cap on direct costs and/or budget cuts, both of which force changes in experimental design from what investigators would view as optimal. Lastly, several investigators reported various problems with insufficient housing to perform required studies or inadequate staffing or staff expertise of the type needed, resulting in delays in study initiation or other issues; the frequency of these types of problems was nearly identical for both investigators performing research in NIH-sponsored facilities and those performing their studies in other facilities not sponsored by NIH.

Conclusions

Based on several lines of evidence, increased demand for both rhesus macaques and marmosets is expected in the coming 5 years. There are also some indications of increasing demand for baboons, but data supporting this forecast is less consistent. It is suspected that the present shortage of rhesus macaques has been exacerbated by the unusually large increase in planned use of this species that occurred in FY16 awards, placing a strain on supplies that is likely to have effects into FY19-FY20 as these awards continue into their outyears, and possibly longer. Use of this species for HIV/AIDS research, a major driver of demand, is also on the rise.

Although alternatives to the NIH-sponsored centers and colonies exist for some species and types of research, the NPRCs and other NIH-sponsored NHP colonies clearly serve as a major resource for many investigators, especially those who lack access to an NHP-capable facility within their own organization. The NPRCs, in particular, offer many research capabilities that do not appear to be routinely available from other major service providers, and may serve as enablers of studies that require large numbers of animals. However, due to present infrastructure limitations and the time required to increase colony production, the current NIH-funded centers and colonies may not be able to satisfy the predicted increase in demand for rhesus macaques and marmosets for at least the near term.

A number of programmatic issues that impact NHP supply or demand were identified by suppliers and investigators in the course of the analysis. Although anecdotal, the issues were noted frequently enough by different individuals that further evaluation is warranted to determine if changes to practices should be implemented.

1. Introduction

NHPs serve as critical animal models for many research areas, including infectious diseases; social, cognitive and behavioral research; reproductive biology; regenerative medicine; aging and neuroscience.[1] The NIH provides support for NHP breeding colonies, facilities, and other research resources to facilitate the effective use of NHP by NIH grantees as well as intramural scientists. This support is provided through grants and cooperative agreements administered by the ORIP within the Office of the Director as well as through other grants, cooperative agreements, and contracts administered by individual institutes. ORIP programs include seven NPRCs; the Caribbean Primate Research Center; and baboon, African green (vervet) monkey, and squirrel monkey colonies located at various academic institutions.

Ensuring an adequate supply of NHPs to sustain research progress has been an ongoing challenge, with periodic shortages or surpluses being experienced at various times over the past several years. Managing a breeding colony to ensure the supply of NHPs is a complex endeavor, requiring, for some species, years of lead time to increase the number of animals that are of an appropriate age for use in research studies. However, with few exceptions, there has been little attempt to characterize NHP supply and demand in a manner that would enable long-term planning and avoidance of shortages.[2]

The NHP Evaluation and Analysis was performed by Leidos at the request of the Division of Comparative Medicine within the NIH ORIP. The study is intended to provide the research community and NIH with an improved understanding of the demand for and supply of NHPs within the U.S. The results will also aid the NIH in determining the best strategy to pursue with regard to the NIH-sponsored

[1] NIH Workshop on Ensuring the Continuing Responsible Oversight of Research with Non-Human Primates, Final Report, December 28, 2016. https://osp.od.nih.gov/wp-content/uploads/NHP_NIH_Workshop_Report_01_18_2017.pdf

[2] EW Lankau, PV Turner, RJ Mullan, and GG Galland, Use of Nonhuman Primates in Research in North America, *J Am Assoc Lab Anim Sci*, **53**:278, 2014.

NHP research resources in order to facilitate execution of NIH's research programs. The study was comprised of two parts: Part 1, described in this report, evaluated supply and demand via a number of quantitative and qualitative methods; Part 2, described in a companion report, convened an expert panel to assess future needs and identify potential solutions to any perceived challenges and barriers.

The overall study addressed several questions with regard to (1) the types of research that employ NHPs and the numbers of animals and species that are used for each, (2) major sources of animals and NHP-related research services and facilities that are available to investigators (including, but not limited to the NIH-sponsored centers), and (3) expectations for future needs over the coming 5 years. The study was designed to use multiple methods to evaluate future demand and supply owing to the uncertainties associated with any single method, and was comprised of four distinct components:

- A review of the capabilities of major U.S. NHP service providers
- An analysis of trends in historical NHP use by NIH awardees and others
- An analysis of historical NHP use data and forecasts of future demand for NHPs reported by major NHP service providers, and definition of their operational characteristics
- Conduct of a survey of NIH-sponsored NHP users to characterize consumer demand

The first component, an initial review of capabilities of major U.S. NHP service providers, was conducted to establish a baseline understanding of major supply sources for NHPs and related services that are available to NIH-sponsored investigators.

The second component consisted of a survey and evaluation of NIH new and renewal grants and cooperative agreements awarded over the past 5 fiscal years[3] to identify trends, if any, in NHP usage that may be predictive of future demand from 2018 to 2022. NIH awardees typically serve as the main source of demand for animals and services provided by the NIH-sponsored NHP centers. In contrast, other large users of NHPs, including commercial pharmaceutical firms and federal laboratories, are believed to rely primarily on commercial NHP providers or their own in-house breeding colonies. Thus, the primary focus of the present study was on NHP usage driven by NIH awardees. Nevertheless, patterns of NHP usage by other communities may be indicative of the larger national picture of demand. Therefore, as a secondary objective, additional information was collected and assessed on NIH intramural use of NHPs and on national NHP importation trends over the past several years.

The third component of the study focused on obtaining and evaluating quantitative and qualitative information on supply of and future demand for NHPs in research and on identifying any emergent trends. While the NIH-sponsored NHP centers and colonies represent one set of research resources that is available to NIH-sponsored extramural investigators, other NHP resources exist within the U.S. that have capabilities that partially overlap with those of the NIH-supported resources. Thus, an additional focus of this component of the study was to explore operational similarities and differences between the NIH-supported centers and colonies and other similar organizations, to contribute to an understanding of the extent to which the centers that are not supported by NIH are presently supporting academic investigators.

The final component of the analysis focused on characterizing the potential consumer population for NIH-sponsored NHP resources and obtaining a better understanding of their needs. To accomplish this objective, a survey was conducted of scientists who currently use or plan to use NHPs in their research in the near term (2018-2022). The survey sought to define distinct subpopulations of users, identify important research capabilities desired by them, identify factors that may affect their decision to

[3] Due to differences in reporting of annual data from different sources, some data are arrayed by federal fiscal year while other data are arrayed by calendar year. In this report, fiscal years are indicated by the convention "FYnn" (e.g., FY13, FY14, etc.) while calendar years are indicated by the convention "20nn" (e.g., 2013, 2014, etc.).

use NIH-sponsored NHP resources for their studies (as opposed to other alternatives they may have), and identify – from the end user's perspective – the extent and nature of problems that may exist in obtaining NHPs or related research capabilities.

2. Methods

2.1 Review of Capabilities of NHP Service Providers

Identification of Relevant Suppliers

Major suppliers of NHP and NHP-related services were identified through a search of the U.S. Department of Agriculture (USDA) Animal Care Search Tool maintained by the Animal and Plant Health Inspection Service (APHIS). This database, which was in existence until early 2017, provided statistical data on all NHPs housed and used for research in the United States through FY15, based on annual reports submitted by each facility in compliance with the Animal Welfare Act.[4]

Based on the FY15 annual report data, the 27 largest suppliers were selected for further assessment (**Table 1**). These 27 organizations, in aggregate, accounted for 85% of all NHPs housed in the U.S. and 80% of all NHPs used in an active research study. The number of facilities to be evaluated was further reduced to 18 centers by (1) excluding 2 NIH facilities and 1 Army facility, (2) excluding 3 large pharmaceutical companies, and (3) excluding 3 other organizations – Harvard Medical School, Envigo CRS, and Wil Research Laboratories – that have ceased their NHP operations or were acquired by another listed firm since FY15. The 3 federal facilities as well as the 3 large pharmaceutical companies were excluded based on the understanding that these facilities are used exclusively to support the intramural studies of their respective organizations, and therefore are not resources that are generally available for extramural NIH-sponsored investigators. The data reported for Harvard Medical School were deemed to represent primarily the animals held and used by the New England Primate Research Center, which has since been closed. Similarly, it was determined that Envigo CRS has terminated its NHP business. Wil Research Laboratories was excluded because this organization was acquired in 2016 by Charles River Laboratories, which is included in the present study.

[4] Due to changes that occurred in 2017 in USDA's public reporting of annual reports submitted by animal facilities in compliance with the Animal Welfare Act, 2015 was the last year in which data for all U.S. facilities was provided in a single consolidated database, allowing a determination of the percentage of total U.S NHP usage represented by a single facility or group of facilities.

Table 1. Major NHP Facilities (2015 Holdings and Usage)

Organization	Total Animals	Animals Used	Included in Study?
University of Louisiana at Lafayette (New Iberia Research Center)	6,966	1,016	Yes
Covance Laboratories Inc.	6,865	5,913	Yes
SNBL USA Ltd	6,839	2,583	Yes
Charles River Laboratories Inc.	6,764	5,423	Yes
University of California - Davis (California NPRC)*	6,078	2,719	Yes
University of Puerto Rico (Caribbean Primate Research Center)*	4,848	2,755	Yes
Tulane University (Tulane NPRC)*	4,691	756	Yes
The Mannheimer Foundation Inc.	4,569	446	Yes
Oregon Health & Science University (Oregon NPRC)*	4,459	2,348	Yes
National Institute of Health*	4,350	3,735	No
MPI Research Inc.	4,115	3,452	Yes
Emory University (Yerkes NPRC)*	3,604	2,006	Yes
Texas Biomedical Research Institute (Southwest NPRC)*	3,502	1,981	Yes
NIAID-Morgan Island*	3,094	0	No
University of Wisconsin - Madison (Wisconsin NPRC)*	2,513	1,389	Yes
Bioqual Inc.	2,412	2,398	Yes
University of Texas M.D. Anderson Cancer Center (Keeling Center for Comparative Medicine and Research)*	1,932	1,052	Yes
Bristol Myers Squibb Company	1,486	1,144	No
University of Washington (Washington NPRC)*	1,316	762	Yes
Merck Sharp & Dohme Corp	1,299	1,241	No
U.S. Army Medical Research Institute of Infectious Disease	1,249	877	No
Pfizer Global Research & Development	1,184	1,142	No
Harvard Medical School (New England Primate Research Center)*	1,164	1,135	No
Primate Products Inc.	1,152	508	Yes
Wil Research Laboratories LLC	1,002	986	No
Wake Forest University*	965	965	Yes
Envigo CRS Inc.	863	751	No

**NIH-sponsored primate research center or breeding colony*

Data Collection Methods

After down-selection as described above, information on the capabilities of each of the remaining 18 organizations was obtained initially by a review of the organization's website. The NPRCs, in particular, maintain a detailed listing of their capabilities at a central website (nprcresearch.org) and the lists obtained from this site were individually reviewed and updated by each center's director and provided for this study. Points of contact (e.g., center directors or marketing staff) were identified for the remaining organizations and these individuals were queried via phone and e-mail to obtain marketing materials (e.g., service catalogs) or other materials containing expanded descriptions of capabilities that were not listed on the websites. Organizations were specifically requested to identify the species of NHPs that they worked with, the species (if any) that they bred, their approximate total holding capacity, and notable specialized facilities and major equipment. When not provided by the organization, NHP holding capacity was assumed based on the total number of animals held in FY15, as provided in the organization's annual Animal Welfare Act report to the USDA.

To augment the above methods, a Request for Information (RFI) was published in the *NIH Guide to Grants and Contracts*, requesting information on capabilities from organizations with typical usage of 400

or more animals per year.[5] Only 7 responses were received, including 3 from organizations previously captured in the 18 organizations identified previously. Of the 4 remaining respondents, 3 organizations – Johns Hopkins University, the Lovelace Biomedical and Environmental Research Institute, and the University of Pittsburgh – were considered to have significant capacity, and their responses were included in the analysis, resulting in a total of 21 organizations being included. The USDA data indicate that these 3 organizations used from 500 to 800 animals per year in 2015, falling just below that of the 18 organizations selected previously.

Assessment

All reported capabilities were summarized in an Excel workbook to facilitate comparisons across organizations. Analysis was performed to identify capabilities that were common to both NIH-sponsored and other NHP centers as well as capabilities that were unique to either the NIH-sponsored or other NHP centers.

2.2 Analysis of Trends in Historical NHP Use by NIH Grantees and Others

Identification of Relevant Awarded Grants and Cooperative Agreements

An initial set of relevant grants and cooperative agreements awarded from FY13 through FY17 was identified by conducting a keyword search of the NIH IMPAC II system using the iSearch tool. Keywords were developed to include the NHPs commonly used in biomedical research (**Figure 1**), including both common and scientific names as well as alternate forms. Generic terms (e.g., nonhuman primate, monkey) were also included to provide the widest possible coverage of all species. A list of all keywords is provided in **Appendix A**. The search was limited to award mechanisms associated with conduct of research or research resource projects (**Figure 2**) and was further limited to new awards and competitive renewals (Application Types 1 and 2) and awards involving a change to the awarding NIH IC for a renewal (Application Type 9), as these application types require inclusion of a Vertebrate Animal Section in the application package. Applications that were not selected for award and contracts were excluded. Most of the relevant awards were identified by searching for keywords in the Vertebrate Animal Section. However, for certain activity codes in which it was not clear that the Vertebrate Animal Sections were available to search,[6] keyword searches were extended to the title and abstract of the grant/cooperative agreement application that was submitted for the ensuing award.

African Green (Vervet) Monkeys
Baboons
Capuchins
Cynomolgus Macaques
Mangabeys
Marmosets
Owl Monkeys
Patas Monkeys
Pigtail Macaques
Rhesus Macaques
Sabaeus Monkeys
Squirrel Monkeys
Tamarins

Figure 1. NHPs Commonly Used in Biomedical Research

[5] RFI: Infrastructure for Research in Nonhuman Primates, Notice Number: NOT-OD-17-099, Release Date: August 14, 2017. The lower limit of 400 animals used per year that was indicated in the RFI was established on the assumption that organizations with lower use levels primarily served their intramural investigators and would not serve as significant sources of NHPs and related services for the larger research community. FY15 USDA APHIS data indicated 37 organizations with holdings of 400 or more animals out of 176 organizations that held NHPs; these 37 organizations accounted for 90% of all animals held.

[6] For any specific award mechanism, the ability to electronically search the Vertebrate Animal Section using iSearch depended on the year in which electronic submissions of applications using the SF424 (R&R) form were required. For late transitioning activities and complex grants and cooperative agreements awarded for FY13-FY16, it was not certain that Vertebrate Animal Sections were electronically searchable. For this reason, keyword searches of titles and abstracts were also used for the following Activity Codes that NIH uses: P Series (all activity codes), R10, R24, S06, U01, U10, U19, U24, U45, U54, and U56.

- Director Program Projects (D Series)
- Fellowship Programs (F Series)
- Research Career Programs (K Series)
- Research Program Projects and Centers (P Series)
- Research Projects (R Series)
- Research-Related Programs (S Series)
- Cooperative Agreements (U Series)

Figure 2. Award Mechanisms (Activity Categories) Included in Analysis

Administrative data on each award identified from the initial keyword search (i.e., fiscal year of award, activity code, award number, award title, principal investigator (PI), performing organization, sponsoring NIH IC, etc.), as well as abstracts were retrieved from the IMPAC II system using iSearch. All data was captured in an Excel spreadsheet. In addition, Vertebrate Animal Sections and/or full applications for the identified awards were retrieved from the IMPAC II database using the Query, View, and Report system, to enable further analysis.

Analysis of Awards

The Vertebrate Animal Section of each identified award and, as needed, the full application, were reviewed to confirm the use of NHPs in the project. Once confirmed, data on planned NHP use was recorded and combined with the previously captured administrative data for further analysis. Data on planned NHP use that was recorded included, for each species used, the number of animals used, further broken down by age and sex as reported in the application. When ages were reported, animals of different ages were grouped into one of four categories: Infant, Juvenile, Adult or Geriatric. Age ranges for each category were established depending on the species (as defined in **Appendix B**).

Each award was categorized for further analysis using defined taxonomies developed in collaboration with ORIP staff to describe the primary scientific area being addressed (primary research area, **Figure 3**) and the type of research being performed (**Figure 4**). A single scientific area and type of research was used for each award to ensure that animal use associated with the award was not multiply counted. Full definitions of the research area and research type taxonomies are provided in **Appendix C**. Categorization of each award was based solely on information contained in the project abstract.

- Auditory System
- Blood Disorder
- Cancer
- Cardiovascular Disease
- Dental/Oral Disease
- Diabetes
- Fetal Development
- HIV/AIDS
- Infectious Disease – Bacterial
- Infectious Disease – Viral (Non-HIV/AIDS)
- Infectious Disease – Parasitic
- Infectious Disease – Fungal
- Molecular Immunology (General)
- Musculoskeletal Disorders
- Neuroscience – Behavioral and Systems
- Neuroscience – Molecular
- Nutritional and Metabolic Disorders (Non-Diabetes)
- Regenerative Medicine & Transplantation
- Reproductive Health
- Respiratory System
- Urologic Diseases
- Visual System
- Other

Figure 3. Primary Research Areas

- Basic Research
- Applied Research – Medical Products
- Applied Research – Surgical Techniques
- Translational Research
- Biologics Development/Testing
- Drug Development/Testing
- Medical Device Development/Testing
- NHP Infrastructure/Resource
- Other

Figure 4. Types of Research

Finally, the site of performance for NHP studies was noted when the studies were proposed to be performed at an animal facility different from that of the organization that was awarded the grant or cooperative agreement. Such study sites were characterized as being either:

- An NPRC or other ORIP-sponsored NHP facility (with the specific facility identified),
- Another university (i.e., an academic center other than an ORIP-sponsored facility),
- A commercial organization, or
- A federal laboratory.

Intramural NIH Usage Data

Data on the species and number of NHPs acquired from external suppliers for use by intramural NIH investigators was provided by the NIH Office of Research Services, Division of Veterinary Resources. Data was provided for each fiscal year from FY13 to FY17, and each purchase of animals was classified by that office according to the supplier and institute end user. Limited information on the planned use of the animals was also provided.

National NHP Import Trends

Data on the species and number of NHPs imported into the U.S. was provided by the Centers for Disease Control and Prevention, National Center for Emerging Zoonoses and Infectious Diseases, Division of Global Migration and Quarantine, and Quarantine and Border Health Services Branch. Data was provided for each fiscal year from FY12 to FY17.

2.3 Analysis of Historical Use Data, Forecasts and Operating Information from Major NHP Service Providers

Organizations Included in Assessment

Data was collected from the 16 organizations listed in **Table 2**, including 7 NIH-sponsored NPRCs, 3 academic centers that house NIH-sponsored NHP colonies, and 6 other academic or commercial organizations.[7] These organizations were selected as described previously for the review of supplier capabilities, using data from FY15 annual reports on animal use to the USDA which indicated that these organizations represented the largest U.S. suppliers of NHPs and associated research services that are readily available to NIH-sponsored extramural investigators. Based on FY15 annual reports, the organizations listed in **Table 2** accounted for 56% of all NHPs used in studies during that year and 77% of all NHPs held but not used for studies.

[7] Data was sought from the same 18 organizations initially selected for the review of capabilities, but 2 organizations declined to respond.

Table 2. NHP Facilities Included in Assessment

1. NIH-Sponsored NPRCs
University of California - Davis (California NPRC)
Oregon Health & Science University (Oregon NPRC)
Texas Biomedical Research Institute (Southwest NPRC)
Tulane University (Tulane NPRC)
University of Washington (Washington NPRC)
University of Wisconsin - Madison (Wisconsin NPRC)
Emory University (Yerkes NPRC)
2. Academic Centers Hosting NIH-Sponsored NHP Breeding Colonies*
University of Puerto Rico (Caribbean Primate Research Center)
University of Texas MD Anderson Cancer Center (Keeling Center for Comparative Medicine and Research)
Wake Forest University
3. Other Academic and Commercial Providers
Bioqual, Inc.
Charles River Laboratories, Inc.
Covance Laboratories, Inc.
The Mannheimer Foundation, Inc.
SNBL USA, Ltd
University of Louisiana at Lafayette (New Iberia Research Center)

**NHP holdings include one or more NIH-sponsored breeding colonies and may include additional colonies not sponsored by the NIH.*

Data Collection and Analysis

The Directors of the seven NPRCs and two additional ORIP-sponsored centers (the Caribbean Primate Research Center and the Keeling Center for Comparative Medicine and Research) were directly solicited by the Division of Comparative Medicine to provide (1) any forecasts of future annual NHP usage that they had developed, focusing on the 2018-2022 timeframe, (2) descriptions of their forecast methodology, and (3) an assessment of any expected changes in future demand for specific NHP-related research services or areas of expertise from the levels that each organization was currently providing. Written responses to the NIH inquiry were provided to Leidos, and follow-up interviews were then conducted with each of these centers to obtain additional insights on each center's expectations of future demand, their abilities to meet this demand, and to identify any other factors that were felt to be significant in assessing national demand for and supply of NHPs for research. Interviews were typically conducted with the center's director; in some cases, additional members of the center's staff were included.

For the remaining seven organizations, knowledgeable points of contact were identified within each organization, and focused interviews were conducted to obtain similar information to that obtained from the ORIP-sponsored centers. Interviewers also sought information on the general characteristics of each organization's customer base, the major drivers of their workload, and their business model in order to provide a qualitative basis to evaluate the extent to which each organization operationally resembled the ORIP-sponsored centers, and therefore, could be considered as an alternative to them. The individuals who were interviewed included center directors, or – in the case of the commercial providers – the firm's president, senior managers of NHP operations, and/or business development leads for NHP sales and services.

In addition to the interviews conducted with the targeted organizations listed in **Table 2**, the previously described RFI that was used to collect information on supplier capabilities also requested comments on future NHP demand. Responses to the RFI were received from three large users of NHPs (listed in **Table 3**) as well as the Federation of American Societies for Experimental Biology. While these

organizations were not interviewed, their inputs were considered together with the information gathered during interviews of the organizations listed in **Table 2**.

Table 3. Additional RFI Respondents

Federation of American Societies for Experimental Biology
The Johns Hopkins University
Lovelace Biomedical and Environmental Research Institute
University of Pittsburgh

Because of the inaccuracies inherent in estimating future demand, several indicators of demand were evaluated to identify consistent directional indicators across multiple measures, including trend analysis of historical NHP-use data, quantitative forecasts or qualitative predictions of future use by each organization, and the extent and nature of any current shortfalls in supply of NHPs. In addition, supply factors were qualitatively assessed, looking at the degree to which various supplier organizations served the academic research community that is traditionally supported by NIH and the ability of supplier organizations to meet any future increases in demand. Various insights into scientific, programmatic, and other factors that may affect NHP demand and/or supply were captured, although the specific impact of these factors may not, in most cases, be quantifiable.

2.4 Survey of NHP Users

Survey Participant Identification

NIH staff obtained the e-mail addresses for the PIs of the awards previously identified as involving use of NHPs from the NIH grants management information system (IMPAC II) and created a distribution list for the survey invitation. NIH staff curated the distribution list and sent the invitations to the PIs.

Survey Design and Administration

A nine-question survey was developed including a mix of response types, to obtain information on the types of NHP facilities available to respondents, species and number of animals they planned to use, location of planned NHP studies, factors of importance for their NHP studies, and problems they had encountered. The complete survey is provided in **Appendix D**. The first question allowed individuals who may have used NHPs in the past but did not plan to use them in the future to opt out of the remainder of the survey and also allowed individuals that received the invitation in error to opt out, but these individuals were included in the calculation of the response rate. The survey was configured to allow anonymous responses, but to allow only a single response from any single device.

A generic NIH e-mail mailbox (NHPAnalysis@od.nih.gov) was used by NIH staff to send e-mail invitations containing a link to the survey site to all participants., Because the method used to determine invitees was limited to the PIs listed (or designated) on the NIH award, it was recognized that some co-investigators who planned to use NHPs might not be included in the initial invitation list; this was considered to be especially likely on large program project grants that involved multiple sub-projects, of which only a few might employ NHPs. To mitigate this problem, the invitation encouraged invitees to forward the message to any other investigators on their awards who expected to use NHPs. A limited number of undeliverable messages were received in response to the invitation, presumably due to changes of institution by an investigator, and these were subtracted from the total number of invitations in determining the response rate.

The survey was open for 2 weeks from late March through early April 2018, and reminders were sent to all invitees at 7 and 12 days after the launch of the survey.

Data Analysis

Response data were downloaded from the survey site as an Excel file and all analyses of quantitative data were conducted using Excel. For selected questions, statistical analyses were applied to evaluate differences in answers from different groups of respondents (i.e., respondents who differed in the NHP facilities available to them, and respondents who differed in the number of animals planned for use). Differences in the distribution of responses to multiple choice questions by different groups were evaluated by a chi square test, while differences among groups in their average numerical ratings for factors of importance were evaluated by ANOVA and post hoc analysis using the Tukey-Kramer procedure. Differences with probability less than or equal to 5% were considered significant. Qualitative data (i.e., narrative responses to questions pertaining to required research capabilities, factors determining choice of NHP facility, and problems encountered) were reviewed by scientists to identify and summarize recurring themes.

3. Results

3.1 Capabilities of Major U.S. NHP Service Providers

In addition to information captured from organizational websites, responses to inquiries were received from all but one of the 18 organizations selected for review. **Table 4** summarizes major areas of commonality and unique (or relatively unique) capabilities of the NPRCs compared to other NHP service providers. Overall, the NPRCs appear to provide a much more diverse portfolio of services than those available from commercial providers and most other universities. In particular, the veterinary medical support procedures available at NPRCs are much more extensive than those at other organizations that were reviewed.

Within the facilities evaluated, a total of 15 different NHP species were identified that are being bred or used in medical research, as follows:

- African Green (Vervet) Monkey
- Brown/Tufted Capuchin
- Common Marmoset
- Cynomolgus Macaque
- Dusky Titi Monkey
- Hamadryas Baboon (and possibly other baboon species)
- Japanese Macaque
- Owl Monkey
- Patas Monkey
- Pigtail Macaque
- Rhesus Macaque
- Sooty Mangabey
- Spider Monkey
- Squirrel Monkey
- White-Capped Mangabey

Table 4. Capabilities of NPRCs vs. Other NHP Service Providers

Overlapping Capabilities	Distinctive Capabilities of NPRCs	Distinctive Capabilities of Other Service Providers

• Animal resource management
• Imaging (conventional)
• Immunology techniques
• Pathology
• Pharmacokinetics and pharmacodynamics
• Stem cells
• Toxicology
• Veterinary medical research support procedures, including:
  - Inoculation/immunization/ article administration
  - Conventional surgical procedures for chronic indwelling catheter systems
  - Fluid collection
  - Gastrointestinal procedures
  - Physical examinations
• Virology
	• Assisted reproductive technologies
	• Bioengineering, bioinformatics, and biotelemetry
	• BSL4/ABSL4
	• Functional magnetic resonance imaging
	• Genetics and functional genomics*
	• Inhalation exposure facility and aerosol exposure*
	• Metabolic phenotyping*
	• Metabolomics, proteomics, and transgenesis*
	• Transplantation biology
	• Veterinary medical research support procedures, including:
	  - Most conventional surgery procedures
	  - Flexible videoendoscopy
	  - Colposcopy, rhinoscopy, and thoracoscopy
	  - Ultrasound guided techniques
	• Viral vectors
		• Juvenile and developmental toxicology†
		• Laboratory of Primate Morphology (skeletal collection) [Univ. of Puerto Rico]
		• Large animal irradiation and radiobiology:
		  - Acute Radiation Syndrome Laboratory [SNBL]
		  - Radiation Survivor Core [Wake Forest Univ.]
		• Neurosurgical procedures and implants [Wake Forest Univ.]

**Capability is available outside of NPRCs but is limited to a single organization*
†Capability is available within a single NPRC

However, only 11 of the above-listed species are currently being bred in the U.S., with rhesus macaques being the most commonly bred species. **Table 5** provides a list of species currently being bred in the U.S. and their sources (limited to the organizations evaluated for this study). For some species (e.g., squirrel monkeys), the NIH-sponsored centers represent the only source of U.S.-bred animals.

Actual numbers of animals available from individual suppliers varies. Most of the organizations that were surveyed have estimated NHP holding capacities of at least 1,000 animals and house multiple species. The current census of each species was not provided and may vary over time. The seven NPRCs, together with the Caribbean Primate Research Center, have a combined estimated NHP holding capacity of 31,500 animals, with the five largest NPRCs and the Caribbean Primate Research Center each able to hold 3,600 or more animals. Other academic centers that maintain NIH-sponsored breeding colonies have a combined estimated holding capacity of 3,600 animals, only some of which is used for the NIH-sponsored colonies. With the exception of the Keeling Center, these academic centers tend to be smaller (under 1,000 animals). Other commercial research and non-profit organizations that were included in the evaluation (including the New Iberia Research Center, which operates in some ways similar to a commercial organization) have a combined estimated holding capacity of 42,600 animals and range in size from 1,200 to 14,000 animals. While these estimates provide approximate holding capacities, actual holding capacity will vary according to both the species housed and the housing conditions (e.g., group housing vs. individual caging).

Table 5. U.S. NHP Breeders

Species	NIH-Sponsored Centers	Other Sources
African Green (Vervet) Monkey	• Wake Forest University	• New Iberia Research Center
Baboon	• Southwest NPRC • University of Texas (Keeling Center)	• The Mannheimer Foundation
Common Marmoset	• Southwest NPRC • Wisconsin NPRC	• The Johns Hopkins University
Cynomolgus Macaque		• New Iberia Research Center • The Mannheimer Foundation • Primate Products Inc.
Dusky Titi Monkey	• California NPRC	
Japanese Macaque	• Oregon NPRC	
Owl Monkey		• University of Texas (Keeling Center)*
Pigtail Macaque	• The Johns Hopkins University • Washington NPRC	
Rhesus Macaque	• California NPRC • Caribbean Primate Research Center • Oregon NPRC • Southwest NPRC • Tulane NPRC • Wisconsin NPRC	• Covance Laboratories • The Johns Hopkins University • New Iberia Research Center • The Mannheimer Foundation • Primate Products Inc. • University of Texas (Keeling Center)*
Sooty Mangabey	• Yerkes NPRC	
Squirrel Monkey	• University of Texas (Keeling Center)	

**Baboon and squirrel monkey colonies at the University of Texas are sponsored by the NIH; their owl and rhesus macaque colonies are not.*

3.2 Historical NHP Use by NIH Grantees and Others

Planned NHP Use by NIH Awardees

In order to provide a more accurate depiction of demand for NHPs in research projects, data for awards supporting the maintenance of breeding colonies (resources) or other NHP infrastructure (i.e., awards associated with supply of animals, rather than demand) were excluded from analyses except where noted.[8] Overall planned use of NHP species for project-driven and resource-related research in FY13-FY17 awards is shown in **Table 6**. Rhesus macaques comprised 65% of all planned use for project-driven research, followed by cynomolgus macaques (15%) and baboons (5.5%). Overall planned use of NHPs for new and renewal research grants and cooperative agreements awarded from FY13 to FY17 and planned use of each species, together with the number of grants and cooperative agreements awarded are shown in **Figure 5**. It should be noted for the purposes of this report that all animal use reported for any single award was allocated to the fiscal year corresponding to the first year of the award. It was not possible from the data obtained to determine the exact number of animals used in any given year. Excluding infrastructure/resource awards, 49% of all animals were associated with 5-year awards, and an additional 21% of animals were associated with 3- or 4-year awards. Thus, the number of animals planned is likely, in many if not most cases, to reflect NHP demand for several years beyond the year to which the animals were allocated in these figures.

[8] NHP infrastructure/resource awards often report the use of all animals in a colony and are separately considered from other types of awards to avoid the distortion that such large numbers create in analyzing patterns of use.

Table 6. Planned NHP Use in Grants and Cooperative Agreements Awarded from FY13 to FY17

Research Awards Other Than Infrastructure/Resource	
Species	Number of Animals
Rhesus Macaque	19,618
Cynomolgus Macaque	4,624
Baboon	1,663
Marmoset	936
Pigtail Macaque	691
Other or Unspecified Macaque (Macaca sp.)	671
African Green (Vervet) Monkey	659
Squirrel Monkey	395
Japanese Macaque	368
Titi Monkey	218
Owl Monkey	59
Capuchin Monkey	54
Tamarin Monkey	32
Mangabey	10
Other NHP or Mixed Species*	176
Total Non-Infrastructure/Resource	30,174
NHP Infrastructure/Resource Awards	
Species	Number of Animals
Rhesus Macaque	23,371
Pigtail Macaque	2,553
Baboon	1,016
Squirrel Monkey	608
African Green (Vervet) Monkey	380
Marmoset	239
Mangabey	180
Cynomolgus Macaque	145
Capuchin Monkey	30
Other or Unspecified Macaque (Macaca sp.)	15
Other NHP or Mixed Species*	14,200
Total Infrastructure	42,737

** Awards involving multiple species in which specific numbers for each species were not reported*

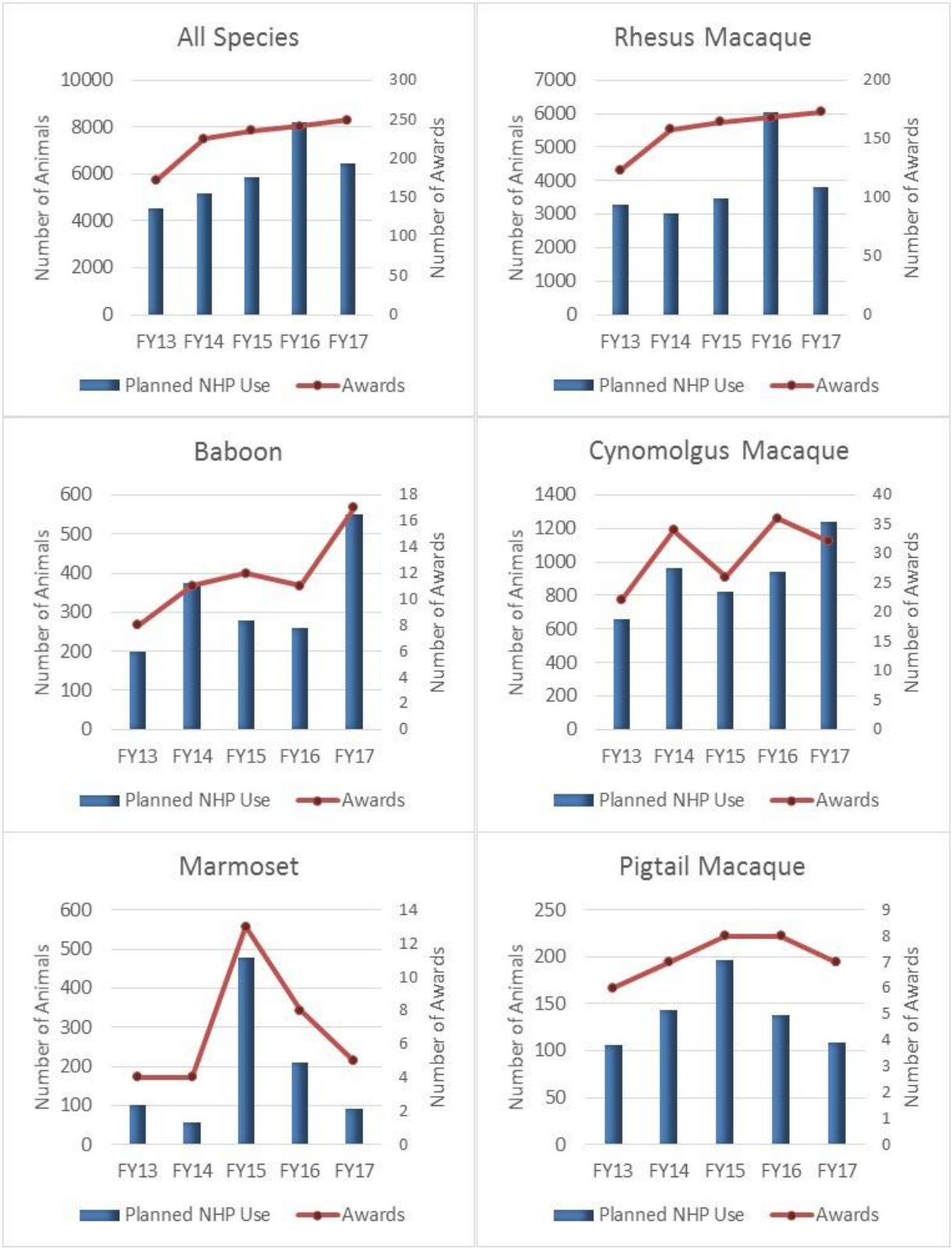

Figure 5. Number of Awards Using NHPs and Planned Use of NHPs in FY13-FY17 Awards, Excluding Infrastructure/Resource Awards, by Species

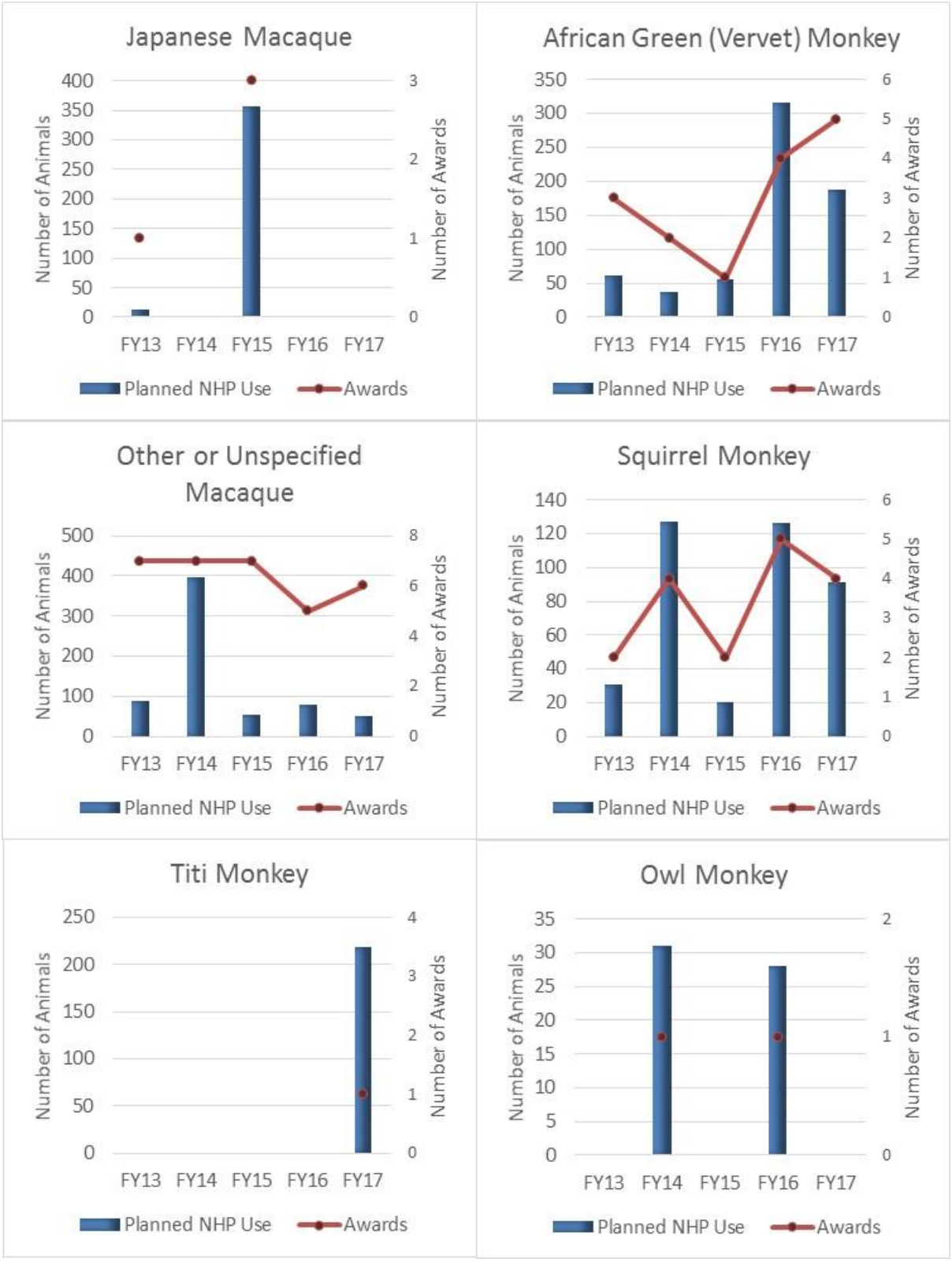

Figure 5. Number of Awards Using NHPs and Planned Use of NHPs in FY13-FY17 Awards, Excluding Infrastructure/Resource Awards, by Species (Continued)

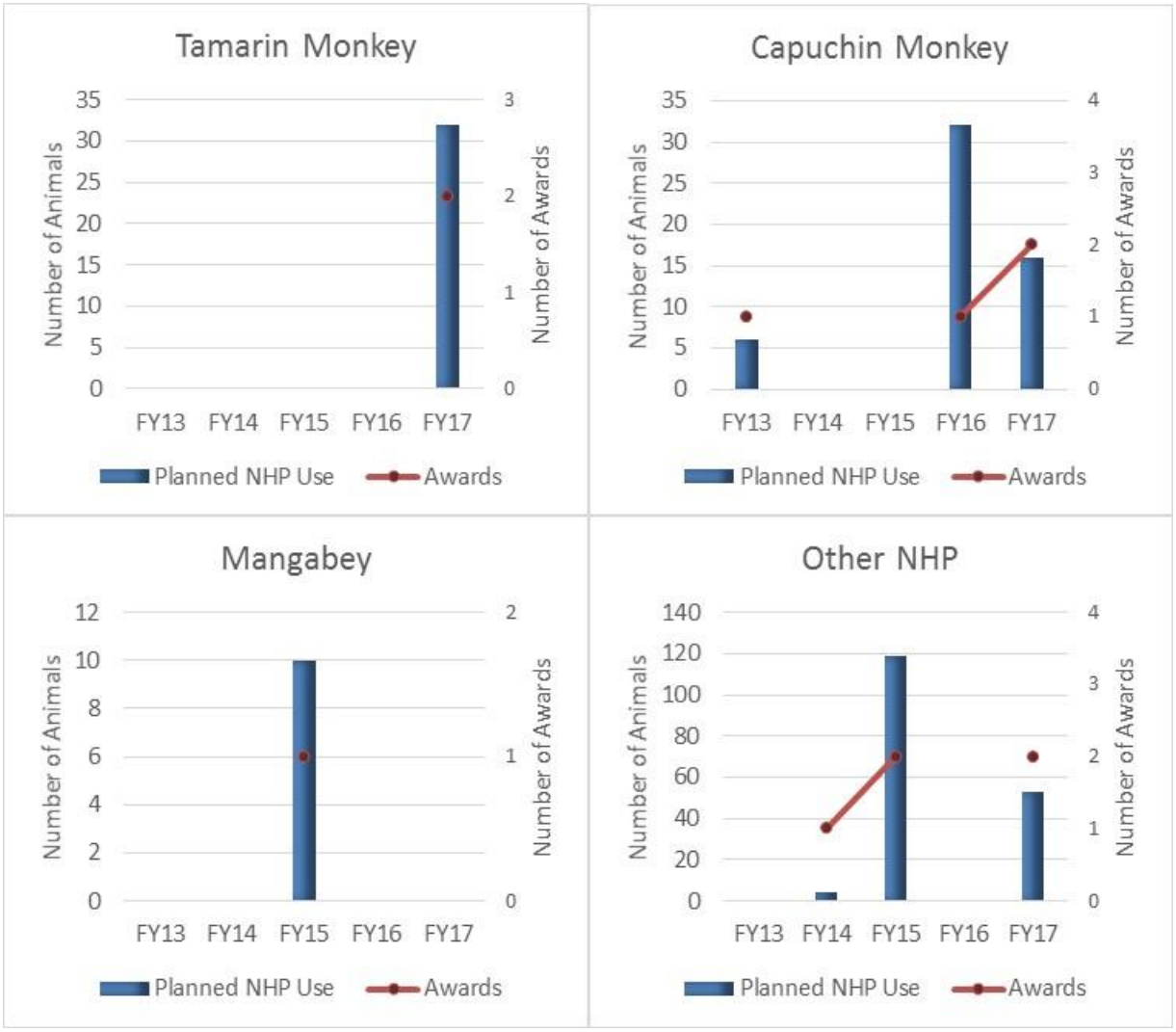

Figure 5. Number of Awards Using NHPs and Planned Use of NHPs in FY13-FY17 Awards, Excluding Infrastructure/Resource Awards, by Species (Continued)

While there was an overall trend of increasing use of NHPs from FY13 to FY17, this trend is driven largely by trends in use of rhesus and cynomolgus macaques. In the case of rhesus macaques, a large increase in planned use occurred in FY16, which may be overlaid by a trend of gradually increasing use since FY14. The increase in FY16 was due to a large increase in planned use for studies related to HIV/AIDs sponsored by NIAID and, to a lesser extent, behavioral and systems neuroscience studies sponsored primarily by NICHD and NIMH (**Figure 6**, **Table 7**). In the case of cynomolgus macaques, use appears to be increasing fairly steadily each year. Although a large increase in planned use of baboons was observed in FY17, data from prior years does not indicate that this increase is part of a longer-term trend. For all other species, planned use was more variable without apparent trends. In general, the planned use of animals for any particular NHP species was not well correlated with the number of awards that employed the species.

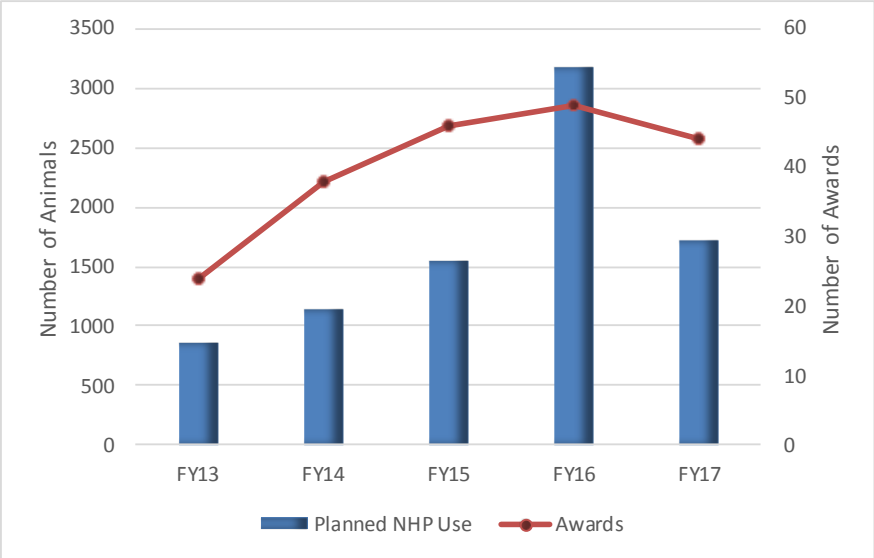

Figure 6a. Planned Use of Rhesus Macaques for HIV/AIDS Research in FY13-FY17 Awards

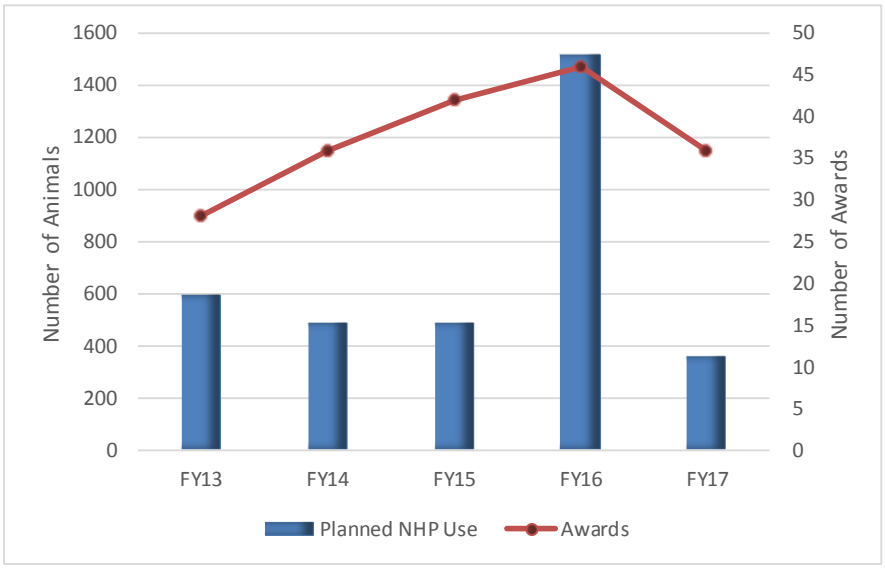

Figure 6b. Planned Use of Rhesus Macaques for Behavioral and Systems Neuroscience Research in FY13-FY17 Awards

Table 7. Planned Use of Rhesus Macaques in FY13-FY17 Awards, Excluding Infrastructure/Resource Awards, by Sponsoring Institute

Institute/Center/Office	Number of Animals by Initial Fiscal Year of Award				
	FY13	FY14	FY15	FY16	FY17
National Cancer Institute (NCI)	30	15	50	86	34
National Center for Advancing Translational Sciences (NCATS)	12	-	-	-	-
National Center for Complementary and Integrative Health (NCCIH)	-	-	-	18	-
National Eye Institute (NEI)	242	250	320	288	266
National Heart, Lung, and Blood Institute (NHLBI)	19	64	287	215	145
National Institute of Allergy and Infectious Diseases (NIAID)	1,111	1,381	1,680	2,855	2,112
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)	12	-	-	-	-
National Institute of Biomedical Imaging and Bioengineering (NIBIB)	4	8	4	4	4
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)	725	537	153	876	268
National Institute of Dental and Craniofacial Research (NIDCR)	106	15	58	156	62
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)	62	9	-	4	57
National Institute of Environmental Health Sciences (NIEHS)	-	-	-	-	49
National Institute of General Medical Sciences (NIGMS)	18		124	4	
National Institute of Mental Health (NIMH)	527	399	245	692	194
National Institute of Neurological Disorders and Stroke (NINDS)	70	114	85	332	242
National Institute on Aging (NIA)	132	43	11	202	78
National Institute on Alcohol Abuse and Alcoholism (NIAAA)	48	24	101	23	36
National Institute on Deafness and Other Communication Disorders (NIDCD)	14	30	46	19	37
National Institute on Drug Abuse (NIDA)	128	139	308	177	153
Office of the Director (OD)/ORIP	12	-	-	100	58
Total	3,272	3,028	3,472	6,051	3,795

Tables providing full details of annual planned use of each NHP species by sponsoring institute are provided in **Appendix E**. At the level of individual NIH institutes and centers, NIAID is the largest sponsor of NHP studies, accounting for 42% of planned use for project-driven research awards over the 5-year period that was reviewed (**Figure 7**). Other major institute sponsors include NICHD (12.9%), NIMH (8.3%), NEI (6.2%), NHLBI (5.6%), NINDS (5.4%), NIA (4.1%), and NIDA (4%). The most notable institute-level trend in NHP use was a general increase in use by NIAID which was driven primarily by increased use of rhesus macaques. Aside from this, the only other institute that displayed a possible trend in use was NIA, which had an average planned use of 122 animals for FY13-FY14 awards, which increased to a fairly constant average of 336 animals for FY15-FY17 awards. However, this aggregate pattern combining numbers from all species was not observed in any of the individual species that comprised the total. Overall, within the award mechanisms and types included in this analysis, awards involving NHP use represented less than 2% of all grants and cooperative agreements awarded each year (**Table 8**).

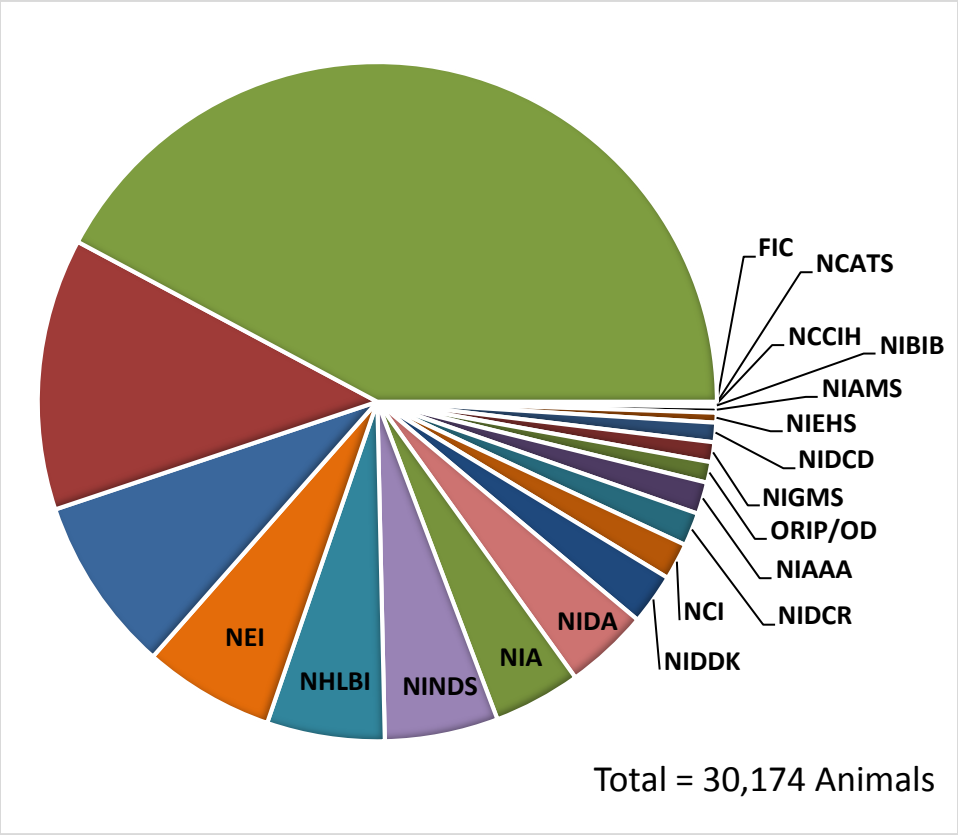

Figure 7. Distribution by Sponsoring Institute of Planned Use of NHPs in FY13-FY17 Awards, All Species, Excluding Infrastructure/Resource Awards

Table 8. Awards Involving NHP Use Compared to Total Awards, by Fiscal Year

	Number of Awards				
	FY13	FY14	FY15	FY16	FY17
NHP Awards	182	231	248	260	256
All Awards	14,082	15,586	15,815	16,930	16,919
NHP Awards as Percent of All Awards	1.3%	1.5%	1.6%	1.5%	1.5%

The distribution by research area of planned NHP use across all years is shown in **Figure 8**. Most research areas displayed no obvious trends in regard to either the numbers of NHPs used or the species employed. The previously noted increase in use of rhesus macaques for HIV/AIDS research is a principal exception. In the case of behavioral and systems neuroscience research, the previously noted surge in FY16 in use of rhesus macaques appears as a singular event: As seen in **Figure 6b**, aside from the FY16 surge, the general trend in use of rhesus macaques over the remaining 4 years was slightly downward. However, use of several other species in this research area increased in FY16 or FY17, including African green (vervet) monkeys, baboons, cynomolgus macaques, marmosets, and squirrel monkeys, so that, across all species, the number of animals planned in FY17 awards was 37%-62% higher than during FY13-FY15 (**Figure 9**). A table providing full details of annual planned use by research area is provided in **Appendix F**.

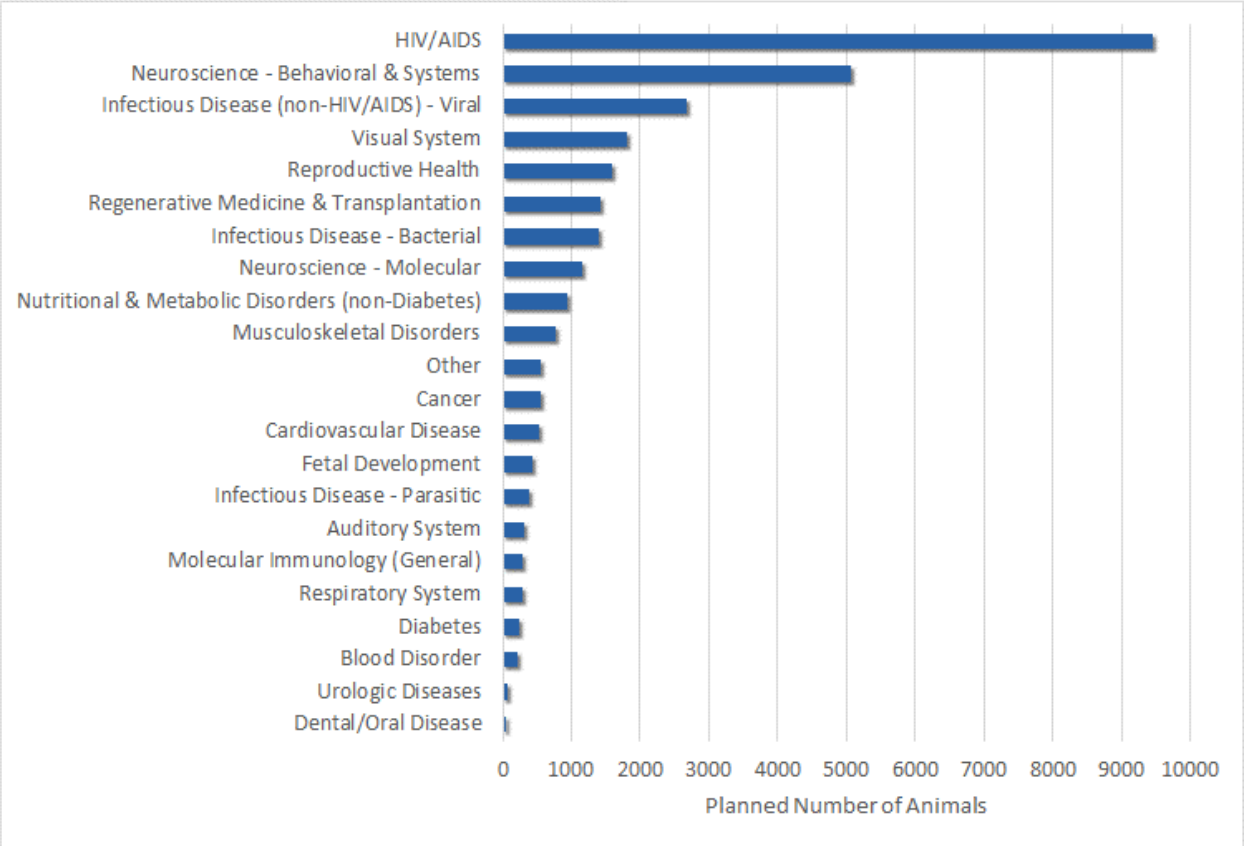

Figure 8. Planned Use of NHPs (All Species) in FY13-FY17 Awards, Excluding Resource/Infrastructure Awards, by Research Area

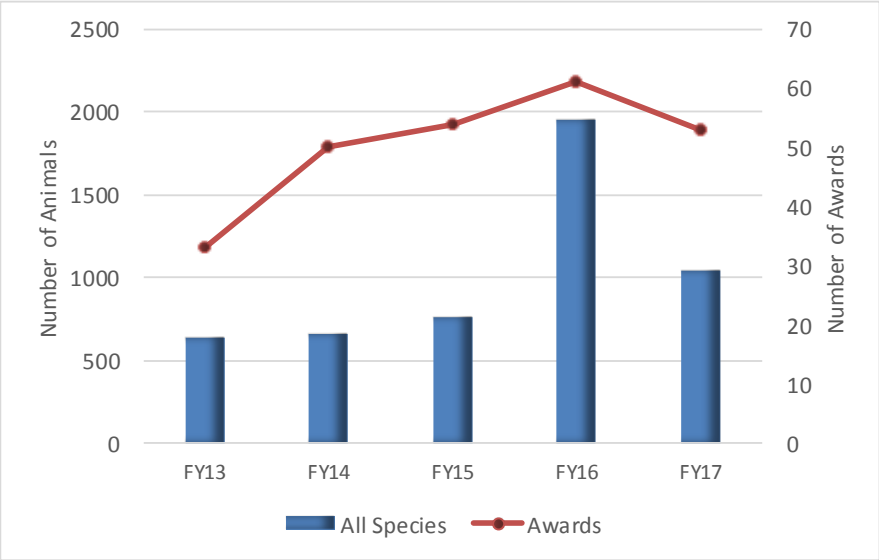

Figure 9. Planned Use of NHPs (All Species) for Behavioral and Systems Neuroscience Research in FY13-FY17 Awards

The breakout of planned use of NHPs by type of research is shown in **Table 9**. Across all years, basic research generally accounted for about half of all planned use, ranging from 46%-58% of use in any single year. Use of NHPs for applied research on medical products (e.g., evaluation of new concepts for therapeutics or vaccines) ranged from 15%-39% of all use in any single year, with the remaining use being devoted mainly to advanced product development and other types of translational research.

Table 9. Planned Use of NHPs in FY13-FY17 Awards, Excluding Infrastructure/Resource Awards, by Type of Research

	Number of Animals by Initial Fiscal Year of Award						
Research Type	FY13	FY14	FY15	FY16	FY17	FY13-FY17	%
Basic Research	2,106	2,457	2,852	4,021	3,740	15,176	50.3%
Applied Research - Medical Products	1,266	1,373	1,589	3,172	949	8,349	27.7%
Drug Development/Testing	265	237	478	504	805	2,289	7.6%
Biologics Development/Testing	529	373	345	189	770	2,206	7.3%
Translational Research	278	698	373	239	121	1,709	5.7%
Medical Device Development/Testing	76	10	76	56	24	242	0.8%
Applied Research - Surgical Techniques	-	-	149	-	21	170	0.6%
Other	16	17	-	-	-	33	0.1%
All Research Types Total	4,536	5,165	5,862	8,181	6,430	30,174	100%

Although data on the sex of the animals used was recorded when available, most applications did not provide full details on this aspect, either failing to identify the sex of the animals used (in approximately 45% of awards) or stating that both males and females would be used without providing specific numbers for each sex (in approximately 15% of awards). Thus, only tentative observations are

possible. Based only on those awards in which specific numbers of each sex were reported, the overall numbers of males and females used across all 5 years that were reviewed are very similar, but some differences in the mix of sexes used are apparent when looking across different research areas (**Table 10**). In addition to studies of fetal development and reproductive health, which involve predominantly females, there was a tendency for greater use of females in studies of nutritional and metabolic disorders (excluding diabetes). Among areas involving large numbers of animals, a preference for males is seen in HIV/AIDS research, neuroscience research, and studies of the visual system. These preferences are also seen when looking at the major NHP species used (i.e., rhesus macaques, cynomolgus macaques, and baboons; data not shown). The reasons for these preferences are not immediately apparent. No obvious changes in the proportions of sexes used across the 5-year period were evident.

Table 10. Planned Use of Male vs. Female NHPs in FY13-FY17 Awards, by Research Area

Research Area	Number of Animals (All Species)		
	Males	Females	Both Sexes
Auditory System	37	10	76
Blood Disorder	54	46	60
Cancer	110	125	168
Cardiovascular Disease	215	98	170
Dental/Oral Disease	0	6	10
Diabetes	69	48	10
Fetal Development	4	279	84
HIV/AIDS	1,514	990	1,330
Infectious Disease - Bacterial	24	104	147
Infectious Disease - Parasitic	28	0	126
Infectious Disease (non-HIV/AIDS) - Viral	259	280	253
Molecular Immunology (General)	60	63	72
Musculoskeletal Disorders	188	109	189
Neuroscience - Behavioral & Systems	1,675	1,034	1,237
Neuroscience - Molecular	470	226	149
Nutritional & Metabolic Disorders (non-Diabetes)	62	449	150
Other	121	109	0
Regenerative Medicine & Transplantation	151	70	234
Reproductive Health	138	1,378	0
Respiratory System	115	30	50
Urologic Diseases	8	54	0
Visual System	312	112	226
All Research Areas Total	5,614	5,620	4,741

As with sex, the ability to evaluate trends in use of different ages of NHPs was limited by variable reporting. Applications did not consistently identify discrete age groups when studies spanned multiple ages. In approximately 60% of awards, it was possible to identify such groups, and planned use across all species by fiscal year within this subset of awards is shown in **Figure 10**. An increased emphasis on juvenile animals is evident in recent years, while interest in infant animals has been variable. The increase in use of juvenile animals was most clearly seen in rhesus macaques and, to a lesser extent, in cynomolgus macaques (data not shown).

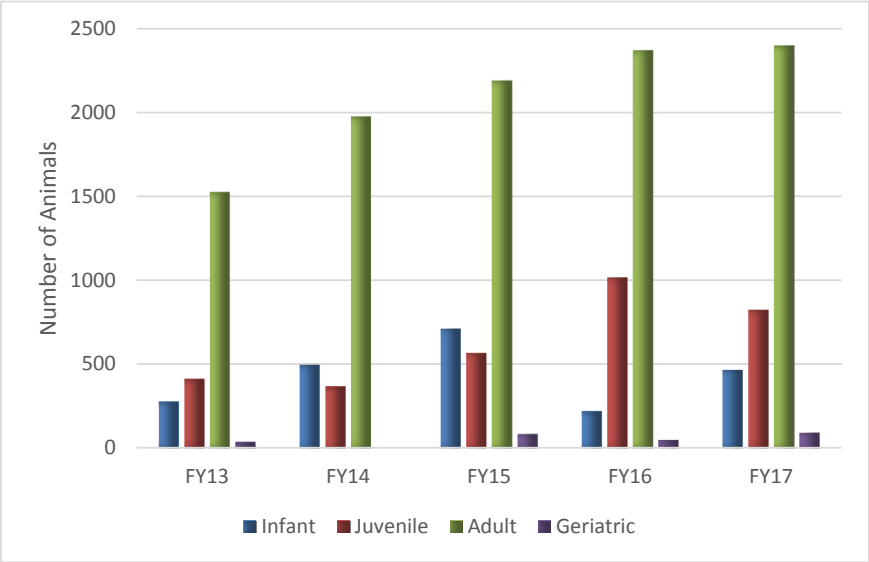

Figure 10. Planned NHP Use by Fiscal Year and Age Group, All Species

Location of NHP Studies Performed Under NIH Awards

Of the 1,121 awards for research projects included in the data set, 766 awards, or two-thirds of all awards, involved studies performed at a site other than an NPRC. These awards comprised 54% of all NHP usage. While the trend toward increasing use of rhesus macaques described above is seen in the aggregated national data, the pattern at individual NPRCs is less consistent. **Figure 11** shows the planned animal use for each NPRC associated with awards to scientists located at the NPRC's host institution ("internal PIs") and those at an organization external to the NPRC host institution who indicated use of the center to perform their studies ("external PIs"). Only Oregon NPRC displayed a consistently increasing trend in use, though surges in FY16 similar to that seen in the aggregate national data are apparent in the use of rhesus macaques at California NPRC, Southwest NPRC, Yerkes NPRC, and Washington NPRC. A large increase in planned rhesus macaque use was also seen in FY16 awards for studies to be performed by the ORIP-sponsored Caribbean Primate Research Center. These data do not necessarily reflect all demand placed on the colonies at each center, since some of the centers sell animals to external investigators for use at their respective institutions.

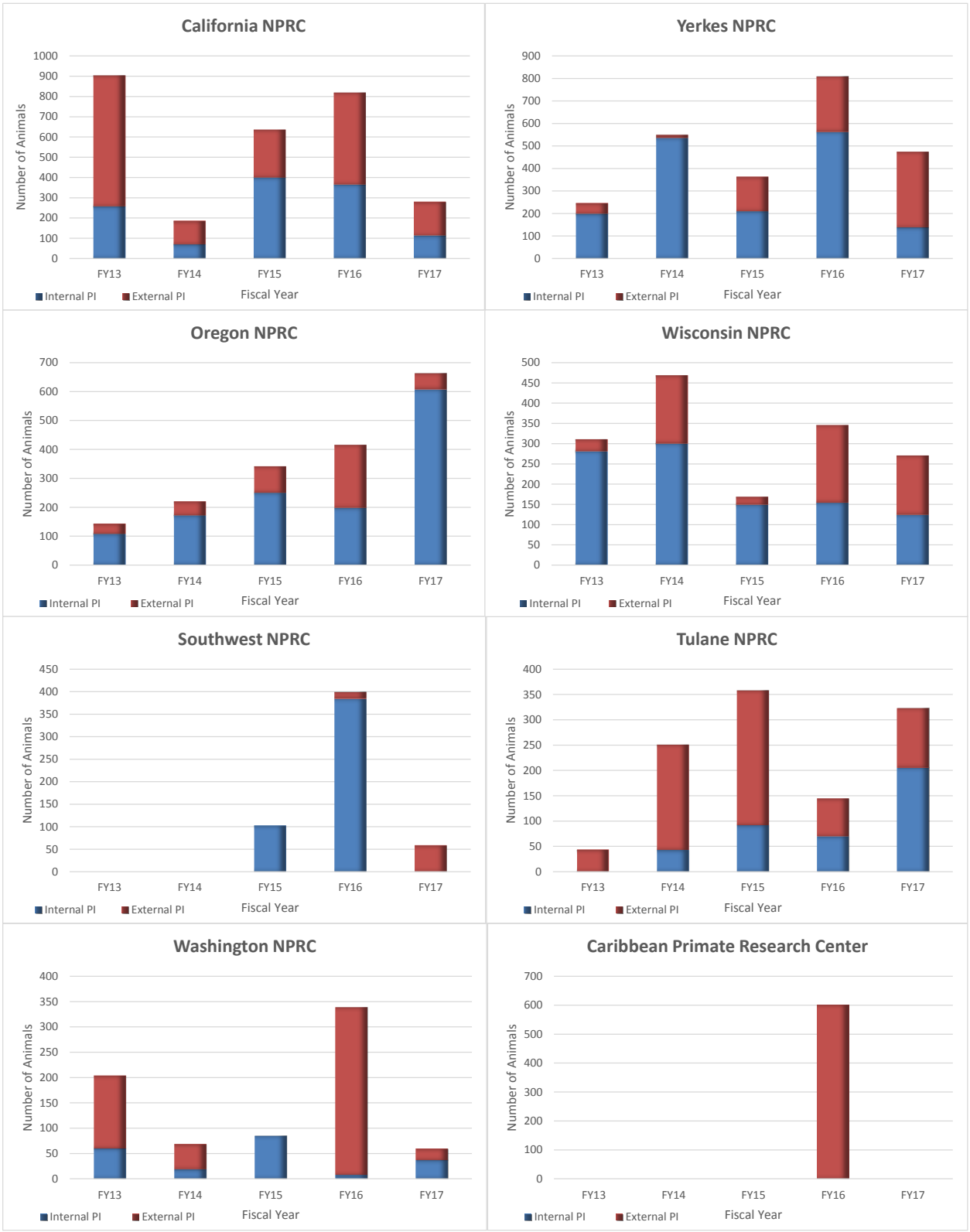

Figure 11. Planned Use of Rhesus Macaques at ORIP-Sponsored NHP Centers, FY13-17

NHP Usage by Intramural NIH Investigators

Annual acquisitions of different NHP species for intramural NIH use from FY13-FY17 are listed in **Table 11**. These data include only those animals acquired from external sources and do not necessarily reflect all intramural use. Nearly three-fourths of all animals acquired during this period were rhesus macaques. No clear upward or downward trend in usage of this species is seen. While there was a large surge in the usage of rhesus macaques in FY16, similar to that seen in extramural awards, by the following year, usage had declined to a level similar to the relatively constant level seen in FY13-FY15. The use of cynomolgus macaques, which comprised 13% of all animals used over the 5-year period, also showed no clear pattern.

Table 11. Annual Acquisition of NHPs for Intramural NIH Use by Species

Species	Number of Animals by Fiscal Year				
	2013	2014	2015	2016	2017
Rhesus Macaque	493	581	531	950	367
Cynomolgus Macaque	80	90	167	150	40
African Green (Vervet) Monkey	18	40	-	71	40
Owl Monkey	9	16	50	58	-
Marmoset	-	69	28	8	21
Squirrel Monkey	-	-	26	22	-
Baboon	-	10	4	15	-
Pigtail Macaque	-	17	-	-	-
Capuchin Monkey	-	-	-	-	4
All Species	600	823	806	1,274	472

Most of the animals acquired for intramural use were employed in infectious disease research. The distribution of animals by NIH institute is shown in **Table 12**. NIAID usage accounted for 81% of all animals acquired during the 5-year period, ranging from 78% to 84% of animals acquired in any single year. Usage by the NCI accounted for an additional 12% of all animals used, and while full details of their use were not available, limited information indicates that the animals acquired for the NCI were all used for studies of retroviruses.

Table 12. Annual Acquisition of NHPs for Intramural NIH Use, by Institute

Institute	Number of NHPs by Fiscal Year				
	2013	2014	2015	2016	2017
National Institute of Allergy and Infectious Diseases	466	685	677	1,001	375
National Cancer Institute	100	28	95	206	64
National Institute of Mental Health	30	60	30	30	
National Heart, Lung and Blood Institute	4	10	4	18	12
National Institute of Child Health and Human Development	-	40	-	-	-
National Institute of Neurological Disorders and Stroke	-	-	-	8	21
National Institute of Drug Abuse	-	-	-	11	-
All Institutes	600	823	806	1,274	472

Most of the NHPs (79%) that were acquired for intramural use were obtained from a variety of different commercial suppliers (**Table 13**), rather than ORIP-sponsored colonies, and the ORIP-sponsored colonies were not a significant supplier of rhesus macaques, particularly in recent years in which only three animals were provided in 2016 and none in 2017. However, the ORIP colonies were the sole suppliers for the lesser-used squirrel monkeys, baboons, and pigtail macaques. Of the 193 animals

supplied by ORIP-sponsored NHP resources, 77 (40%) were squirrel monkeys from an ORIP-sponsored colony located at the MD Anderson Cancer Research Center, or baboons from an ORIP-sponsored colony that was located at the University of Oklahoma and is currently being transferred to the MD Anderson Cancer Research Center. The Washington NPRC also served as the sole supplier of pigtail macaques used intramurally, although this species was only used in a single year.

Table 13. Annual Acquisition of NHPs for Intramural NIH Use, by Supplier Type

Source	Number of NHPs by Fiscal Year					FY13- FY17 Total	% of Total
	2013	2014	2015	2016	2017		
Commercial Supplier*	431	675	606	1,010	414	3,136	79%
Other University Supplier	108	117	110	216	46	597	15%
NPRC/Other ORIP-Sponsored Colony	32	31	90	40	-	193	5%
NIH Intramural Colony	29	-	-	-	-	29	1%
Other Federal Laboratory	-	-	-	8	12	20	1%
All Sources	600	823	806	1,274	472	3,975	100%

**Some acquisitions from commercial suppliers are from breeding colonies maintained under contracts with NIAID.*

National NHP Import Trends

Since FY12, over 90% of the NHPs imported into the U.S. have been cynomolgus macaques (**Table 14**). Imports of this species from FY14 to FY17 were highly variable, and were on average 50% higher than during FY12-FY13, but this increase is not believed to be due to increased demand. Rather, a reduction in the number of airlines willing to transport NHPs from China occurred during the FY12-FY13 time period, limiting imports. Rhesus macaques comprise a much smaller proportion of imported animals, with no clear trend being evident. Among the less frequently used species, demand for imported marmosets appears to be generally increasing (despite a decrease in imports in 2016), while demand for imported African green (vervet) monkeys and squirrel monkeys appears to be declining, and there have been no imports of pigtail macaques in the past 5 years.

Table 14. U.S. Imports of NHPs, by Fiscal Year

Species	Number of Animals Imported by Fiscal Year					
	2012	2013	2014	2015	2016	2017
Cynomolgus Macaques	14,471	16,999	25,690	20,043	28,777	20,110
Rhesus Macaques	997	2,054	1,600	1,604	986	1,392
Pigtail Macaques	284	-	-	-	-	-
Marmoset	-	64	144	189	99	249
African Green (Vervet) Monkey	96	349	297	347	211	85
Squirrel Monkey	196	125	47	94	-	-
Capuchin Monkey	-	15	2	22	-	-
Other	27	72	44	1	23	25
Total	16,071	19,678	27,824	22,300	30,096	21,861

3.3 Historical NHP Use, Forecasts, and Operating Information from Major NHP Service Providers

There was considerable variation across the surveyed organizations with regard to both the methods used to predict future demand and the level of detail in their historical usage data (when provided). For this reason, the results described below are limited to the subset of organizations that used each method or provided sufficiently detailed historical data to evaluate trends for individual species. Results from individual organizations have been de-identified to protect their proprietary or commercially sensitive information.

Historical Usage Trends

Historical usage data were reported by six organizations, based on either in-house usage by the organization or, in some cases, sales of animals to external organizations. Annual usage data were reported by all six organizations for the 2013-2016 timeframe, with four organizations providing 2012 data and four organizations providing partial or complete usage data for 2017.

While these data are incomplete and year-to-year variability was high for most of the organizations, there appears to be a trend of increasing usage of rhesus macaques in recent years (**Figure 12**). All six organizations reported a consistent increase in usage of rhesus macaques from 2015 to 2016, with four of the six organizations experiencing 50% to 100% increases in 2016 as compared to 2015. When summed across all six organizations, the number of rhesus macaques used in 2016 was 62% higher than in 2015 and 33% higher than in 2014. In the partial data provided for 2017, two of the four organizations that reported 2017 usage experienced further large increases in usage from 2016 to 2017, although the total number of animals reported to be used by these four organizations was only slightly above the number reported by the same four organizations in 2016. However, some of these data were reported in mid-2017, so year-to-date usage and totals reported may be less than the actual number of animals used during the year. A notable drop in usage of rhesus macaques occurred in 2015; the reasons for this drop are not immediately apparent.

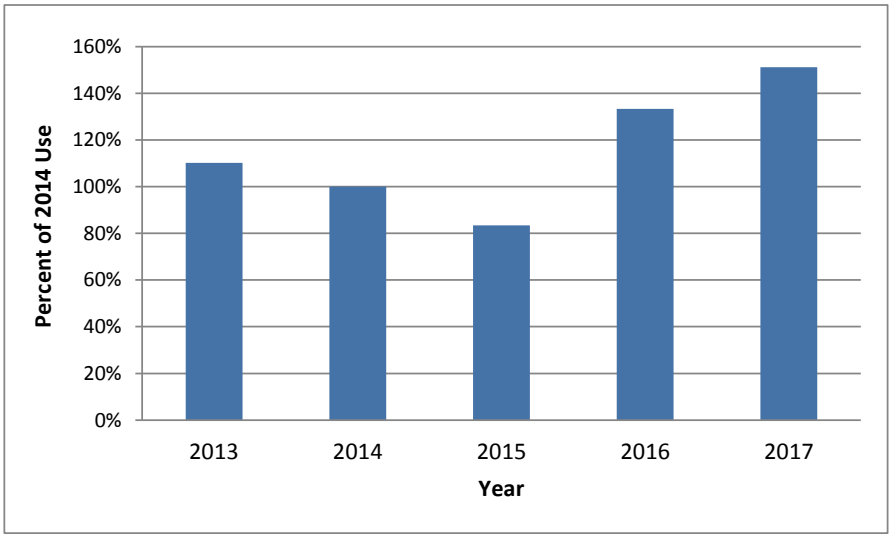

Figure 12. Weighted Average Annual Use of Rhesus Macaques, as Percentage of 2014 Usage at Each Reporting Center

Six centers reported data for calendar years 2014-2016; four of these six centers reported data for 2013, and four of six centers reported data for 2017 (which may not include all 2017 usage at these centers, as data for some centers was reported as year-to-date data in mid-2017). The sizes of the reporting centers varied widely, with actual annual usage ranging from a low of 31 animals to a high of 700 animals. In order to normalize data for the variation in colony size across the different centers as well as the number of reporting centers in a given year, the data were normalized based on the reported use for 2014, since all centers reported data for 2014. The percent change from 2014 usage at each center in each year was multiplied by the number of animals used by the center in 2014 and divided by the total number of animals used in 2014 across all centers (excluding, for 2013 and 2017, the contributions of centers that did not report data for those years). The results were then summed across all centers to obtain the weighted average change for the year.

Aside from rhesus macaques, usage of marmosets also increased significantly, although historical data was only provided by a single center: At this center, usage increased from fewer than 60 animals

per year in 2014 and 2015 up to 190 animals in 2016 and 372 animals in 2017. Historical usage data for other NHP species (pigtail macaques, baboons, owl monkeys, and squirrel monkeys) was, in most cases, reported by only a single center, since these species are less commonly used, and the data were either too variable to identify any trends or indicated a relatively constant level of use.

Forecasts of Future Demand

Six of the NPRCs provided quantitative forecasts of future demand for the species that they breed. These organizations and eight others also provided qualitative predictions of whether demand for species that they either supplied or used would increase, decrease, or remain about the same within their respective organizations. Predictions of demand were not always provided for every species bred or used by the reporting organization. Among those organizations that provided predictions, there was broad agreement across almost all of the organizations (including academic centers and commercial organizations) that demand for rhesus macaques will increase at their centers (**Figure 13**). Increasing demand for marmosets was also reported by all three of the centers that breed this species. An additional center also reported increased demand for marmosets at their center, even though they do not currently house this species. Increasing demand for marmosets was also predicted by the Federation of American Societies for Experimental Biology in their response to the RFI. Among the NPRCs that provided quantitative forecasts, demand for rhesus macaques was expected to increase by an estimated 20% to 50%, depending on the center, although at the highest forecast increase, the estimated demand could not be supported within the current physical infrastructure and funding of the center. However, most of the estimated increases were in the 20% to 25% range. Among the commercial organizations and other academic organization that were interviewed, four similarly predicted increased demand for rhesus macaques, and two also predicted increased demand for baboons, although the latter view was not shared by the two NPRCs that use baboons. Increasing demand for cynomolgus macaques (not listed in Figure 2) was also predicted by some organizations, although primarily for use by the biotechnology and pharmaceutical industry in the evaluation of the pharmacokinetics, pharmacodynamics, efficacy, and safety of new biologics and drugs.

Species	NPRCs (N)							Other Academic (A) and Commercial (C) Centers						
	N1	N2	N3	N4	N5	N6	N7	A1	A2	A3	A4	C1	C2	C3
Rhesus Macaque	⇧	⇔		⇧	⇧	⇧	⇧	⇧	⇧	⇧		⇧	⇧	⇧
Japanese Macaque						⇔								
Pigtail Macaque			⇔											
Baboon (spp.)				⇔		⇔				⇧		⇧		
Squirrel Monkey										⇧				
Marmoset				⇧			⇧				⇧			
Owl Monkey										⇧				

⇧ Prediction of increased usage at center relative to average historical usage

⇩ Prediction of decreased usage at center relative to average historical usage

⇔ No major change in usage predicted at center.

Figure 13. Predictions of Future Demand by NPRCs and Other NHP Research Centers and Providers

Other Indicators of Future Demand for NHPs

An additional indicator of future demand is the degree to which NHP centers are able to meet all current investigator requests for animals, as current shortfalls may indicate continuing high demand in the future. Supply problems have been reported by seven of the NIH-sponsored centers and colonies as well

as some other organizations that were interviewed, typically involving rhesus macaques, but occasionally involving other species. Issues reported include:

- Inability of a center to meet some requests for rhesus macaques that involved specific MHC requirements for infectious disease studies.
- Inability of a center to support investigators who have an immediate need for marmosets due to a long waiting list for external sales of this species.
- Inability of a center to meet all requests for Specific Pathogen Free (SPF) rhesus macaques from its in-house colony; as of mid-2017, only 61% of 2016 requests had been filled, and the center had to purchase animals from external sources to meet some requests.
- Delivery of rhesus macaques by a center from its in-house colony is staggered in about 70% of all projects due to inability to provide all required animals at onset of studies; staggered delivery may prolong duration of studies and in some cases, require investigators to seek grant extensions.
- Lead time for delivery of rhesus macaques by a center has increased from a few weeks to 3 to 6 months. In addition, the center has, on occasion, been unable to meet certain specific requirements for young animals or animals with certain physical characteristics (e.g., obese animals).
- Inability of an NIH-sponsored center to support mission-complementary non-NIH-sponsored external collaborations with industry and reduction of external animal sales to preserve animals for NIH-sponsored studies.
- Inability of a center to meet all requests for rhesus macaques, squirrel monkeys, and owl monkeys. Deliveries of rhesus macaques are being delayed by up to 1 year.
- Inability of a commercial supplier to meet some requirements for rhesus macaques with certain age restrictions; the supplier is now preselling animals, in some cases, up to 2 years in advance of expected use, to customers who want to ensure future availability of animals for their studies.
- Shortages and delayed delivery of baboons by a center.

Scientific and Other Factors Expected to Affect Future Demand for and Supply of NHPs

The subject matter experts interviewed at the various centers identified a number of scientific or other factors that they believed will, or could, affect future demand for NHPs in research and the ability of suppliers to meet investigator requirements. These factors are described below. No attempt was made to independently validate these opinions or to seek a consensus, although as indicated below, some of the factors were identified by more than one individual during separate interviews. A future goal of the overall project is to convene an expert panel to address factors affecting NHP supply, future needs, and research demands.

Scientific and programmatic factors that were mentioned included:

- A perceived shift in program emphasis by the NIAID toward studies on vaccine exploration and development as well as studies on therapeutics for HIV, both of which will involve comparatively larger numbers of animals than basic research studies. Increased demand for rhesus macaques was also expected to be driven by requirements to test emerging viral, vector-based vaccine regimens for HIV.
- Growth in the development of antibody-like anticancer drugs will drive increased use of cynomolgus macaques for drug assessment.
- There will be increased usage of African green (vervet) monkeys in the study of a variety of age-related disorders (e.g., Alzheimer's disease, age-associated hypertension), due to the similarity of this species' age-related diseases to those of humans.

- There will be increased demand for both rhesus macaques and marmosets for development of genetic animal models of disease.
- Investigators are increasingly requesting animals with specific genetic characteristics (e.g., MHC type), a trend noted by several individuals that is making it more difficult for suppliers to meet requirements, and which is expected to continue.
- Increased demand for SPF rhesus macaques is predicted to continue. One supplier noted that, while AIDS research has historically been a major driver of demand for SPF rhesus macaques, SPF animals are increasingly being requested for studies unrelated to AIDS. This supplier believed that the increase in demand for SPF animals may reflect an increasing reluctance of university vivariums to accept herpes B virus positive animals into their facilities, rather than a scientific requirement for the studies being performed.
- Increased NIH emphasis on considering sex as a biological variable (SABV) is perceived to have potential to create supply challenges in the future for certain types of studies (e.g., increased use of females in infectious disease studies reduces their availability for studies of reproductive health).

In addition to these scientific and programmatic factors, several individuals commented on concerns that the supply of cynomolgus macaques or other NHP species from China may be reduced in the future. Over the past 4 years, the U.S. has imported an average of over 23,000 cynomolgus macaques per year.[9] China currently supplies most of these cynomolgus macaques, and this is the primary species used by U.S. industry for drug and biological efficacy and safety studies. There is concern that reduced importation of cynomolgus macaques (as well as Chinese origin rhesus macaques) would have a second-order effect on demand for the Indian-origin rhesus macaques that are most widely used in academic research, as industrial users turn to domestically bred Indian-origin rhesus macaques for their needs. Such a situation would be expected to reduce the supply of animals available for academic research as well as drive up their cost.

The individuals who held concerns about the viability of future imports from China identified several contributing factors that may lead to reduced imports. These opinions should be considered hypothetical at this point. It was noted that the rapid expansion of the Chinese pharmaceutical industry is creating an alternative market for Chinese NHP breeders that is potentially more attractive to them than the U.S. market[10]; anecdotal evidence in support of this view was provided by a commercial importer who commented that one of their Chinese suppliers had recently decided to no longer export to the U.S. However, another major commercial supplier did not seem overly concerned about this situation, believing that the strong long-term business relationships they had cultivated with Chinese suppliers would serve to overcome any problems. An alternative view suggested by one individual was that the Chinese government was working behind the scenes to actively restrict exports, via restrictions on air carriers, in order to promote the Chinese pharmaceutical industry and encourage foreign drug manufacturers to have their preclinical studies performed in China. In a related point, it has been noted by many observers that air transport remains a point of vulnerability in importation of NHPs from China as well as other countries. Several commercial suppliers that rely on imported animals noted their relationships with charter air carriers as a means to overcome the refusal by most commercial carriers to

[9] Source: Data furnished by U.S. Centers for Disease Control and Prevention, Division of Global Migration and Quarantine.

[10] China has also been establishing itself as a as an international hub of nonhuman primate research (https://www.theatlantic.com/science/archive/2018/06/china-is-genetically-engineering-monkeys-with-brain-disorders/561866/)

transport NHPs. However, specifically with respect to China, one supplier observed that the large volume of merchandise purchased from Chinese suppliers through Amazon has increased the competition for air freight transport, and some charter carriers would prefer, for business reasons, to work with Amazon rather than carry NHPs for importers.

Supply Factors: Compatibility of Suppliers with NIH Investigator Requirements

Although, in theory, all of the organizations included in this report can serve as suppliers of NHPs for NIH-sponsored investigators, the organizations have distinctly different customer foci and operating models, which influence the likelihood that they can effectively support the needs of these investigators.

The NPRCs, as well as most of the other academic centers included in this study, serve a primarily academic set of customers, both internal to and external to the NHP centers, and they operate in a research-driven, collaborative fashion; they work with their customers as principal- or co-investigators to develop grant applications and perform research on areas of mutual interest. While some animals may be sold to external organizations, most are used in-house by internal or collaborative external investigators.

In contrast, four of the five commercial organizations included in this report supply, for the most part, pharmaceutical firms and other commercial medical product development firms, or serve as contract suppliers of animals to U.S. Government organizations that perform in-house NHP research. Commercial or Federal customers comprise 80% to 95% of their customer base, and these firms sell their animals to customers for external use. The firms themselves may maintain in-house breeding colonies, either as their own colonies or dedicated colonies maintained for a specific customer under contract, but they also import animals for resale to their customers. In-house studies may be performed but are conducted on a fee-for-service basis, unlike the research-driven, collaborative approach found in the NPRCs and most other academic centers. The scientific capabilities of these firms are also primarily focused on drug and biological development rather than basic research. Thus, the commercial organizations as a group may be less attractive as a resource for NIH-sponsored investigators.

The remaining three organizations that were surveyed (including two academic centers and one commercial organization) represent a hybrid between these two extremes, having a mixed customer base involving the operation of dedicated colonies under contract to commercial or Federal customers, as well as the maintenance of non-dedicated colonies that generate animals which can be sold to academic or other investigators for external use or may be used in-house in collaboration with an external investigator. Within the two academic centers that employ this hybrid model, in-house studies are typically research-driven projects, similar to those conducted by the NPRCs.

Supply Factors: Expansion Capacity to Meet Future Demand by NIH-Sponsored Investigators

Despite the increased demand for rhesus macaques predicted by the various centers, there appears to be little reserve infrastructure capacity within the NIH-sponsored centers to meet this demand at the present time. Three of the NPRCs reported that they are currently operating at their maximum or near-maximum capacity. California NPRC indicated that it has current housing available in its facilities to increase its production from 500 to 600 animals per year, and the Keeling Center similarly reported that it is using 80% of its current physical infrastructure. In addition, some of the centers that are in warmer climates and use outdoor field cages to house their animals have the ability to significantly expand their colonies within their current acreage (given additional funding for housing and animal maintenance), but others that are in colder climates and rely on indoor housing would require acquisition or construction of new buildings to expand their colonies.

Three suppliers who maintain rhesus macaque breeding colonies that are not supported by NIH did indicate plans to increase production in response to current shortages and the expected rise in demand, growing their colony sizes by 10% to 20%.

Other Programmatic Observations

Interviewees offered additional programmatic observations and recommendations that are broadly applicable to NHP supply and demand. These include:

- A suggestion that NIH increase funding of program project (P01) grants, in which a group of investigators are often all using the same pool of NHPs for different but complementary studies, thus maximizing the research use of each animal.
- NIH policy currently imposes a $500,000 per year limit on direct costs for grants, which hasn't been raised for many years. While exemptions to this limit are possible, it was observed that they are rarely granted by the IC. The cap on direct costs limits the ability of investigators to use NHPs, and as costs for NHPs increase, studies that employ them become relatively unattractive.
- Representatives from commercial organizations noted that, in general, the NPRCs do not sell their animals to external organizations (i.e., for use outside of the NPRC), and it would be helpful to industry if more of the NPRC animals were made available for industry sales.

3.4 Characterization of Demand by NIH-Sponsored NHP Investigators

Characteristics of the Responding Participants

A total of 1,115 invitations were distributed and 624 responses (56%) were received, but 16 of the respondents indicated that they had received the invitation in error and were not NHP users. Of the 608 remaining respondents, 566 (50.7% of invitees) confirmed that they were using or planning to use NHPs during the 2018-2022 time period. There were 42 respondents (3.8% of invitees) who indicated that they had used NHPs in the past but would not be using NHPs during the 2018-2022 time period; 26 of these former NHP users indicated that they had discontinued use of NHPs due to changes in the scientific focus of their research and associated needs for animal models, while 16 former NHP users discontinued use of NHPs for other unspecified reasons, unrelated to the scientific focus of their research.

Although 566 respondents confirmed that they were using or planned to use NHPs during the 2018-2022 time period, only 510 of these confirmed NHP users completed the remainder of the survey. Thus, 510 was used as the denominator in calculating overall percentages for most of the survey questions. This number represents approximately 46% of the originally targeted population of 1,115 principal investigators but may represent a smaller fraction of the total population of NHP users among NIH awardees, since original invitees were encouraged to forward their invitation to any co-investigators who planned to use NHPs. Thus, the total size of the surveyed population is indeterminate. Forty-one respondents failed to provide estimates of the numbers of animals that they planned to use, although they did indicate their planned species and answered other questions; these respondents were excluded from calculations of the percent of responders associated with different NHP use levels.

The distributions of confirmed NHP users by organization type and type of NHP facility at the respondent's organization are shown in **Table 15** and **Table 16**, respectively. Most respondents were from universities or other academic institutions, and just over 80% of the respondents were located at organizations that had an animal facility capable of supporting studies in NHPs, with roughly a third of all respondents located at an organization that either hosted an NPRC or hosted another NIH-sponsored NHP breeding colony.

Table 15. Organization Type of NHP Users

Organization Type	Number	(%)
University or Other Academic Institution	446	(87.5%)
For-Profit Organization	32	(6.3%)
Non-Profit Organization	27	(5.3%)
U.S. Federal Government Agency	4	(0.8%)
Other	1	(0.2%)
Total	510	(100%)

Table 16. Type of NHP Facility at NHP User's Organization

NHP Facility Type	Number	(%)
NPRC	142	(27.8%)
NIH-Sponsored NHP Breeding Colony (Other than NPRC)	29	(5.7%)
NHP-Capable Facility (Not Sponsored by NIH)	240	(47.1%)
No NHP-Capable Facilities	99	(19.4%)
Total	510	(100%)

Although the response rate was relatively high, the respondents do not appear to be fully representative of the target population (i.e., all NHP users among NIH award recipients). In comparing the performing organizations for the survey respondents with those for relevant NIH awards, the proportion of survey respondents from organizations that host the NPRCs was higher than the proportion of awards made to these organizations. The distribution of research areas reported by respondents (shown in **Figure 14**) also appeared to vary somewhat from that found in the awarded grants and cooperative agreements. Direct comparison of the incidence of each research area in the survey respondents with that in the awards is not possible because of differing methods used to classify research areas. Nevertheless, certain research areas (including fetal development, cardiovascular disease, diabetes, nutritional and metabolic disorders, and regenerative medicine and transplantation) occurred 3 to 4 times more frequently within the survey respondents than in the award data, suggesting that investigators in these areas may be over-represented in the survey responses.

Estimated NHP Use

Estimated annual use of NHPs by species and location of facilities where work will be performed is shown in **Table 17**. Most respondents indicated planned use of only a single species. There were 26% of respondents who estimated use of two species, and approximately 6% of respondents estimated use of three species. Rhesus macaques were the species most commonly planned for use, followed by cynomolgus macaques, African green (vervet) monkeys, marmosets, squirrel monkeys, and baboons. Estimated use of most species was, overall, relatively constant across all 5 years that were estimated. An upward trend in the estimated use of marmosets was seen across all years, although this increase is expected to occur at facilities other than those sponsored by NIH. The use of baboons at NPRCs was also predicted to surge from 2019-2021, but this trend was not seen at other locations.

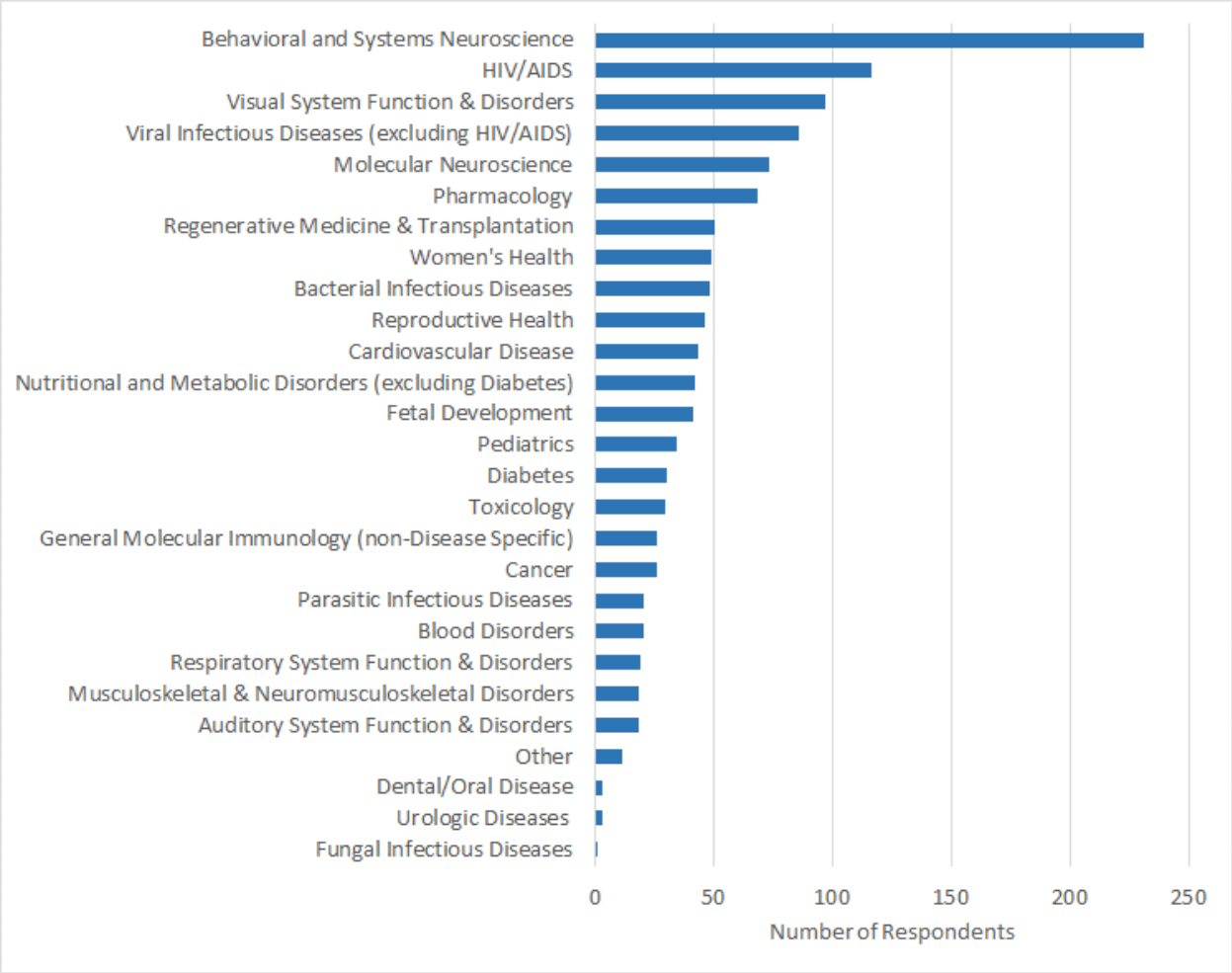

Figure 14. Research Areas Involved in NHP Use

Table 17. Estimated Annual NHP Use, by Species and Location of Studies

Species	NHP Study Site	Estimated NHP Use by Calendar Year				
		2018	2019	2020	2021	2022
Rhesus Macaque	NPRC	4,596	4,613	4,538	4,189	4,028
	Other NIH-Sponsored NHP Center	1,595	1,740	1,725	1,633	1,685
	Other NHP Center (Not NIH-Sponsored)*	1,898	1,897	1,855	1,820	1,822
	Total All Sites	8,089	8,250	8,118	7,642	7,535
Cynomolgus Macaque	NPRC	321	303	399	390	355
	Other NIH-Sponsored NHP Center	1,825	1,802	1,794	1,753	1,737
	Other NHP Center (Not NIH-Sponsored)*	800	811	854	725	635
	Total All Sites	2,946	2,916	3,047	2,868	2,727
African Green / Vervet Monkey	NPRC	20	36	30	20	20
	Other NIH-Sponsored NHP Center	490	506	506	506	490
	Other NHP Center (Not NIH-Sponsored)*	578	630	700	737	812
	Total All Sites	1,088	1,172	1,236	1,263	1,322
Marmoset	NPRC	359	342	341	311	311
	Other NIH-Sponsored NHP Center	21	21	24	24	24
	Other NHP Center (Not NIH-Sponsored)*	476	623	672	743	863
	Total All Sites	856	986	1,037	1,078	1,198
Squirrel Monkey	NPRC	24	24	44	44	40
	Other NIH-Sponsored NHP Center	583	575	585	590	600
	Other NHP Center (Not NIH-Sponsored)*	199	187	169	167	161
	Total All Sites	806	786	798	801	801
Baboon	NPRC	282	403	379	359	254
	Other NIH-Sponsored NHP Center	30	47	27	27	27
	Other NHP Center (Not NIH-Sponsored)*	246	228	226	214	199
	Total All Sites	558	678	632	600	480
Pigtail Macaque	NPRC	204	209	212	197	195
	Other NIH-Sponsored NHP Center	118	112	112	106	106
	Other NHP Center (Not NIH-Sponsored)*	13	12	19	19	11
	Total All Sites	335	333	343	322	312
Owl Monkey	NPRC	6	0	0	0	0
	Other NIH-Sponsored NHP Center	10	0	0	0	0
	Other NHP Center (Not NIH-Sponsored)*	29	44	42	42	42
	Total All Sites	45	44	42	42	42
Japanese Macaque	NPRC	60	55	40	15	15
	Other NIH-Sponsored NHP Center	0	0	0	0	0
	Other NHP Center (Not NIH-Sponsored)*	4	4	4	5	5
	Total All Sites	64	59	44	20	20
Capuchin Monkey	NPRC	26	18	18	20	20
	Other NIH-Sponsored NHP Center	7	7	7	7	7
	Other NHP Center (Not NIH-Sponsored)*	2	2	2	2	2
	Total All Sites	35	27	27	29	29
Mangabey	NPRC	6	12	22	22	22
	Other NIH-Sponsored NHP Center	0	0	0	0	0
	Other NHP Center (Not NIH-Sponsored)*	0	0	0	0	0
	Total All Sites	6	12	22	22	22
Tamarin	NPRC	0	0	0	0	0
	Other NIH-Sponsored NHP Center	0	0	0	0	0
	Other NHP Center (Not NIH-Sponsored)*	9	9	9	8	8
	Total All Sites	9	9	9	8	8

** NHP facilities not directly supported by NIH located in an academic or non-profit organization, commercial research organization, or federal agency*

Table 17. Estimated Annual NHP Use, by Species and Location of Studies (Continued)

Species	NHP Study Site	Estimated NHP Use by Calendar Year				
		2018	2019	2020	2021	2022
Other Macaque Species	NPRC	0	0	0	0	0
	Other NIH-Sponsored NHP Center	4	4	4	4	0
	Other NHP Center (Not NIH-Sponsored)*	16	16	16	13	13
	Total All Sites	20	20	20	17	13
Other	NPRC	10	10	10	10	10
	Other NIH-Sponsored NHP Center	0	0	0	0	0
	Other NHP Center (Not NIH-Sponsored)*	15	40	24	24	24
	Total All Sites	25	50	34	34	34

** NHP facilities not directly supported by NIH located in an academic or non-profit organization, commercial research organization, or federal agency*

Based on estimates of sexes used (when provided), the use of males and females was relatively balanced overall within the six major species, with the possible exception of African green (vervet) monkeys, in which use of females was more prevalent. **Table 18** shows the estimated use of males and females for each species. The estimated distribution by sex was only provided by respondents as the approximate percent of each sex among all animals planned for the 5-year period. A significant number of respondents (10% to 15%, depending on species) were either unable to estimate the distribution of animals by sex in their studies, or were indifferent as to the sex of the NHPs.

Location of Planned NHP Studies

Table 19 compares the local NHP capabilities of the respondents with the location at which they planned to have their NHP studies performed. There were 266 respondents (52%) who indicated that their NHP studies would be performed at an NIH-sponsored facility, either an NPRC or another center that housed an NIH-sponsored breeding colony. However, these respondents accounted for 70.6% of all animals estimated to be used over the 5-year period. Among the 411 respondents who had an NHP facility within their own organization, most (85%) planned to use the facilities of their own organization. Respondents located at NPRCs or other centers with an NIH-sponsored breeding colony were most likely to have their studies performed within their own organization, and when they did plan to use an external organization, it was another NIH-sponsored center. Respondents who were not co-located with an NIH-sponsored NHP facility but did have an NHP-capable facility within their own organization were somewhat more likely to use an external organization to perform their NHP studies than those co-located with an NIH-sponsored facility, a difference that was statistically significant. Of the respondents who did not have an NHP-capable facility within their own organization, 68% chose to have their studies performed at an NIH-sponsored site, with approximately half having their studies performed at an NPRC. In those cases in which the study site was not an NPRC, but rather was a center that maintained an NIH-sponsored breeding colony, it was not always clear that the species being used is the same species being supported by NIH; some of these centers maintain several breeding colonies, only some of which are sponsored by NIH.

Table 18. Estimated Sex Distribution for Major NHP Species

	Number of Respondents by Species					
Reported Sex Distribution for Animals Used	Rhesus Macaques	Cynomolgus Macaques	African Green (Vervet) Monkeys	Marmosets	Squirrel Monkeys	Baboons
100% Female	27 (7%)	13 (13%)	0 (0%)	1 (3%)	0 (0%)	4 (11%)
75% Female/25% Male (Or Mostly Female)	33 (9%)	7 (7%)	6 (30%)	7 (18%)	0 (0%)	3 (8%)
50% Female/50% Male	154 (42%)	50 (51%)	5 (25%)	24 (63%)	13 (68%)	13 (34%)
25% Female/75% Male (Or Mostly Male)	42 (11%)	6 (6%)	6 (30%)	0 (0%)	2 (11%)	6 (16%)
100% Male	57 (15%)	7 (7%)	1 (5%)	2 (5%)	2 (11%)	8 (21%)
Unknown (Or Will Use Either Sex As Available)	55 (15%)	15 (15%)	2 (10%)	4 (11%)	2 (11%)	4 (4%)
Total	368 (100%)	98 (100%)	20 (100%)	38 (100%)	19 (100%)	38 (100%)
	Number of Animals by Species					
	Rhesus Macaques	Cynomolgus Macaques	African Green (Vervet) Monkeys	Marmosets	Squirrel Monkeys	Baboons
Total Estimated Female Use (Excluding "Unknown")	15,938 (44%)	7,017 (51%)	3,577 (59%)	2,824 (56%)	1,894 (48%)	1,292 (47%)
Total Estimated Male Use (Excluding "Unknown")	20,119 (56%)	6,643 (49%)	2,450 (41%)	2,236 (44%)	2,082 (52%)	1,478 (53%)

Table 19. Location of Planned NHP Studies as a Function of NHP Facility Type at the Investigator's Own Organization

	Location of Planned NHP Studies (Number and % of NHP Facility Type)					
NHP Facility Type	**Investigators'** Own Organization	Separate NPRC	Separate NIH-Sponsored NHP Facility	Separate Academic or Non-profit NHP Facility	Separate Commercial Research Organization	Separate Federal Lab
NPRC (n=142)	132 (93%)	9 (6%)	1 (1%)	-	-	-
NIH-Sponsored NHP Breeding Colony (Other than NPRC) (n=29)	25 (86%)	2 (7%)	2 (7%)	-	-	-
NHP-Capable Facility (Not Sponsored by NIH) (n=240)	194 (81%)	25 (10%)	2 (1%)	11 (5%)	7 (3%)	1 (0%)
No NHP-Capable Facilities (n=99)	-	49 (49%)	19 (19%)	10 (10%)	18 (18%)	3 (3%)
TOTAL ALL FACILITY TYPES	351 (69%)	85 (17%)	24 (5%)	21 (4%)	25 (5%)	4 (1%)

External investigators (i.e., investigators who are not co-located with an NIH-sponsored NHP facility) can generate 50% or more of the NHP demand at many of the NIH-sponsored centers. Thus, factors that may influence their choice of study site are of particular interest, and it was hypothesized that study size may be a contributing factor, since even those organizations that have NHP facilities may not have sufficient space or staff to enable studies involving large numbers of animals. In order to evaluate the impact of study size on study location, total estimated animal use was used as a surrogate measure of study size. External investigators were separated into two groups: those who had an NHP facility within their organization and those who did not. Each of these groups was then further separated into three groups: small users, who estimated use of 10 or fewer animals per year on average over the 5-year period covered in the survey, including all species used; medium users, whose estimated average use was 11 to 30 animals per year; and large users, whose estimated average use was 31 or more animals per year. Approximately 50% of all respondents were small users, 29% were medium users, and 21% were large users. These groups were then analyzed with respect to the location at which they planned to have their studies performed (**Table 20**). Among the respondents who had an NHP facility within their organization, large NHP users were more likely than small or medium users to employ an NHP facility external to their own organization. However, for respondents who did choose to employ an external NHP facility, no statistically significant differences were noted between small, medium, and large users with regard to the type of organization that they chose to perform their studies, and this was also the case with respondents who lacked an NHP facility within their own organization.

Table 20. Effect of Estimated Animal Use on Choice of Study Site by Investigators Located External to an NIH-Sponsored NHP Facility

	Respondents with NHP Facility at Own Organization, by User Type (n=223)			Respondents with No NHP Facility Available, by User Type (n=87)		
NHP Study Site	Small	Medium	Large	Small	Medium	Large
Own Facilities	86%	86%	69%	0%	0%	0%
NPRC	7%	8%	17%	49%	50%	58%
Other NIH-Sponsored Center	1%	0%	0%	23%	14%	17%
Non-NIH-Sponsored Center*	6%	6%	14%	28%	36%	25%
Total of User Type	100%	100%	100%	100%	100%	100%

** Other academic or non-profit organization, commercial research organization, or federal agency separate from the respondent's own organization*

Critical Research Capabilities

Each respondent was given the opportunity to identify up to four capabilities of an NHP service provider that they considered most critical for their research, and a total of 1,416 capabilities were listed by respondents. These capabilities fell into 14 broad categories; these categories and frequently mentioned specific capabilities within each are summarized in **Table 21**. While **Table 21** identifies common themes in the responses, several of the capabilities identified by respondents were highly specific for the disease or area of research that they studied (e.g., a particular animal model), and were unique to each respondent. In general, investigators performing studies in NIH-sponsored facilities expressed similar needs to those whose studies were being performed in other facilities, and only a few capabilities were limited to one or the other of these two groups. Investigators whose studies were being performed in NIH-sponsored facilities appeared to have a somewhat higher interest in social group housing, facilities for studies on neonates and infants, high biological containment (ABSL-3), ultrasound, breeding and reproductive technologies, vaccine development, and specialized animals (SPF, infant, and geriatric animals). Investigators whose studies were being performed in other (non-NIH-sponsored) facilities indicated a higher interest in capabilities for drug testing and regulated studies, biotelemetry or remote monitoring, neurophysiological and electrophysiological techniques, and advanced imaging facilities such as magnetic resonance imaging (MRI) and functional MRI (fMRI).

Table 21. Critical Research Capabilities for NHP Service Providers, All Respondents

Capability Area: Imaging Facilities (n=235, 46.1% of all respondents)	Number of Respondents (% of Capability Area)		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Structural MRI	142 (27.8%)	66 (24.8%)	76 (31.1%)
Positron Emission Tomography	47 (9.2%)	26 (9.8%)	21 (8.6%)
fMRI	41 (8.0%)	16 (6.0%)	25 (10.2%)
Computed Tomography	24 (4.7%)	13 (4.9%)	11 (4.5%)
Ultrasound	19 (3.7%)	16 (6.0%)	3 (1.2%)
Ophthalmic Imaging	6 (1.2%)	4 (1.5%)	2 (0.8%)
Neuroimaging (Other or Unspecified)	5 (1.0%)	2 (0.8%)	3 (1.2%)
Optical Coherence Tomography	4 (0.8%)	1 (0.4%)	3 (1.2%)
Capability Area: Behavioral Testing (n=137, 27.5% of all respondents)	Number of Respondents (% of Capability Area)		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Specialized Behavioral Testing (Not Further Defined)	36 (7.1%)	12 (4.5%)	24 (9.8%)
Cognitive Testing	18 (3.5%)	10 (3.8%)	8 (3.3%)
Motor Performance Testing	18 (3.5%)	6 (2.3%)	12 (4.9%)
Monitoring of Self-Administration (Drugs, Alcohol)	6 (1.2%)	3 (1.1%)	3 (1.2%)
Capability Area: General Veterinary Support (n=126, 24.7% of all respondents)	Number of Respondents (% of Capability Area)		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Tissue Sampling/Biopsy	40 (7.8%)	31 (11.7%)	9 (3.7%)
Blood Sampling	39 (7.6%)	29 (10.9%)	10 (4.1%)
General Surgical Support	7 (1.4%)	4 (1.5%)	3 (1.2%)
General Animal Health Evaluation	7 (1.4%)	5 (1.9%)	2 (0.8%)
Sample Administration	7 (1.4%)	6 (2.3%)	1 (0.4%)
Capability Area: Veterinary Surgical Facilities and Services (n=109, 21.4% of all respondents)	Number of Respondents (% of Capability Area)		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Neurosurgery	12 (2.4%)	4 (1.5%)	8 (3.3%)
Sterile Surgery	8 (1.6%)	1 (0.4%)	7 (2.9%)
Survival Surgery	6 (1.2%)	3 (1.1%)	3 (1.2%)
Abdominal Surgery	5 (1.0%)	3 (1.1%)	2 (0.8%)
Capability Area: Housing and Facilities (n=100, 19.6% of all respondents)	Number of Respondents (% of Capability Area)		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Social Group Housing	17 (3.3%)	14 (5.3%)	3 (1.2%)
Specialized Housing to Prevent Cross Infection	9 (1.8%)	3 (1.1%)	6 (2.5%)
Neonatal/Infant Nursery	9 (1.8%)	9 (3.4%)	-
Primate Enrichment Support	7 (1.4%)	2 (0.8%)	5 (2.0%)
Electrophysiology Specialized Housing	6 (1.2%)	2 (0.8%)	4 (1.6%)

Table 21. Critical Research Capabilities for NHP Service Providers, All Respondents (Cont.)

Capability Area: Biological Containment (n=88, 17.3% of all respondents)	Number of Respondents (% of Capability Area)		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
(A)BSL3	48 (9.4%)	32 (12.0%)	16 (6.6%)
(A)BSL2	26 (5.1%)	16 (6.0%)	10 (4.1%)
(A)BSL4	9 (1.8%)	5 (1.9%)	4 (1.6%)
Capability Area: Vaccine Development and Immunology (n=47, 9.2% of all respondents)	**Number of Respondents (% of Capability Area)**		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Viral Challenge	16 (3.1%)	12 (4.5%)	4 (1.6%)
Viral Load Assay	6 (1.2%)	6 (2.3%)	-
Capability Area: Specific Primate Types and Characteristics (n=47, 9.2% of all respondents)	**Number of Respondents (% of Capability Area)**		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
SPF Animals	7 (1.4 %)	7 (2.6%)	-
Infant Animals	6 (1.2%)	6 (2.3%)	-
Geriatric Animals	4 (0.8%)	4 (1.5%)	-
Capability Area: Breeding and Reproductive Technologies (n=43, 8.4% of all respondents)	**Number of Respondents (% of Capability Area)**		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Breeding Capability	13 (2.5%)	10 (3.8%)	3 (1.2%)
Timed Mating	12 (2.4%)	9 (3.4%)	3 (1.2%)
Assisted Reproductive Technologies	8 (1.6%)	8 (3.0%)	-
Capability Area: Biotelemetry and Remote Monitoring (n=41, 8.0% of all respondents)	**Number of Respondents (% of Capability Area)**		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Biotelemetry and Remote Monitoring	41 (8.0%)	12 (4.5%)	29 (11.9%)
Capability Area: Pathology Services (n=30, 5.9% of all respondents)	**Number of Respondents (% of Capability Area)**		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Necropsy	16 (3.1%)	13 (4.9%)	3 (1.2%)
Capability Area: Aerosol Exposure (n=21, 4.1% of all respondents)	**Number of Respondents (% of Capability Area)**		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Aerosol Exposure	21 (4.1%)	12 (4.5%)	9 (3.7%)

Table 21. Critical Research Capabilities for NHP Service Providers, All Respondents (Cont.)

Capability Area: Drug Testing and Regulated Studies (n=21, 4.1 % of all respondents)	Number of Respondents (% of Capability Area)		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Good Laboratory Practices (GLP)	10 (2.0%)	1 (0.4%)	9 (3.7%)
Pharmacokinetics	10 (2.0%)	3 (1.1%)	7 (2.9%)
Toxicology/Safety Testing	6 (1.2%)	1 (0.4%)	5 (2.0%)
Capability Area: Other Techniques and Capabilities (n=163, 33.3 % of all respondents)	Number of Respondents (% of Capability Area)		
Specific Capabilities Required	All Respondents (n=510)	NIH-Sponsored Facility Users (n=266)	Other Facility Users (n=244)
Neurophysiology	20 (3.9%)	4 (1.5%)	16 (6.6%)
Electrophysiology	14 (2.7%)	4 (1.5%)	10 (4.1%)
Molecular Biology and Genetic Techniques	13 (2.5%)	7 (2.6%)	6 (2.5%)
Vision Studies and Testing	12 (2.4%)	6 (2.3%)	6 (2.5%)
Flow Cytometry	12 (2.4%)	12 (4.5%)	-
Cardiovascular System Tests	10 (2.0%)	5 (1.9%)	5 (2.0%)
Pulmonary Function Tests	8 (1.6%)	3 (1.1%)	5 (2.0%)
Motor Function Assessment	8 (1.6%)	2 (0.8%)	6 (2.5%)
Drug Administration	8 (1.6%)	4 (1.5%)	4 (1.6%)
Immunoassays	7 (1.4%)	3 (1.1%)	4 (1.6%)
Metabolic Testing and Assessments	7 (1.4%)	7 (2.6%)	-
Specialized Microscopy (Confocal, Fluoroscopy, Other)	6 (1.2%)	3 (1.1%)	3 (1.2%)
Optogenetics	4 (0.8%)	-	4 (1.6%)

Factors Influencing Selection of NHP Facility

Average importance ratings for several different factors thought to possibly influence an investigator's choice of NHP facility for performance of their studies are shown in **Table 22**, along with average ratings within four sub-groups: (1) respondents who remained within their own organization; (2) respondents who chose to use an NPRC external to their own organization; (3) respondents who chose to use a facility external to their own organization that is not an NPRC but maintains an NIH-sponsored breeding colony; and (4) respondents who chose to use a facility external to their own organization that is not sponsored by NIH. Each factor was rated on a 7-point scale from critically important (1) to no importance (7). The distribution of ratings for each factor are shown in **Figure 15**. Overall, basic animal availability (i.e., the ability to provide a sufficient number of animals of the required species, age, and sex needed for research in a timely manner) was considered the most critical factor.[11] Among respondents who used an external organization for their NHP studies, few differences were apparent between respondents who chose to have their studies performed at an NPRC and those who chose to use another external organization. The most notable observation is that local access to animals was significantly more important to those who remained within their own organization than to those who – by choice or because their own organization lacked an NHP-capable facility – used an external organization to perform their NHP studies. Certain factors – including access to specialized animal models and personnel with expertise in specialized techniques – appeared to be more important to those who selected an NPRC

[11] See Appendix D for full definitions of each factor.

external to their own organization as compared with those who remained within their own organization. While these factors are suggestive of reasons why individuals seek out an external organization to perform their studies, the difference in the ratings of these factors by individuals in the other two groups that used an external organization for their studies, when compared to individuals who remained within their own organization, was not statistically significant. Although basic animal availability was considered critical or very important by 84.5% of all respondents, availability of specialized animals (i.e., either SPF or genetically characterized animals) was only considered to be somewhat important or relatively unimportant to most respondents. Availability of specialized animals was somewhat more important to investigators working in the infectious disease, immunology, and transplantation areas than to those in other research areas.

Table 22. Average Importance Ratings for Factors Potentially Influencing NHP Study Site Selection

	Average Rating by Respondents Choosing NHP Study Site				
Factor	All Sites (n=510)	Own Organization (n=351)	Separate NPRC (n=85)	Other Separate NIH-Sponsored Facility (n=24)	Other Separate Facility (n=50)
Basic Animal Availability	1.79	1.84	1.55	1.92	1.72
Access to Specialized Equipment or Facilities	2.04	1.91	2.09	2.29	2.66
Access to Expertise in Relevant Techniques	2.08	2.21	1.76†	1.63	1.86
Access to Expertise in Relevant Models	2.16	2.35	1.71†	1.58	1.84
Local Access to Animals	2.20	1.44*	3.66	4.29	4.10
Cost	2.42	2.42	2.38	2.50	2.42
Prior Relationship with Performing Organization	2.45	2.57	2.07†	1.92	2.50
SPF Animal Availability	3.42	3.33	3.74	3.79	3.28
Genetically Characterized Animal Availability	4.29	4.43	3.66†	4.08	4.48

**Different from all other groups (p <.05)* *†Different from respondents using own organization (p <.05)*

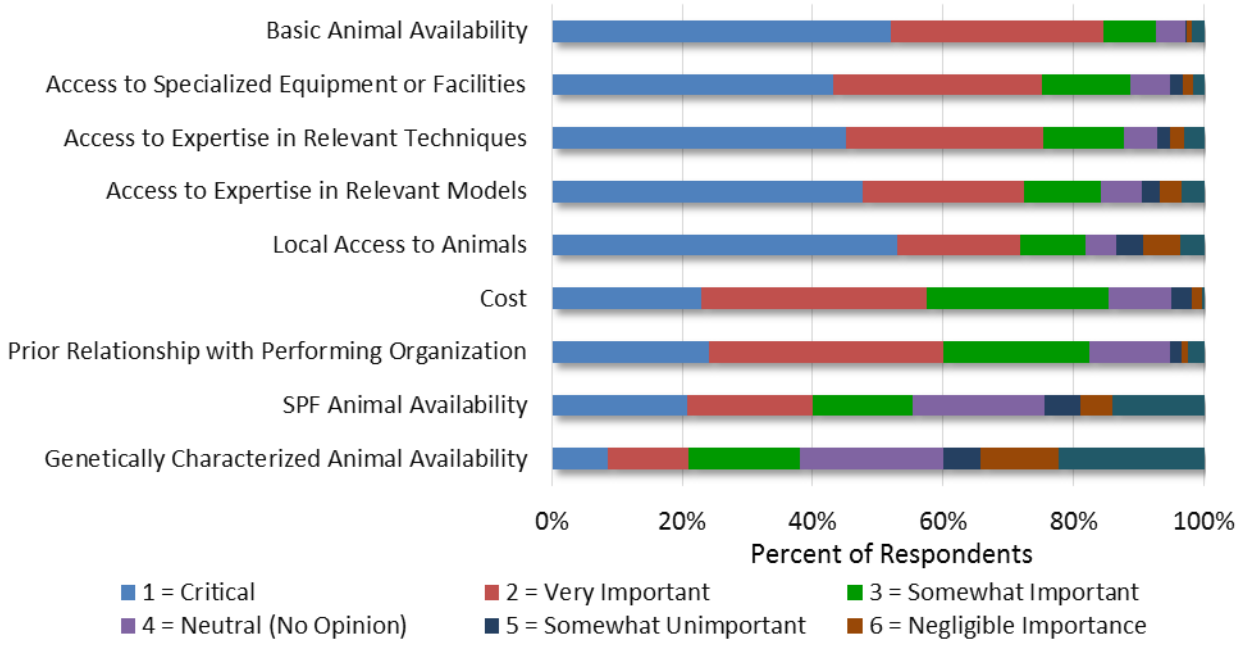

Figure 15. Distribution of Factor Ratings for Factors Potentially Influencing NHP Study Site Selection

Problems Obtaining NHPs or Research Services

Survey respondents were invited to comment on any problems encountered within the past 2 years in either obtaining NHPs or related research services that delayed their research, altered their experimental design, or influenced how they performed their research, and 50% of all respondents identified one or more problems. The reported problems fell into one of four broad categories that were partially overlapping in their scope (**Table 23**).

Table 23. Major Problem Areas Impacting on NHP Research

Issues Reported	Number of Respondents (%)
Limited Availability of Animals – Inability to obtain NHPs of the required species, sex, and age, or with other specific characteristics in a timely manner	143 (28%)
Programmatic or Policy Barriers – NIH (or other agency) policies or practices that constrain the conduct of NHP research	57 (11%)
Facility Issues – Problems with insufficient housing to perform required studies or inadequate staffing or staff expertise of the type needed	56 (11%)
Increased Cost – Concerns regarding impacts of NHP cost on research	43 (8%)

NHP availability was the most frequently cited problem. More than one quarter of all respondents noted problems in obtaining animals that delayed the initiation or execution of their studies, with 2.5% of respondents indicating delays from 6 months to a year or more. To accommodate the limited availability, 9 respondents (1.8%) specifically noted that the limited availability of NHPs necessitated changes in their research strategy or experimental design. There were 17 respondents (3.3%) who specifically mentioned problems with obtaining rhesus macaques. An additional 52 respondents (10.2%) who reported rhesus

macaques as the only species they plan to use also identified availability problems that presumably related to this species. Problems with obtaining marmosets were indicated by 16 respondents, representing 42% of all respondents who used this species. Problems in obtaining baboons were also indicated by 7 respondents, representing 18% of all respondents using this species. Issues with obtaining SPF animals (primarily rhesus macaques, but also baboons and pigtail macaques) were also noted by 10 respondents.

Respondents commented on a variety of programmatic or policy barriers that constrain NHP research. Seven respondents (1.4%) commented on the peer review process, noting that the reviewers in NIH study sections often do not have the appropriate expertise to review NHP work and do not fully appreciate the timeline and costs associated with NHP studies, which can have a negative impact on peer review scores. Respondents felt that study sections are populated by reviewers who are biased toward rodent and other lower vertebrate or invertebrate models and inappropriately take budgets into account even though they are not supposed to do this. Five respondents (1%) noted the impact of direct cost limits on R01 or other awards which limit the number of NHPs that can be used. An additional 1% of respondents noted that budget cuts, some of which are made by NIH IC Advisory Councils after peer review, can force reductions in the number of animals used and alter experimental design. The perceived impact of the SABV policy was also occasionally mentioned (by less than 1% of respondents), as investigators are concerned about supporting larger numbers of animals to detect sex differences; this concern likely reflects a misunderstanding of the SABV policy, which is often equated with sex differences research.[12] Local requirements imposed by the Institutional Animal Care and Use Committee (IACUC) or veterinary staff that negatively impacted on study execution were also noted occasionally, as were delays in obtaining IACUC approval.

Regarding facility issues, the most commonly cited problem was insufficient housing space for NHPs or insufficient caging of the type required for respondents' research, resulting in delays in initiating studies until space or appropriate housing became available. This problem was cited by 22 respondents (4.3% of all respondents), although in a few cases the issue appeared to be a short-term problem associated with facility renovation. Issues with insufficient numbers of research or veterinary staff to support timely execution of studies, or challenges in retaining staff experienced with NHP work were noted by 2.4% of respondents, while problems with quality of research staff and ability to perform required procedures was noted less frequently (1.2% of respondents). Although it might have been expected that facility issues would be less prevalent at NIH-sponsored NHP centers than at other centers, since the NIH-sponsored centers specialize in NHPs, the nature and frequency of all of these problems were nearly identical for both the investigators performing research in NIH-sponsored facilities and those performing their studies in their own (non-NIH-sponsored) facilities.

Finally, the increased cost of purchasing NHPs was cited, in several cases in relation to the aforementioned cap on direct costs and/or budget cuts, both of which force changes in experimental design from what investigators would view as optimal. Some respondents also noted the high cost of transporting animals, which may be factored into the purchase cost as well as increasing per diem costs, which were noted at both NIH-sponsored and other NHP facilities.

[12] The SABV policy is presented in NOT-OD-15-102 and discussed further in an article published in FASEB J. 30, 519–524 (2016): https://www.fasebj.org/doi/pdf/10.1096/fj.15-279554. In this article Dr. Janine Clayton, Director of the NIH Office of Research on Women's Health, indicates "considering sex as a biological variable" is not the same as "sex differences research." Further guidance on the SABV is located at: https://orwh.od.nih.gov/sites/orwh/files/docs/NOT-OD-15-102_Guidance.pdf.

4. Discussion

4.1 Future Demand for NHPs

Several methods, each with its own limitations, were used to assess future demand for NHPs over the coming 5 years. Historical data were obtained both from awards and from several individual centers to evaluate trends. Changes in future use were also qualitatively predicted by several NHP suppliers. Finally, supply problems currently being experienced for certain species were perceived as an indicator of future demand. Because of differences in methods and reporting of data, quantitative results obtained using these different methods cannot be directly compared, but qualitatively, they can be viewed as a body of evidence to support conclusions regarding changes (if any) in future demand.

Predicted Changes in Future Demand

All indicators point to an increasing demand for rhesus macaques and shortages of this species, for at least the near term. These indicators include trends of increased use both in NIH awards and in historical use reported by NPRCs and other NHP suppliers, current shortages reported both by suppliers and investigators, and near unanimous forecasts of suppliers that rhesus macaque use and/or sales of animals at their respective locations will increase in the future compared to historical levels. It is suspected that the present situation with rhesus macaques has been exacerbated by the unusually large increase in planned use of this species that occurred in FY16 awards, placing a strain on supplies that is likely to have effects into FY19-FY20 as these awards continue into their outyears, and possibly longer. It is notable that planned use of rhesus macaques in FY17 returned to levels only somewhat higher than FY15 levels. This suggests that the present level of high demand may eventually return to baseline historical levels. However, setting aside the FY16 surge, the underlying longer-term trend still appears to be toward increasing use. This trend is particularly notable in the area of HIV/AIDS research, which historically accounted for 43% of all planned rhesus macaque use in awards during the FY13-FY17 period.

Most indicators also point to an increase in demand for marmosets, although the data supporting this conclusion are less extensive and more subjective than that for rhesus macaques. The most convincing indicators of increasing demand are the reports by several centers of increasing investigator interest and shortages, consistent with problems in supply reported by roughly a third of the marmoset users who responded to the investigator survey. There is also a scientific rationale for increased usage of marmosets, particularly in the use of transgenic marmosets for neuroscience research. Given the many reports of shortages of this species, a surprising and conflicting finding is the lack of a clear trend toward increasing usage of marmosets in the NIH award data. In fact, after a large increase in usage in 2015, levels dropped back to levels similar to FY13-FY14. Import trends appear to show a fairly progressive increase in this species since 2012, but it is unclear from the available data who is using these imported animals. It is possible that the suppressed level of use in NIH awards over the past 2 years reflects supply limitations, rather than decreased demand. Determination of trends in the NIH awards data for marmosets and other lesser-used NHP species is challenging, since there are typically 10 or fewer awards per year for each species, and underlying trends can easily be obscured by a single award that happens to use an unusually large number of animals.

Some indicators point to increasing demand for baboons, but the signs are mixed. A large increase in planned use was seen in FY17 awards relative to previous years and present shortages have been reported by some investigators. However, the longer term trend is unclear, and increases in demand were only predicted by two of the four centers that breed or use this species.

The trend in historical award data suggests that demand for cynomolgus macaques is also increasing, but the importance of this finding for NIH-sponsored NHP centers is questionable since, unlike

several other species, cynomolgus macaques are largely imported, and the increase among NIH-sponsored investigators, while significant, represents only a small increase relative to the total U.S. use of this species which is widespread in the commercial sector. Most planned use of cynomolgus macaques in NIH awards occurred at study sites other than the NIH-sponsored centers, either in the facilities of the performing organization for the award or at a commercial research organization. Approximately 60% of the animals were being used for applied research on medical products, biologics or drug development and testing, or in other translational research, which is in keeping with heavy use of this species by industry for medical product development. The planned use by NIH awardees is only 5% or less of the total number of animals imported each year, most of which presumably go to industrial users and commercial test organizations. Thus, while demand by NIH-sponsored investigators may be increasing, current suppliers may be able to accommodate this increase.

No specific predictions are possible for other NHP species, due to a lack of clear trends and relatively low levels of use for many of the species. It does appear, however, that the overall use of NHPs is generally increasing in neuroscience research due to a combination of increases in the use of several different species.

Limitations of the Demand Analysis

As noted above, each of the methods used to predict future demand is subject to limitations. In the case of the two methods used to assess historical trends, it must be recognized that there is inherent uncertainty in predicting the future from past behavior. Similarly, there are many challenges associated with other methods of predicting future demand for NHPs, due to uncertainties over future funding in different areas of science, grant application success rates, and programmatic priorities of research sponsors. No single method of prediction is likely to be accurate. As an example provided by the staff at one NPRC, a survey of their users conducted in 2015 seeking to identify their future needs produced data that correctly predicted a future shortage but did not accurately predict actual demand in the 2016-2017 timeframe. One of the commercial organizations interviewed for this study similarly reported that its industry customers only forecast their requirements 12 to 18 months into the future, and that even these short-term projections are unreliable. While some factors that influence demand can at least be identified, if not precisely quantified, other factors, such as human disease outbreaks that stimulate work in an area, are completely unpredictable.

The NIH award data used for historical trend analysis represents the most comprehensive data source in the present study, but unlike historic usage data from the individual centers, specific information is missing on the year(s) in which NHPs will be used in each award. Data on planned animal use were taken from the Vertebrate Animal Sections of each awarded application. Most of the Vertebrate Animal Sections that were reviewed provided total number of animals to be used but did not provide details on the schedule under which they would be used. Thus, an animal might be assigned to a study for only a single year (or part of a year) during a multi-year award, or alternatively, the same animal might be used continuously throughout the entire award period. Some studies are terminal, necessitating the breeding of replacement animals, while other animals may be returned to their breeding colony and used for other studies. Considerations of time and expense precluded a more comprehensive review of each application's research plans to ascertain these types of information.

The alternative approach that was adopted in this study was to allocate all animals that were planned for a grant or cooperative agreement to the first fiscal year of the award. Since 70% of the grants and cooperative agreements that were included in the analysis had durations of at least 3 years and almost half were 5-year awards, it is deemed likely that many of the animals reported for the first fiscal year of the award will be used during subsequent years, i.e., the total number of animals is believed to reflect a "bow wave" of future demand in the years immediately following award. This approach also

implicitly assumes that all studies will proceed in accordance with the plans contained in the Vertebrate Animal Section of the initial application, such that actual NHP use will be the same as planned use. This may not be the case, as research plans may be adjusted based on several factors, including available animals and data obtained.

The qualitative forecasts of the major NHP suppliers represent a source of expert judgment on future demand, but the methods used by the various centers to forecast future demand varied considerably. The most common method – employed by three NPRCs – was to estimate future demand based on the projected NHP use in grants that had been awarded to the center and its external collaborators, plus a percentage of the projected NHP use in applications that had been submitted but not yet awarded, with the percentage based on the historic success rate of the center in obtaining new research awards. This method is intuitively reasonable, given the many uncertainties involved. One center employed a variation on this approach, estimating future usage from current usage levels based on a planned and institutionally approved increase in the number of investigators in the center. This approach implicitly assumes that newly hired investigators would be awarded grants at the same rate as current investigators and would, on average, use a similar number of NHPs in their studies as the current investigators. Other centers simply used their historical average usage to forecast future demand, but this approach implicitly assumes that past usage is representative of future needs. Qualitative predictions of increased demand were, in some cases, based on (1) perceptions of emerging trends in science or institute priorities that were expected to drive increased use of certain NHP species, or (2) informal assessments of interest received from investigators (the latter was particularly true for predictions of increased demand for marmosets).

Although estimates of future use were solicited from investigators included in the survey of users, these estimates are not believed to be useful to predict future demand due to several confounding factors that limit their utility. First, the degree to which the estimates of future use provided by survey respondents are representative of and can be scaled to the larger population is unknown. The population of investigators who completed the survey presumably represents only a fraction of all current and future NHP users, but the exact fraction is not known. The target population of 1,115 NIH awardees was derived from awards that were initiated from FY13 to FY17. Some of these awards have since expired, but the degree to which the non-responders to the survey include active NHP users is not determinable. Individuals who did respond may have also made assumptions regarding award of future grants that may or may not prove to be true. Finally, the amount of rigor that respondents used in developing their estimates was likely to be low in many cases since, to promote high participation, the survey was intentionally designed to be simple and allowed for the use of rough estimates. The average time that respondents used to complete the entire survey was less than 10 minutes. In particular, the estimates of African green (vervet) monkey and squirrel monkey use provided by survey respondents were unexpectedly high and appear to be overly optimistic, as the overall estimates exceed combined planned use in actual awards over the past 5 years and were driven by just a few large users of these species. Finally, there is no directly comparable historical data on annual use of the various NHP species for direct comparison to the present estimates of future use, so it cannot be determined if the present estimates suggest a change in demand relative to historical levels. While the absolute numbers of animals estimated by survey respondents may not be accurate, the trends seen in the data (i.e., relatively constant levels for most species, with increases in marmoset and baboon use) may be indicative of future trends.

4.2 Supply of NHPs and Related Services and Ability to Meet Future Demand

While the review of suppliers indicates that alternatives to the NPRCs and other NIH-sponsored centers exist for some species and some types of research, the review of historical award data as well as the survey of investigators indicated that the NPRCs and other NIH-sponsored centers serve as a major

source of NHP supply and services for NIH-sponsored investigators. Half of all NHPs planned for use in grants and cooperative agreements awarded over the past 5 years were proposed to be studied in NPRCs or other NIH-sponsored NHP facilities, with 28% of planned NHP use driven by investigators co-located with the host institution for the NIH-sponsored facility, and 22% of use driven by investigators who were at external organizations. Among survey respondents, approximately one-fourth of the investigators who were not co-located with an NIH-sponsored facility planned to have their NHP studies performed at one, and more than two-thirds of investigators who lacked an NHP facility within their own organization planned to use an NIH-sponsored facility for their studies. These data are in general agreement with the historical award data from the past 5 years which indicate that on average, 19% of the awards that were made to organizations that do not host a NIH-sponsored NHP facility involved NHP studies performed at an NIH-sponsored facility.

There are several alternatives to the NPRCs and other NIH-sponsored centers as sources for the most commonly used species of NHPs, rhesus macaques, including both commercial and other university-based suppliers. Similarly, the second most commonly used species, cynomolgus macaques, are available either as domestically bred or imported animals from several suppliers. But sources for other species are less common, with only three breeding colonies identified for baboons, three for marmosets, two for African green (vervet) monkeys, and one for many other species. At least among the major supplier organizations included in this analysis, the NIH-sponsored breeding colonies are the only suppliers of pigtail macaques, Japanese macaques, and squirrel monkeys, and appear to be the predominant suppliers of baboons and marmosets.

In terms of research capabilities, the NPRCs appear to provide a much more diverse portfolio of services than those available from commercial providers and most other universities that were included in the analysis. In particular, the veterinary medical support procedures available at the NPRCs are much more extensive than those at the other organizations that were reviewed. However, some of the apparent differences may be based upon the readily available information from the NPRCs and the way the information was gathered from other organizations. The NPRCs, as a group, provided a detailed listing of their capabilities, often breaking down their capabilities to the 2nd or 3rd level of detail, resulting in a list of over 250 different capabilities. Other universities and commercial organizations were not provided with the NPRC capability lists. Rather, each organization was given the opportunity to identify their capabilities as they saw fit and may only have provided a more general description. Moreover, the fact that many investigators use the facilities of their own institutions suggests that some of the capabilities most desired by investigators are likely to be available within academic centers that maintain smaller NHP populations and therefore, were not included within the analysis.

There is significant uncertainty as to the ability of the current NIH-funded centers and colonies to meet the predicted increase in demand for rhesus macaques. While some expansion of rhesus macaque production in the NIH-sponsored colonies is possible within the current infrastructure, many of the current NIH-sponsored centers appear to have little ability to rapidly expand their colonies due to infrastructure constraints, and space or housing limitations that delayed studies were one of the problems frequently identified by survey respondents. One individual who was interviewed noted that NIH currently only funds operations of the NPRCs, leaving it up to each parent university to develop new physical infrastructure; it was felt that this approach may limit ability to meet future demand. If given additional funding, some of the NPRCs do have space to expand their housing capacity. In addition to physical infrastructure, expansion would require additional personnel for centralized clinical care, husbandry, training, and veterinary oversight to support increased usage of animals.

Even given sufficient infrastructure and additional funding, large increases in rhesus macaque breeding colony size cannot be achieved rapidly, due to both the annual breeding cycle of the animals and the continuing demands for females in studies, which can remove reproductively active animals from

the colony and reduce breeding productivity. There is also a long lead time between an increase in colony birth rate and increased availability of animals for study (typically, at least 2 to 3 years after birth, although studies requiring sexually mature animals or studies on aging require still older animals). These issues are somewhat less prominent for marmosets, due to their smaller size (requiring less space for housing), higher birth rate, and shorter life span as compared to rhesus macaques, but production of marmosets is currently constrained by the availability of breeding pairs as well as limited expertise in development of marmoset colonies.

To some extent, increases in demand for rhesus macaques may be accommodated by planned expansions in colonies reported by some of the non-NIH-funded centers. But it is not clear that their planned increases in production will be sufficient to accommodate future demand and, given the current customer base of some of these providers, some of the additional production may flow to industry or Federal government users rather than NIH-funded academic investigators. Further exploration by NIH of these capabilities may be warranted.

4.3 Factors Driving Demand for Services by NIH-Sponsored NHP Facilities

Based on survey results, investigators who required large numbers of animals and were not co-located with an NPRC or other NIH-sponsored NHP facility showed some preference to have their studies performed at an NPRC, despite having NHP-capable facilities within their own organization. This could reflect more limited housing capabilities at some organizations, although the present data do not allow a determination of the specific reasons. Also, many large users who have NHP facilities remain within their own organization, presumably because they prefer to have more direct involvement in study performance, which local access allows. Although large users represented only 21% of all users, they are likely to have a disproportionate effect on demand since they accounted for 75% of all estimated NHP use.

Aside from study size, the survey revealed few indicators that might predict investigators who will seek services in the future from NIH-sponsored NHP centers. Capability requirements for users of both NIH-sponsored and other NHP facilities were largely similar. Respondents who required drug efficacy and safety testing and GLP capabilities appeared to be more likely to use facilities not sponsored by NIH, even though some NPRCs have these capabilities. On the other hand, investigators requiring access to special populations of NHPs (such as SPF or geriatric animals) as well as those involved in vaccine development and those requiring specialized capabilities for studies of reproductive health and neonatal and infant populations may be more inclined to obtain services from NIH-sponsored centers.

4.4 Programmatic Factors Affecting NHP Use

Through interviews with NPRC Directors and other major suppliers as well as though the investigator survey, a number of programmatic issues that potentially may affect demand for NHPs or their supply were identified. Areas specifically identified as impacting on NHP use included selection of peer reviewers, budget reductions after completion of peer review, caps on direct funding, and perceived SABV requirements. Although anecdotal, the issues were noted frequently enough by different individuals that further evaluation is warranted to determine if changes to practices should be implemented, or if further education and outreach to investigators is needed regarding the application of NIH policies.

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Appendix A – Keywords Used for Electronic Searches of Award Files

Generic Keywords

- Nonhuman primate
- Non-human primate
- Primate
- Monkey

Keywords for Genus: Aotus

- Aotus
- Owl monkey

Keywords for Genus: Callitrix

- Callithrix
- Marmoset

Keywords for Genus: Cebus

- Cebus
- Capuchin

Keywords for Genus: Cercocebus

- Cercocebus
- Mangabey
-

Keywords for Genus: Chlorocebus

- Chlorocebus sabaeus
- C. sabaeus
- African green monkey
- Sabaeus monkey
- Chlorocebus pygerythrus
- C. pygerythrus
- Vervet

Keywords for Genus: Erythropatas

- Erythrocebus patas
- E. patas
- Patas monkey

Keywords for Genus: Macaca

- Macaca
- Macaca mulatta
- M. mulatta
- Macaca fascicularis
- M. fascicularis
- Macaca nemestrina
- M. nemestrina
- Macaque
- Rhesus macaque
- Cynomolgus macaque
- Pigtail macaque

Keywords for Genus: Papio

- Papio
- Baboon

Keywords for Genus: Saguinus

- Saguinus
- Tamarin

Keywords for Genus: Saimiri

- Saimiri
- Saimiri boliviensis
- S. boliviensis
- Saimiri oerstedti
- S. oerstedti
- Saimiri sciureus
- S. sciureus
- Saimiri ustus
- S. ustus
- Saimiri vanzolinii
- S. vanzolinii
- Squirrel monkey

Appendix B – Age Categories

Species	Age Category and Age Ranges			
	Infant	Juvenile	Adult	Geriatric
African Green (Vervet) Monkey	Less than 12 months	1-4 years	4-15 years	Over 15 years
Baboon (all species)	Less than 12 months	1-4 years	4-15 years	Over 15 years
Common Marmoset	Less than 6 months	6-18 months	1.5-8 years	Over 8 years
Cynomolgus Macaque	Less than 12 months	1-4 years	4-17 years	Over 17 years
Japanese Macaque	Less than 12 months	1-4 years	4-15 years	Over 15 years
Pigtail Macaque	Less than 12 months	1-4 years	4-15 years	Over 15 years
Rhesus Macaque	Less than 12 months	1-4 years	4-17 years	Over 17 years
Sooty Mangabey	Less than 12 months	1-4 years	4-15 years	Over 15 years
Squirrel Monkey	Less than 12 months	1-4 years	4-15 years	Over 15 years
Tamarin	Less than 7 months	7-30 months	2.5-10 years	Over 10 years

Appendix C – Award Classification Taxonomies

C.1 Research Area Taxonomies and Definitions

The terms listed in **Table C-1** were used to classify the scientific focus of each award. Research categories were broadly defined and generally spanned multiple diseases or conditions, but certain diseases (i.e., AIDS, diabetes) were assigned their own categories due to the particularly high level of research funding and interest in these diseases. In addition, infectious disease research was further broken down according to the type of infectious agent, due to the high level of investment in infectious disease research involving NHPs. A single category designated as the primary research area was assigned to each award and used for further analysis.

Table C-1. Primary Research Area Taxonomy

Primary Research Area Category	Supplemental Inclusion/Exclusion Criteria
Auditory System	Includes studies of normal auditory processing and disorders/diseases of the auditory system.
Blood Disorder	None
Cancer	Includes all studies on cancer, except HIV/AIDS-associated cancers (classified separately under "HIV/AIDS").
Cardiovascular Disease	None
Dental/Oral Disease	None
Diabetes	None
Fetal Development	Includes normal fetal development as well as the effects of disease, alcohol, etc., on fetal development (except HIV/AIDS effects, classified separately under "HIV/AIDS").
HIV/AIDS	Includes all studies of direct effects of AIDS (including effects on fetal development), studies addressing therapy for AIDS, drug and vaccine development, and studies of AIDS co-morbidities.
Infectious Disease – Bacterial	Includes all bacterial infectious disease research (to include vaccine development and testing). Excludes general studies of infectious disease not specifically directed towards bacterial diseases (classified separately as "Molecular Immunology [General]").
Infectious Disease – Viral (non-HIV/AIDS)	Includes all viral infectious disease research (to include vaccine development and testing), other than HIV/AIDS (classified separately under "HIV/AIDS"). Excludes general studies of infectious disease not specifically directed towards HIV infection (classified separately as "Molecular Immunology [General]").
Infectious Disease – Parasitic	Includes all parasitic infectious disease research (to include vaccine development and testing). Excludes general studies of infectious disease not specifically directed towards parasitic diseases (classified separately as "Molecular Immunology [General]").
Infectious Disease – Fungal	Includes all fungal infectious disease research (to include vaccine development and testing). Excludes general studies of infectious disease not specifically directed towards fungal diseases (classified separately as "Molecular Immunology [General]").
Molecular Immunology (General)	Includes all studies of the function of the immune system not directed towards a specific infectious disease or transplantation immunology (classified separately).
Musculoskeletal Disorders	Includes studies of neuromuscular disease (e.g., Parkinson's disease).
Neuroscience – Behavioral and Systems	Includes studies of behavior and cognition including function of neural circuits and systems, including effects of disease (e.g., Alzheimer's disease) and alcohol/substance abuse on these behaviors/systems.
Neuroscience – Molecular	Includes studies of molecular mechanisms underlying neurological function/disorders. These studies will be targeted to the sub-cellular level (e.g., genetic manipulation).

Table C-1. Primary Research Area Taxonomy (Continued)

Primary Research Area Category	Supplemental Inclusion/Exclusion Criteria
Nutritional and Metabolic Disorders (Non-Diabetes)	Includes studies on obesity, metabolic disorders (various), and nutrition disorders (various). Does not include diabetes (classified separately).
Regenerative Medicine & Transplantation	Includes studies on general stem cell research, transplantation rejection, preventing rejection, graft vs. host disease, etc.
Reproductive Health	Includes studies of effects on reproductive capacity and pregnancy (for effects on fetus, see Fetal Development).
Respiratory System	Includes studies on non-infectious respiratory diseases and insults (e.g., environmental toxicant exposure), as well as asthma or other inflammatory conditions that affect the respiratory tract.
Urologic Diseases	Includes studies on renal function and similar.
Visual System	Includes studies of visual processing and ophthalmic disorders.
Other	Used for studies not fitting within any other category.

C.2 Research Type Taxonomy and Definitions

The terms listed in **Table C-2** were used to classify the phase of research addressed by each award. A single category was assigned to each award and used for further analysis.

Table C-2. Research Type Taxonomy

Category	Definition
Basic Research	Basic research is formally defined as "systematic study directed toward greater knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind." Basic biomedical research is targeted at understanding the underlying mechanisms of disease, injury, or normal biological function and behavior, as well as the development of novel research tools (e.g., animal models) for mechanistic studies and/or the study of medical countermeasures.
Applied Research – Medical Products	Applied research is formally defined as "systematic study to gain knowledge or understanding necessary to determine the means by which a recognized and specific need may be met." Applied biomedical research for medical products typically explores the use of a defined countermeasure concept or set of concepts against a particular disease or condition, or it evaluates physical or biological characteristics of the countermeasure itself. Applied research can demonstrate proof of concept for a countermeasure and may seek to optimize a countermeasure but falls short of formal preclinical development activities.
Applied Research – Surgical Techniques	Applied research is formally defined as "systematic study to gain knowledge or understanding necessary to determine the means by which a recognized and specific need may be met." Applied biomedical research for surgical techniques typically explores the use of a defined concept or set of concepts for surgical intervention in a particular disease or condition, in order to demonstrate proof of concept and optimize the application of the technique.

Table C-2. Research Type Taxonomy (Continued)

Category	Definition
Translational Research	Translational research fosters the multidirectional integration of basic research, patient-oriented research, and population-based research, with the long-term aim of improving the health of the public. T1 research expedites the movement between basic research and patient-oriented research that leads to new or improved scientific understanding or standards of care (e.g., drug development, pharmacogenomics, and some studies of disease mechanisms and research into new areas such as genetics, genomics, and proteomics). T2 research facilitates the movement between patient-oriented research and population-based research that leads to better patient outcomes, the implementation of best practices, and improved health status in communities (e.g., clinical epidemiology, health services [outcomes] research, and community-based participatory research). T3 research promotes interaction between laboratory-based research and population-based research to stimulate a robust scientific understanding of human health and disease (e.g., emerging disciplines such as molecular and genetic epidemiology).
Biologics Development/Testing	This category includes studies that have as their objective formal preclinical development of a biologic (including vaccines) as a prerequisite to initiation of clinical trials, in order to establish optimal dosing, toxicity, kinetics, etc. Generally involves studies conducted in accordance with GLP (for toxicity testing). For products intended for FDA approval under the Animal Rule, may also include advanced testing of efficacy under GLP.
Drug Development/Testing	This category includes studies that have as their objective formal preclinical development of a drug as a prerequisite to initiation of clinical trials in order to establish optimal dosing range, toxicity, kinetics, etc. Generally involves studies conducted in accordance with Good Laboratory Practice (GLP) (for toxicity testing). For products intended for Food and Drug Administration (FDA) approval under the Animal Rule, may also include advanced testing of efficacy under GLP.
Medical Device Development/Testing	This category includes studies that have as their objective formal preclinical development of a medical device as a prerequisite to initiation of clinical trials or (when applicable) as direct evidence supporting approval of a device under the Premarket Notification (510(k)) process, in order to establish usability, safety, performance, etc. Generally involves studies conducted in accordance with GLP (for toxicity testing).
NHP Infrastructure/Resource	This category is reserved for development and maintenance of NHP breeding colonies and closely related activities including development of NHP reagents or other research resources that are broadly applicable to studies employing NHPs.
Other	Used for studies not fitting within any other category.

Appendix D – Survey Questions

Thank you for participating in the NIH ORIP Nonhuman Primate Survey! Your responses are completely anonymous. The survey includes 9 questions that pertain to the areas of research that will require use of nonhuman primates during the next 5 years (2018-2022,), species requirements, facility requirements, and the factors that dictate where investigators choose to have their nonhuman primate studies performed. If you do not plan to use nonhuman primates in your research, or received the survey invitation in error, please answer Question 1 to opt-out of the survey; otherwise, please answer all questions.

1. Please select from one of the choices below to confirm whether you expect to use nonhuman primates in your current and/or future research (selecting choice B , choice C, or choice D will opt you out of the survey, completing your participation).

- ☐ A. I am currently using or expect to use nonhuman primates in my research during the period from 2018-2022.
- ☐ B. I have used nonhuman primates in my past research but do not currently expect to use them in my research from 2018-2022 due to changes in the scientific focus of my research and associated needs for animal models.
- ☐ C. I have used nonhuman primates in my past research but do not currently expect to use them in my research from 2018-2022 for reasons unrelated to the scientific focus of my research.
- ☐ D. I received the survey invitation in error; I haven't used and don't plan to use nonhuman primates in my research.

2. Please indicate the type of research organization in which you currently work (select one):

- ☐ University or other academic institution
- ☐ Non-profit organization
- ☐ For-profit organization
- ☐ U.S. Federal Government agency
- ☐ Other

3. Please indicate whether your organization has an animal facility that can support studies in nonhuman primates (select one):

- ☐ My organization operates a NIH-sponsored National Primate Research Center (NPRC)*.
- ☐ My organization maintains a NIH-sponsored nonhuman primate breeding colony (but is not a NPRC).
- ☐ My organization has an animal facility that can support studies in nonhuman primates, but this facility is not sponsored directly by NIH.
- ☐ The animal facilities (if any) in my organization cannot support studies in nonhuman primates.

*The National Primate Research Centers are located at Emory University, the University of California - Davis, the University of Washington, the Oregon Health Sciences University, the University of Wisconsin - Madison, Tulane University, and the Texas Biomedical Research Institute.

4. Please select from the following list the statement that best describes the organization which you expect will house the nonhuman primates used in your future research and perform studies on them; if you have not yet planned your future studies in sufficient detail to determine where studies will be performed, select the statement that in your judgment represents the most likely alternative based on where your current studies are performed or other considerations as you deem appropriate (select one; if you expect to use more than one type of organization, select the choice that describes where most work will be done):

- ☐ Studies will be performed using the animal facilities of my organization.
- ☐ Studies will be performed at a NIH-sponsored National Primate Research Center that is separate from my organization.
- ☐ Studies will be performed at a NIH-sponsored nonhuman primate facility that is NOT a National Primate Research Center and is separate from my organization.
- ☐ Studies will be performed using animal facilities that are not directly sponsored by NIH and are located at an academic or non-profit institution that is separate from my organization.
- ☐ Studies will be performed at a commercial research organization that is separate from my organization.
- ☐ Studies will be performed at a U.S. Federal Government agency that is separate from my organization.

5. From the following list, please select the area(s) that best describe the focus of your current or future planned (time period 2018-2022) research involving nonhuman primates (select as many as apply)

- ☐ Auditory System Function & Disorders
- ☐ Visual System Function & Disorders
- ☐ Blood Disorders
- ☐ Cancer
- ☐ Cardiovascular Disease
- ☐ Respiratory System Function & Disorders
- ☐ Fetal Development
- ☐ Women's Health
- ☐ Reproductive Health
- ☐ Bacterial Infectious Diseases
- ☐ Viral Infectious Diseases (excluding HIV/AIDS)
- ☐ HIV/AIDS
- ☐ Parasitic Infectious Diseases
- ☐ Fungal Infectious Diseases
- ☐ General Molecular Immunology (non-Disease Specific)
- ☐ Musculoskeletal & Neuromusculoskeletal Disorders
- ☐ Behavioral and Systems Neuroscience
- ☐ Molecular Neuroscience
- ☐ Nutritional and Metabolic Disorders (excluding Diabetes)
- ☐ Diabetes
- ☐ Urologic Diseases
- ☐ Dental/Oral Disease
- ☐ Pediatrics
- ☐ Regenerative Medicine & Transplantation
- ☐ Pharmacology
- ☐ Toxicology
- ☐ None of The Above

6a: Please use the drop-down menu to select the nonhuman primate species that you currently use or anticipate using in your research over the next 5 years. In the following Questions 6b and 6c, please estimate (i) the approximate number of animals of this species that you expect to use in each of the next 5 years, and (ii) the approximate gender mix within the animals of this species that will be used. If you anticipate using more than one species, you may enter data for up to 2 additional species in Questions 6d-6i; otherwise, skip to Question 7. Your estimated usage should include both currently funded grants and any new grants that you anticipate receiving during this period. Exact usage data is not required – your "best guess" or estimate is sufficient.

___[species]_____

6b. Please enter your planned usage of above-listed species by year.

2018 _____

2019 _____

2020 _____

2021 _____

2022 _____

6c. Enter the approximate gender mix within the animals you plan to use (across all years listed above):

- ☐ 100% female
- ☐ 75% female/25% male (or mostly female)
- ☐ 50% female/50% male
- ☐ 25% female/75% male (or mostly male)
- ☐ 100% male
- ☐ Unknown (or I'll use whatever sex is available)

6d. Enter 2nd species (if needed)

___[species]_____

6e. Please enter your planned usage of species #2 by year:

2018 _____

2019 _____

2020 _____

2021 _____

2022 _____

6f. For species #2, enter the approximate gender mix within the animals you plan to use (across all years listed above)

- ☐ 100% female
- ☐ 75% female/25% male (or mostly female)
- ☐ 50% female/50% male
- ☐ 25% female/75% male (or mostly male)
- ☐ 100% male
- ☐ Unknown (or I'll use whatever sex is available)

6g. Enter 3rd species (if needed)

___[species]_____

6h. Please enter your planned usage of species #3 by year:

2018 _____

2019 _____

2020 _____

2021 _____

2022 _____

6i. For species #3, enter the approximate gender mix within the animals you plan to use (across all years listed above)

- ☐ 100% female
- ☐ 75% female/25% male (or mostly female)
- ☐ 50% female/50% male
- ☐ 25% female/75% male (or mostly male)
- ☐ 100% male
- ☐ Unknown (or I'll use whatever sex is available)

7. In the boxes provided below, please briefly describe up to 4 research capabilities that are most important for your nonhuman primate service provider to possess in order to successfully support your research. A research capability may be a specialized service or specialized facilities or instruments. Examples include ability to conduct motor performance or specialized behavioral testing, provide biotelemetry support, perform aerosol exposures, perform functional MRI studies, conduct studies requiring high biological containment (e.g., ABSL 3 or ABSL 4), etc. (Each entry is limited to 100 characters.)

Capability 1 _____

Capability 2 _____

Capability 3 _____

Capability 4 _____

8a. The following is a list of factors that might influence an investigator's choice of a particular organization to house or perform nonhuman primate studies. For each of the listed factors, please use the drop-down list to select a number from 1-7 that describes the importance of the factor to your choice of the organization(s) that have supported your nonhuman primate studies in the past, or that you expect to use in the future. (1 = Critical, 2 = Very Important, 3 = Somewhat Important, 4 = Neutral (No Opinion), 5 = Somewhat Unimportant, 6 = Negligible Importance, and 7 = No Importance.)

Local Access: The performing organization is collocated with or is in close proximity to my laboratory, providing convenient local access to animals and allowing myself and/or my immediate staff to directly participate in the performance of studies that employ the animals, without excessive travel	1 = Critical 2 = Very Important 3 = Somewhat Important 4 = Neutral (No Opinion) 5 = Somewhat Unimportant 6 = Negligible Importance 7 = No Importance
Access to Expertise in Relevant Models: The performing organization can provide personnel with specialized expertise (not present within my immediate research team) in nonhuman primate models of the biological systems or diseases that are the focus of my research	1 = Critical 2 = Very Important 3 = Somewhat Important 4 = Neutral (No Opinion) 5 = Somewhat Unimportant 6 = Negligible Importance 7 = No Importance
Access to Expertise in Relevant Techniques: The performing organization can provide personnel with specialized expertise (not present within my immediate research team) in research techniques that is necessary for the performance of my research.	1 = Critical 2 = Very Important 3 = Somewhat Important 4 = Neutral (No Opinion) 5 = Somewhat Unimportant 6 = Negligible Importance 7 = No Importance
Access to Specialized Equipment or Facilities: The performing organization provides access to specialized instruments, equipment or facilities that are not available within my own laboratory and are necessary for the performance of my research.	1 = Critical 2 = Very Important 3 = Somewhat Important 4 = Neutral (No Opinion) 5 = Somewhat Unimportant 6 = Negligible Importance 7 = No Importance

Prior Relationship: I have an established collaboration with the performing organization, or have otherwise used them to support my prior studies, with good results.	1 = Critical 2 = Very Important 3 = Somewhat Important 4 = Neutral (No Opinion) 5 = Somewhat Unimportant 6 = Negligible Importance 7 = No Importance
Basic Animal Availability: The performing organization is able to provide a sufficient number of animals of the required species, age and sex needed for my research in a timely manner.	1 = Critical 2 = Very Important 3 = Somewhat Important 4 = Neutral (No Opinion) 5 = Somewhat Unimportant 6 = Negligible Importance 7 = No Importance
Availability of Specific Pathogen Free (SPF) Animals: The performing organization is able to provide a sufficient number of SPF animals in a timely manner.	1 = Critical 2 = Very Important 3 = Somewhat Important 4 = Neutral (No Opinion) 5 = Somewhat Unimportant 6 = Negligible Importance 7 = No Importance
Availability of Genetically Characterized Animals: The performing organization is able to provide a sufficient number of animals with specific genetic characteristics that I need for the performance of my research (e.g., MHC types or other genetic profile).	1 = Critical 2 = Very Important 3 = Somewhat Important 4 = Neutral (No Opinion) 5 = Somewhat Unimportant 6 = Negligible Importance 7 = No Importance
Cost: The performing organization provides the capabilities that I need for my research at the lowest cost, compared to other suitable alternatives.	1 = Critical 2 = Very Important 3 = Somewhat Important 4 = Neutral (No Opinion) 5 = Somewhat Unimportant 6 = Negligible Importance 7 = No Importance

8b. Are there any other factors, separate from those listed in Question 8a, that are critical or very important to you in selecting a service provider for your nonhuman primate studies? If so, please briefly describe these factors using the text box provided.

9. Have you experienced problems within the past two years that delayed your research, altered your experimental design, or influenced how you performed your research, because you encountered challenges obtaining or accessing nonhuman primates or related research support capacities? If so, please briefly describe them.

Appendix E – Planned NHP Use by Sponsoring Institute

Table E-1. Planned NHP Use for Research Awards, Excluding Infrastructure/Resource Awards, by Sponsoring Institute

Institute/Center and Species	Number of Animals by Initial Fiscal Year of Award					
	FY13	FY14	FY15	FY16	FY17	FY13-17
Fogarty International Center						
Capuchin Monkey	6					6
National Cancer Institute						
Baboon				3		3
Cynomolgus Macaque	6	32	3	108	88	237
Marmoset		15		8		23
Other/Unspecified Macaques	50					50
Rhesus Macaque	30	15	50	86	34	215
National Center for Advancing Translational Sciences						
Rhesus Macaque	12					12
National Center for Complementary and Integrative Health						
Rhesus Macaque				18		18
National Eye Institute						
African Green (Vervet) Monkey	35					35
Baboon					4	4
Cynomolgus Macaque	10	38	54	6	24	132
Marmoset			64			64
Other NHP			42			42
Other/Unspecified Macaques	24	34	19	41	35	153
Pigtail Macaque			19	15		34
Rhesus Macaque	242	250	320	288	266	1,366
Squirrel Monkey		50				50
National Heart, Lung, and Blood Institute						
Baboon	12	11	11	67	36	137
Cynomolgus Macaque	134	111	264	234	3	746
Pigtail Macaque	5		35	40		80
Rhesus Macaque	19	64	287	215	145	730
National Institute of Allergy and Infectious Diseases						
African Green (Vervet) Monkey	27	18		30	132	207
Capuchin Monkey					10	10
Baboon	45	131	60	102	18	356
Cynomolgus Macaque	353	448	288	328	648	2,065
Marmoset	64		12	21	10	107
Other NHP					50	50
Other/Unspecified Macaques		354				354
Owl Monkey		31		28		59
Pigtail Macaque	44	95	97	29	78	343
Rhesus Macaque	1,111	1,381	1,680	2,855	2,112	9,139
Squirrel Monkey					32	32
Tamarin Monkey					10	10

Table E-1. Planned NHP Use for Research Awards, Excluding Infrastructure/Resource Awards, by Sponsoring Institute (Continued)

Institute/Center and Species	Number of Animals by Initial Fiscal Year of Award					
	FY13	FY14	FY15	FY16	FY17	FY13-FY17
National Institute of Arthritis and Musculoskeletal and Skin Diseases						
Pigtail Macaque			45	30		75
Rhesus Macaque	12					12
National Institute of Biomedical Imaging and Bioengineering						
Cynomolgus Macaque				3		3
Marmoset			6			6
Rhesus Macaque	4	8	4	4	4	24
National Institute of Child Health and Human Development						
Baboon	18	166	96	83	248	611
Cynomolgus Macaque	12	60	69		86	227
Japanese Macaque	12		96			108
Marmoset	37			98		135
Other/Unspecified Macaques			5			5
Pigtail Macaque	32					32
Rhesus Macaque	725	537	153	876	268	2,559
Squirrel Monkey		10				10
Titi Monkey					218	218
National Institute of Dental and Craniofacial Research						
Cynomolgus Macaque		6	10	64		80
Rhesus Macaque	106	15	58	156	62	397
National Institute of Diabetes and Digestive and Kidney Diseases						
African Green (Vervet) Monkey					36	36
Baboon	120		65		45	230
Cynomolgus Macaque	54		10	16	66	146
Japanese Macaque			160			160
Marmoset			12			12
Other/Unspecified Macaques		10			5	15
Rhesus Macaque	62	9		4	57	132
National Institute of Environmental Health Sciences						
Cynomolgus Macaque		86	6			92
Rhesus Macaque					49	49
National Institute of General Medical Sciences						
Baboon			46		45	91
Cynomolgus Macaque				48		48
Rhesus Macaque	18		124	4		146
National Institute of Mental Health						
African Green (Vervet) Monkey				146		146
Baboon			1		32	33
Cynomolgus Macaque		20	6	21		47
Japanese Macaque			100			100
Marmoset		2	32	30	68	132
Rhesus Macaque	527	399	245	692	194	2,057
Squirrel Monkey			8	4		12

Table E-1. Planned NHP Use for Research Awards, Excluding Infrastructure/Resource Awards, by Sponsoring Institute (Continued)

Institute/Center and Species	Number of Animals by Initial Fiscal Year of Award					
	FY13	FY14	FY15	FY16	FY17	FY13-FY17
National Institute of Neurological Disorders and Stroke						
Baboon		16			34	50
Capuchin Monkey				32	6	38
Cynomolgus Macaque	40	53	61	49	28	231
Marmoset			14		6	20
Other NHP		4	77			81
Other/Unspecified Macaques	13		17	38		68
Pigtail Macaque	25	30		24	14	93
Rhesus Macaque	70	114	85	332	242	843
Squirrel Monkey	9	40		122	35	206
National Institute on Aging						
African Green (Vervet) Monkey		20	55	140		215
Baboon		17			87	104
Cynomolgus Macaque				16	99	115
Marmoset		32	266		8	306
Other/Unspecified Macaques			14		12	26
Rhesus Macaque	132	43	11	202	78	466
Tamarin Monkey					22	22
National Institute on Alcohol Abuse and Alcoholism						
Baboon	5	31		4		40
Cynomolgus Macaque		23		48	114	185
Rhesus Macaque	48	24	101	23	36	232
National Institute on Deafness and other Communication Disorders						
Cynomolgus Macaque	2					2
Marmoset		6	71	54		131
Rhesus Macaque	14	30	46	19	37	146
National Institute on Drug Abuse						
Baboon		4				4
Cynomolgus Macaque		88	12		80	180
Mangabey			10			10
Other NHP					3	3
Pigtail Macaque					16	16
Rhesus Macaque	128	139	308	177	153	905
Squirrel Monkey	22	27	12		24	85
Office of the Director/Office of Research Infrastructure Programs						
African Green (Vervet) Monkey					20	20
Cynomolgus Macaque	48		40			108
Pigtail Macaque		18				18
Rhesus Macaque	12			100	58	258

Table E-2. Planned NHP Use for Infrastructure/Resource Awards, by Sponsoring Institute

Institute/Center and Species	Number of Animals by Initial Fiscal Year of Award					
	FY13	FY14	FY15	FY16	FY17	FY13-FY17
National Institute of Allergy and Infectious Diseases*						
Rhesus Macaque				6		6
Squirrel Monkey				18		18
Office of the Director/Office of Research Infrastructure Programs						
African Green (Vervet) Monkey	10	15	355			380
Baboon	449		132		435	1,016
Capuchin Monkey			30			30
Cynomolgus Macaque				95	50	125
Mangabey	10			170		180
Marmoset			59	120	60	239
Other NHP or Mixed Species†	2,000	7,200	5,000			14,200
Other/Unspecified Macaques			15			15
Pigtail Macaque		800		3	1750	2553
Rhesus Macaque	6,120	48	2,591	11,906	2,700	23,277
Squirrel Monkey			509	69	12	590

* Colonies supported by NIH contracts are not included in these data

† Awards involving multiple species in which specific numbers for each species were not reported

Appendix F – Planned NHP Use by Research Area

Table F-1. Planned NHP Use for Research Awards, Excluding Infrastructure/Resource Awards, by Research Area

Research Area and Species	Number of Animals by Initial Fiscal Year of Award					
	FY13	FY14	FY15	FY16	FY17	FY13-FY17
Auditory System						
Cynomolgus Macaque	2					2
Marmoset		6	71	54		131
Other/Unspecified Macaques	8					8
Rhesus Macaque	22	30	35	13	30	130
Squirrel Monkey		50				50
Blood Disorder						
Baboon		11	6		3	20
Cynomolgus Macaque			69	34	3	106
Rhesus Macaque	7	40	15		20	82
Cancer						
Baboon				3		3
Cynomolgus Macaque	6	32	3	140	88	269
Other/Unspecified Macaques	50					50
Rhesus Macaque	157	7	10	26	34	234
Cardiovascular Disease						
Baboon	12		2	67	33	114
Cynomolgus Macaque	134	83	44	52		313
Rhesus Macaque	12	10	68		2	92
Dental/Oral Disease						
Baboon			10			10
Cynomolgus Macaque		6	10			16
Rhesus Macaque		15				15
Diabetes						
Baboon					21	21
Cynomolgus Macaque			10		36	46
Japanese Macaques			96			96
Rhesus Macaque			54		22	76
Fetal Development						
Baboon	112	16				128
Cynomolgus Macaque		86				86
Rhesus Macaque	36		116		73	225
HIV/AIDS						
African Green (Vervet) Monkey					36	36
Cynomolgus Macaque	27	139	173	116	42	497
Mangabey			10			10
Pigtail Macaque	44	143	122	53	85	447
Rhesus Macaque	865	1,143	1,543	3,177	1,720	8,448
Squirrel Monkey					20	20

Table F-1. Planned NHP Use for Research Awards, Excluding Infrastructure/Resource Awards, by Research Area (Continued)

Research Area and Species	Number of Animals by Initial Fiscal Year of Award					
	FY13	FY14	FY15	FY16	FY17	FY13-FY17
Infectious Disease - Bacterial						
African Green (Vervet) Monkey	27	18				45
Baboon	45	131	36		45	257
Cynomolgus Macaque	173	62	107	73	99	514
Marmoset	10			21		31
Pigtail Macaque			6		18	24
Rhesus Macaque	42	180	69	44	194	529
Infectious Disease – Parasitic						
Baboon				12		12
Cynomolgus Macaque		74				74
Owl Monkey		31		28		59
Rhesus Macaque	12	11	90	47	83	243
Infectious Disease (non-HIV/AIDS) - Viral						
African Green (Vervet) Monkey		20		30	132	182
Baboon					52	52
Capuchin Monkey					10	10
Cynomolgus Macaque	150	124	58	45	307	684
Marmoset	54	15		8	10	87
Other NHP					50	50
Other/Unspecified Macaques		354				354
Pigtail Macaque			4			4
Rhesus Macaque	333	305	153	75	361	1,227
Squirrel Monkey					12	12
Tamarin Monkey					10	10
Molecular Immunology (General)						
Baboon		17				17
Cynomolgus Macaque		149			20	169
Rhesus Macaque	39	9			50	98
Musculoskeletal Disorders						
African Green (Vervet) Monkey			55			55
Capuchin Monkey					6	6
Cynomolgus Macaque	40	44	58	8		150
Other/Unspecified Macaques			6	15		21
Pigtail Macaque	25		45			70
Rhesus Macaque	42	51	22	187	85	387
Squirrel Monkey		40		47		87

Table F-1. Planned NHP Use for Research Awards, Excluding Infrastructure/Resource Awards, by Research Area (Continued)

Research Area and Species	Number of Animals by Initial Fiscal Year of Award					
	FY13	FY14	FY15	FY16	FY17	FY13-FY17
Neuroscience - Behavioral & Systems						
African Green (Vervet) Monkey				140	20	160
Baboon	5	33		20	92	150
Capuchin Monkey	6			32		38
Cynomolgus Macaque		65	24	54	188	331
Japanese Macaques			100			100
Marmoset		34	20	60	56	170
Other NHP		4	77		3	84
Other/Unspecified Macaques	5	13	25	23	12	78
Pigtail Macaque				30	5	35
Rhesus Macaque	593	488	489	1,520	363	3,453
Squirrel Monkey	31	27	20	79	59	216
Tamarin Monkey					22	22
Titi Monkey					218	218
Neuroscience – Molecular						
African Green (Vervet) Monkey				146		146
Baboon		2	1		7	10
Cynomolgus Macaque		3	3	103	73	182
Marmoset			44	20	18	82
Other/Unspecified Macaques			5			5
Rhesus Macaque	328	82	118	72	124	724
Nutritional & Metabolic Disorders (non-Diabetes)	116	212	216	240	156	940
Baboon				29	80	109
Japanese Macaques	12		160			172
Marmoset				48		48
Other/Unspecified Macaques					5	5
Rhesus Macaque	104	212	56	163	71	606
Other						
Cynomolgus Macaque					150	150
Marmoset			266			266
Rhesus Macaque			114	28		142
Regenerative Medicine & Transplantation						
Baboon			128	90	24	242
Cynomolgus Macaque	21		210	274	120	625
Pigtail Macaque	5			40		45
Rhesus Macaque		78	78	168	180	504
Reproductive Health						
Baboon	18	166	96	38	188	506
Cynomolgus Macaque	12	60			86	158
Marmoset	37				8	45
Rhesus Macaque	418	121	78	181	79	877
Squirrel Monkey		10				10
Respiratory System						
Cynomolgus Macaque	30			36		66
Pigtail Macaque	32					32
Rhesus Macaque	20		42	85	37	184

Table F-1. Planned NHP Use for Research Awards, Excluding Infrastructure/Resource Awards, by Research Area (Continued)

Research Area and Species	Number of Animals by Initial Fiscal Year of Award					
	FY13	FY14	FY15	FY16	FY17	FY13-FY17
Urologic Diseases	62		12			74
Baboon	8					8
Cynomolgus Macaque	54					54
Marmoset			12			12
Visual System						
African Green (Vervet) Monkey	35					35
Baboon					4	4
Cynomolgus Macaque	10	38	54	6	24	132
Marmoset			64			64
Other NHP			42			42
Other/Unspecified Macaques	24	31	19	41	35	150
Pigtail Macaque			19	15		34
Rhesus Macaque	242	246	322	265	267	1,342