

# ORWH Sex/Gender Administrative Supplement Program: Evaluation and Concept Clearance

## ORWH SAGE Team

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# Agenda



- **Brief overview of ORWH Sex/Gender Administrative Supplement (SAGE Admin. Supp.) program**
- **SAGE Admin. Supp. Evaluation data**
- **Impact of the SAGE Admin. Supp. Program**

# Did the program accomplish its intended objectives?



- **To support research highlighting the impact of sex/gender influences in human health and illness, including basic, preclinical, clinical, translational, and behavioral studies?**
  - **Add the Opposite Sex/Gender**
  - **Increase Sample Size (N)**
  - **Analyze Existing Data**
- **To stimulate the investigators to addresses\*:**
  - **Goal 1: Increase sex differences research in basic science studies**
  - **Goal 2: Incorporate findings of sex/gender in the design and development of new technologies, medical devices, and therapeutic drugs**
  - **Goal 3: Actualize personalized prevention, diagnostics, and therapeutics for girls and women**

*\*[NIH Strategic Plan for Women's Health Research](#), *Moving into the Future with New Dimensions and Strategies for Women's Health Research: A Vision for 2020 for Women's Health Research**



# Assessment Parameters

## **Multi-factorial approaches to assess the success of the program:**

- **Demographic Information (Personally Identifiable Information, PII) of the Applicants and Awardees**
- **Bibliometric data of supplement awardees**
- **Survey of the supplement awardees**
- **Subsequent grant applications**
- **Workshop of supported investigators**

# Administrative Supplements for Research on Sex/Gender Influences (Admin Supp)



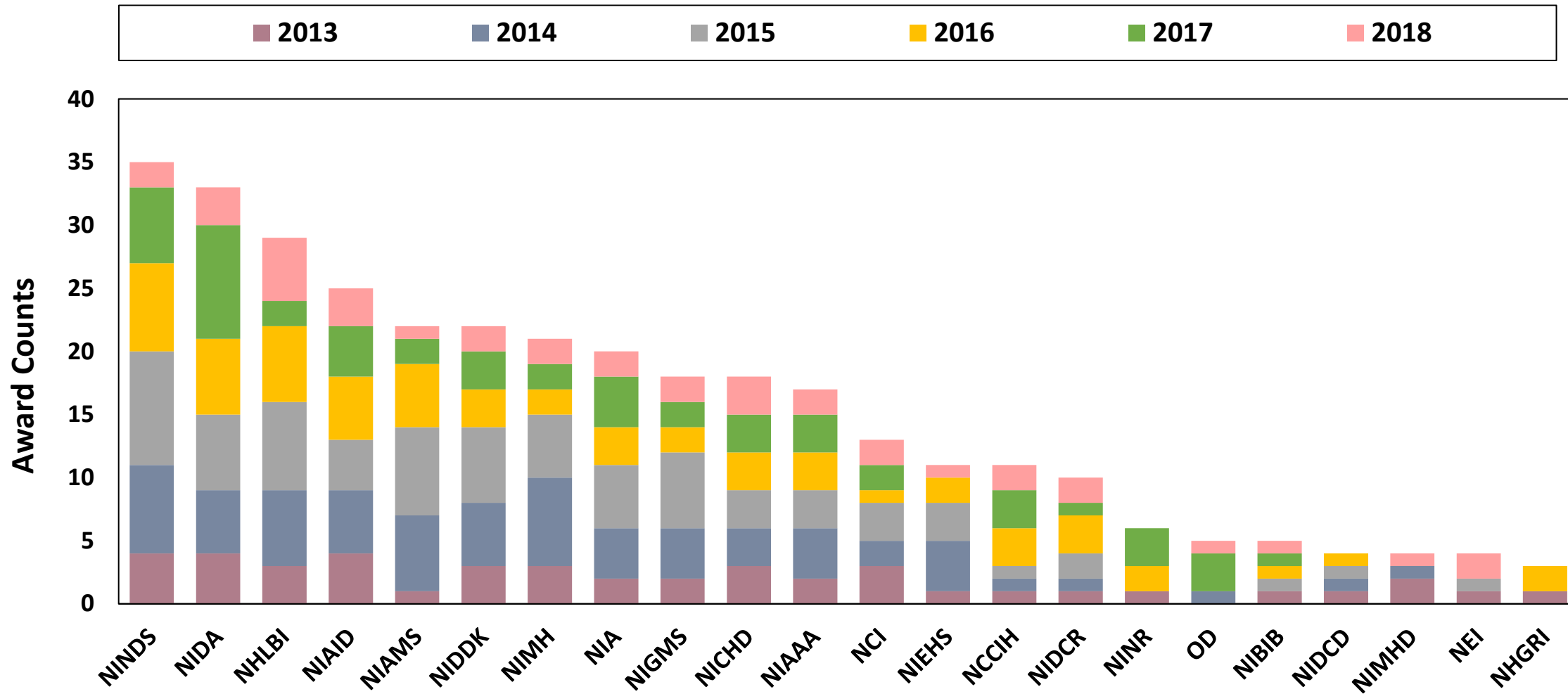
- In FY 2013, ORWH initiated a trans-NIH program to catalyze exploratory research on sex/gender\* differences by providing “**Administrative Supplements (Admin. Supp.)**” to ongoing peer-reviewed NIH-funded grants.
- The Admin. Supp. program supported following types of Research Approaches:
  - Add the Opposite Sex/Gender
  - Increase Sample Size (N)
  - Analyze Existing Data
- The proposed research must address at least one of the objectives from Goals 1 through 3 of the [NIH Strategic Plan for Women's Health Research](#).

*[\\*IOM Report, 2001](#), “Exploring the Biological Contributions to Human Health: Does Sex Matter?”*

*Sex-based studies: Sex is the classification of living things, generally as male or female.*

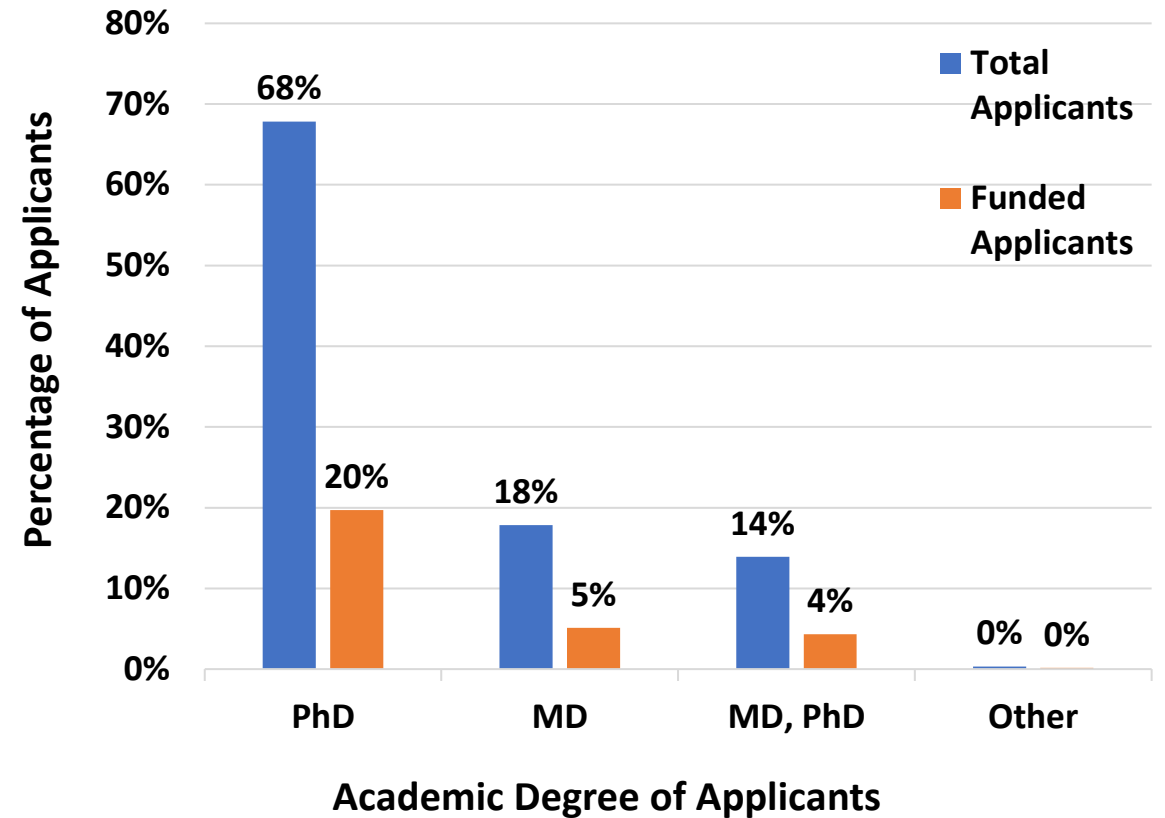
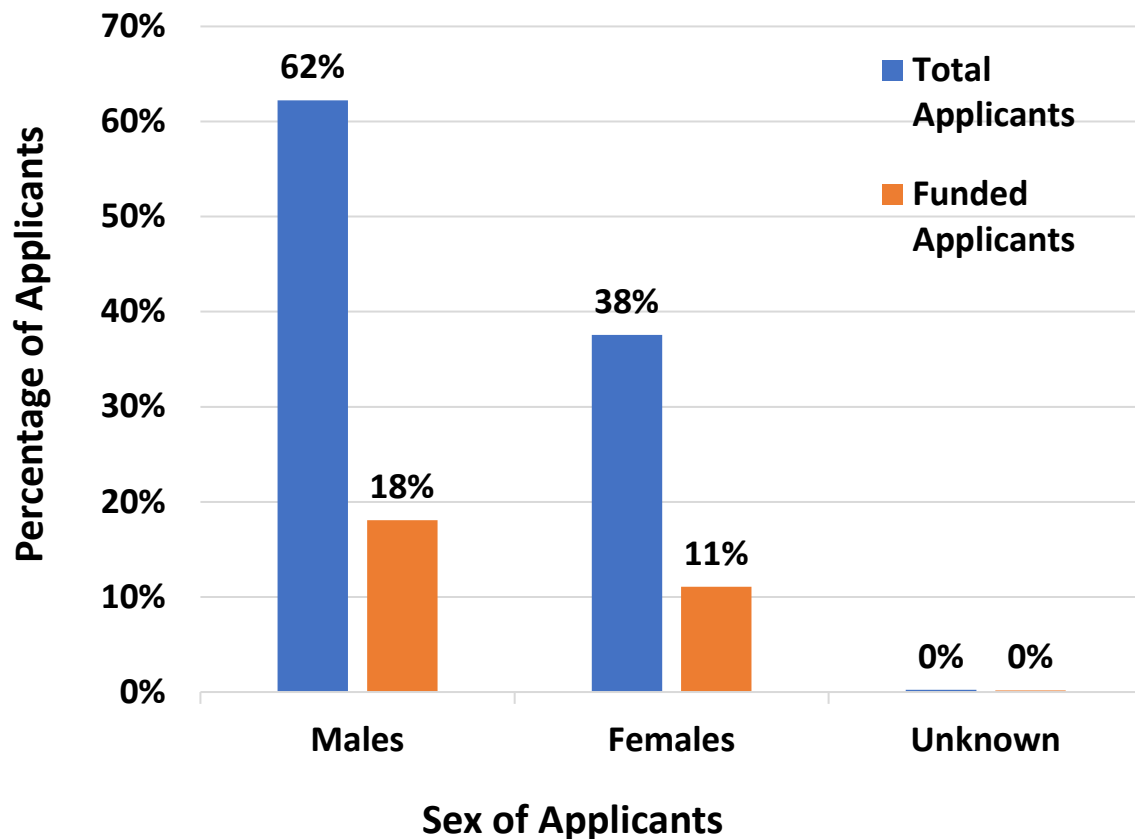
*Gender-based studies: Gender refers to a person's self-representation as male or female, or how that person is responded to by social institutions based on the individual's gender presentation.*

# ORWH Funded SAGE Admin. Supps. (FY 2013 – 2018)



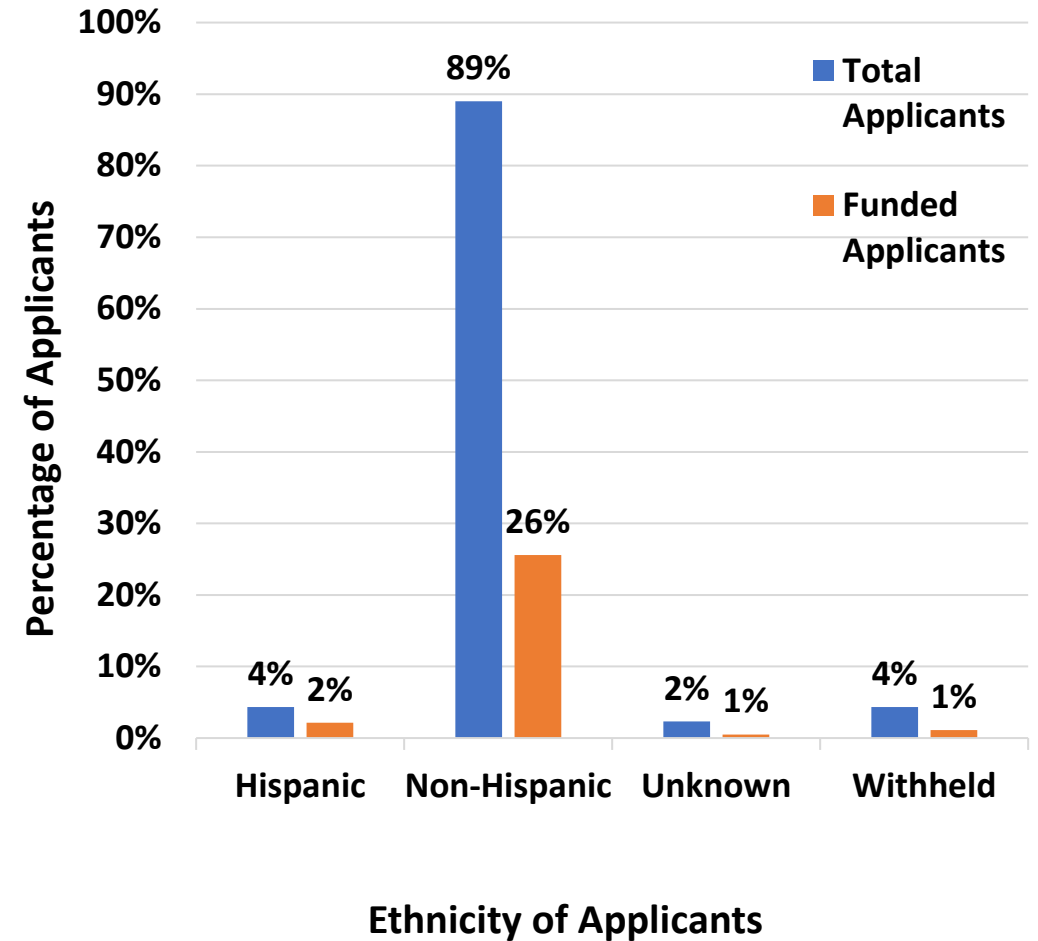
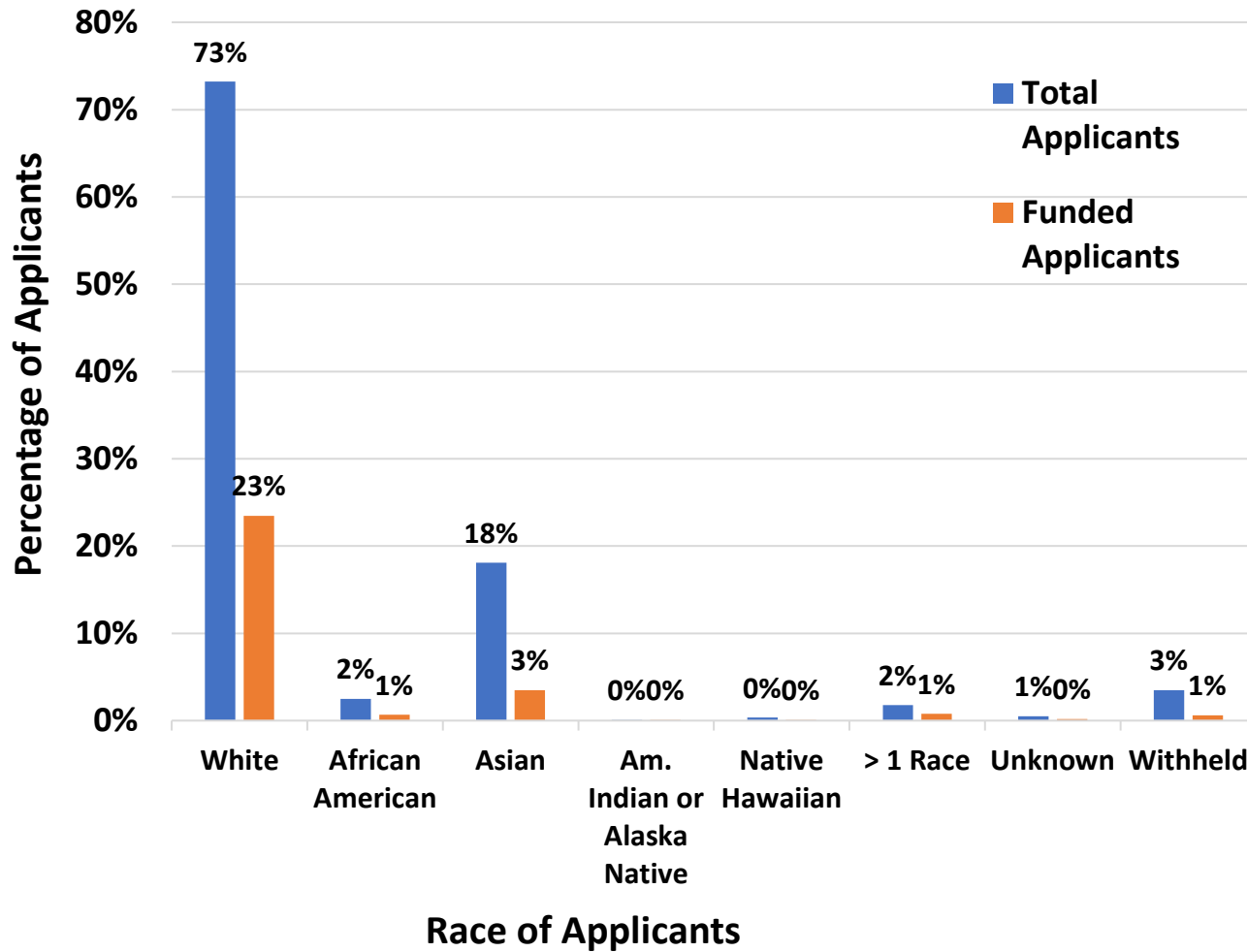
ORWH funded 22 ICOs, except 6 (CC, CIT, CSR, FIC, NCATS, and NLM)

# Sex and Academic Degree of the Applicants - SAGE Admin. Supp. (FY 2013 - 2018)



**Disclaimer:** The demographic information (Personally Identifiable Information, PII) was provided in a report (#1314-20) by the Division of Statistical Analysis and Reporting (DSAR), NIH. The PII data presentation was cleared by the OER on Tuesday, February 23, 2021.

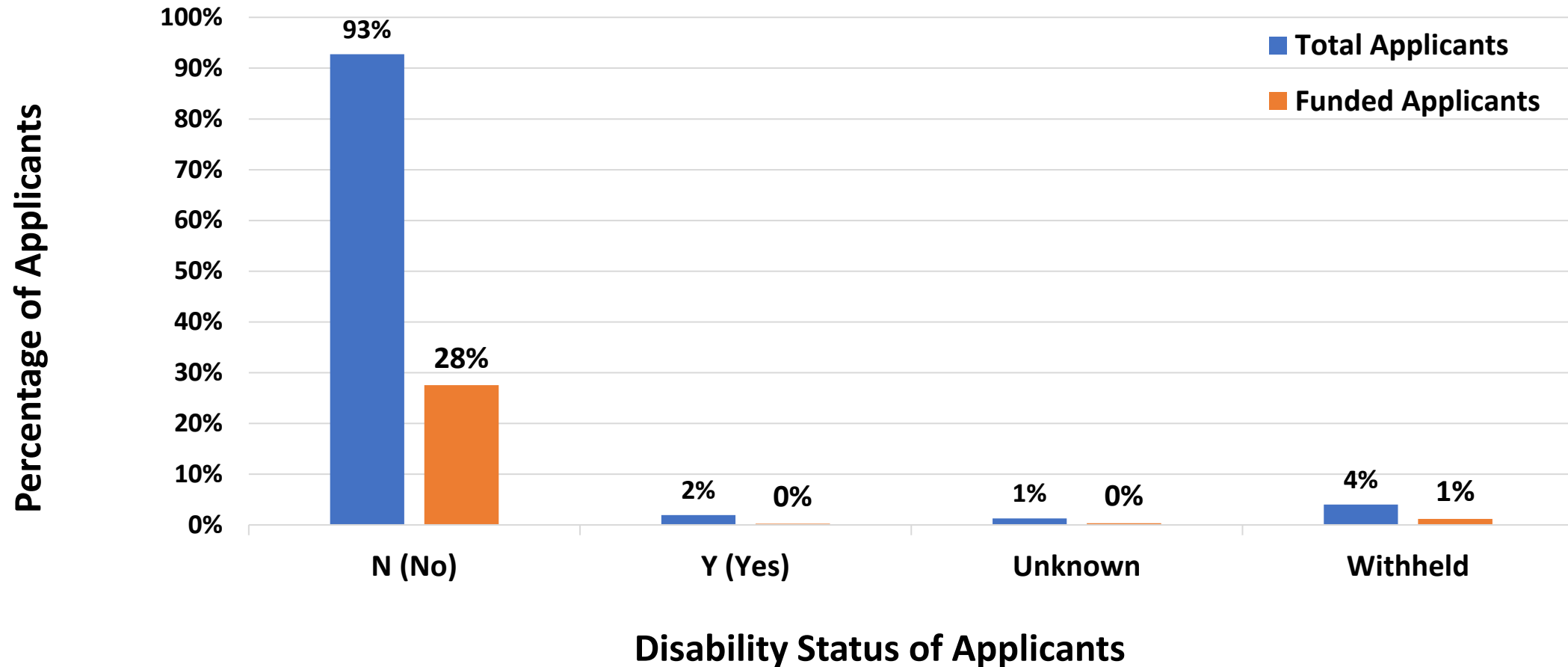
# Race and Ethnicity of the Applicants - SAGE Admin. Supp. (FY 2013 - 2018)



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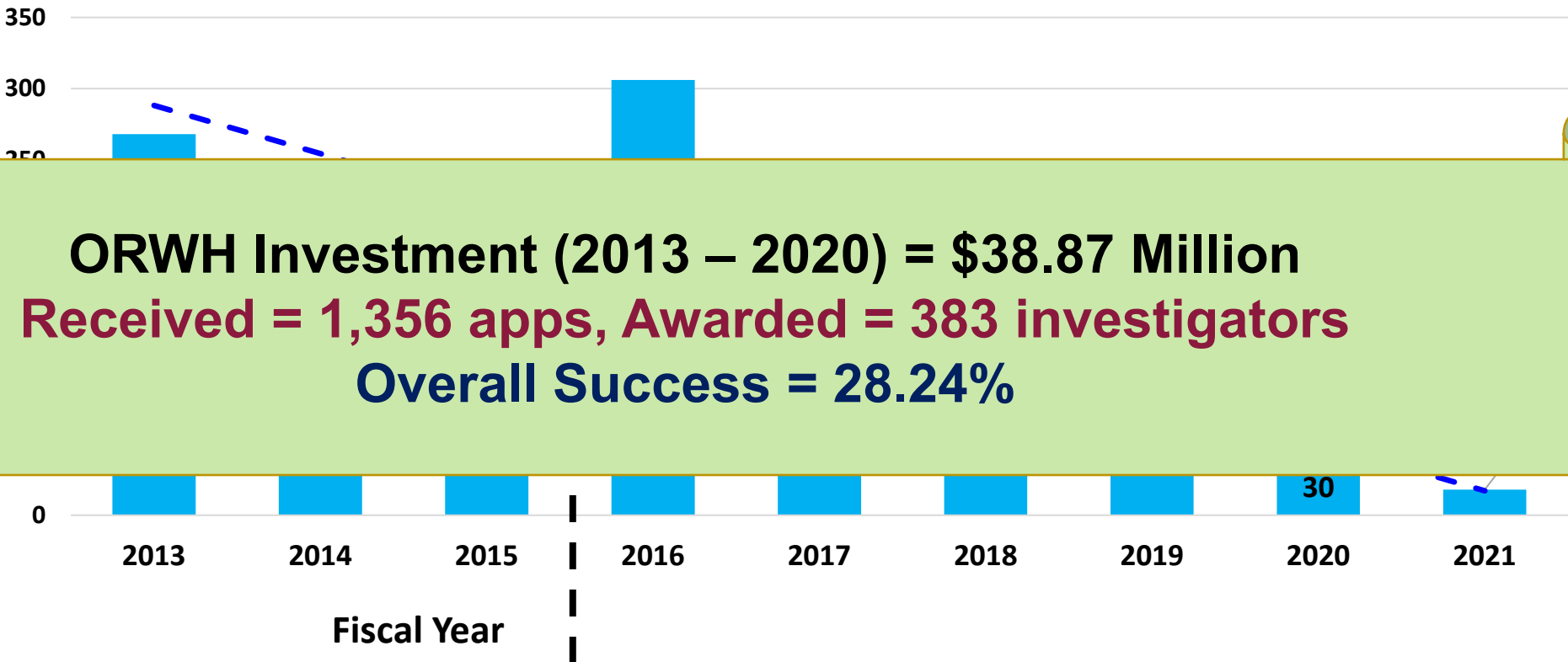


# Disability Status of the Applicants - SAGE Admin. Supp. (FY 2013 - 2018)



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# SAGE Admin. Supp. Total Applications\* Received (FY 2013 – 2021)

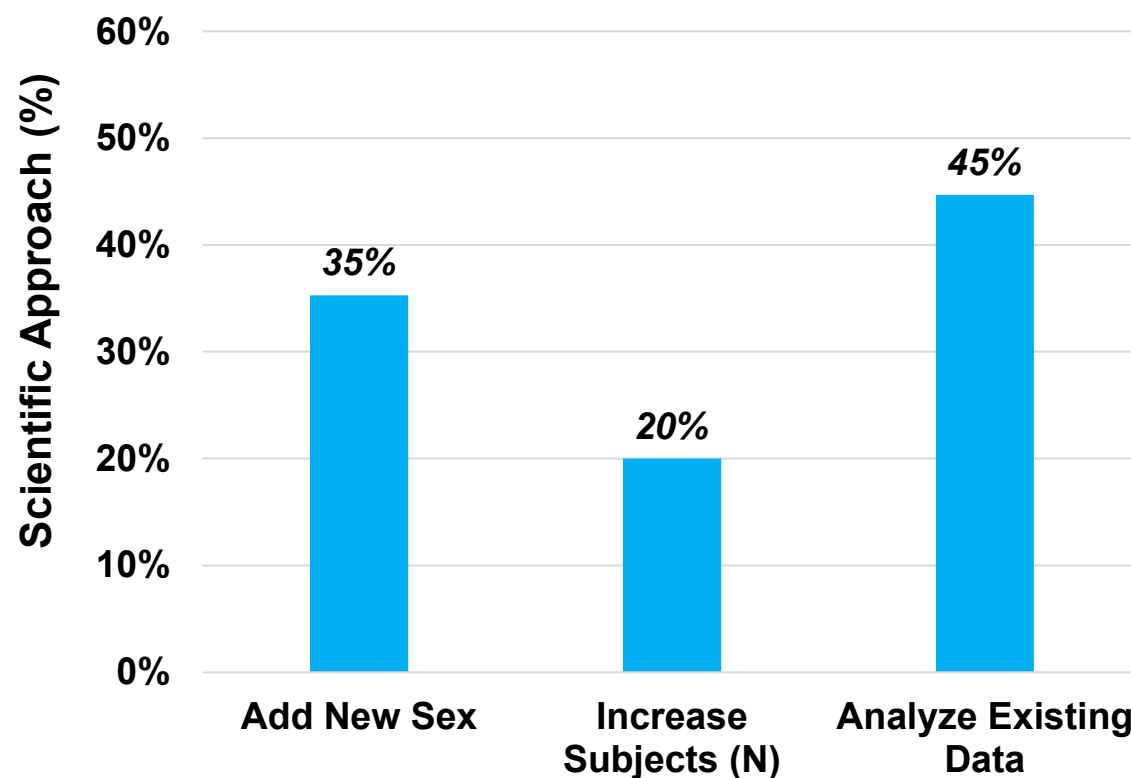
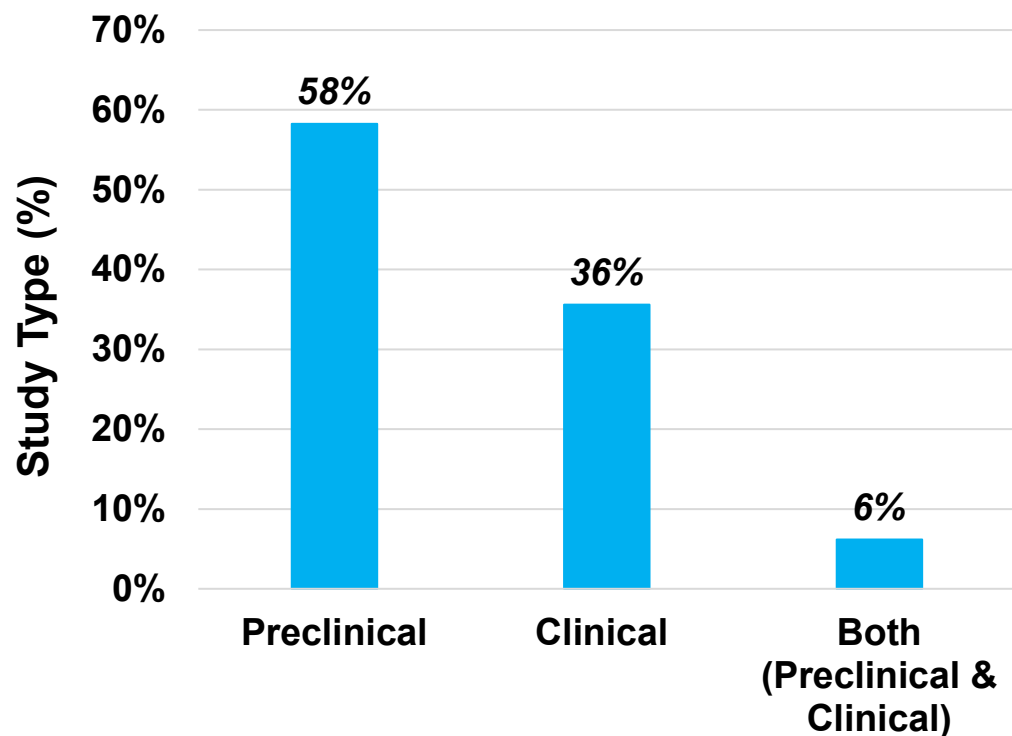


**ORWH Investment (2013 – 2020) = \$38.87 Million**  
**Received = 1,356 apps, Awarded = 383 investigators**  
**Overall Success = 28.24%**

NIH issued SABV policy  
([NOT-OD-15-102](#)) in June 2015

\*Based on the QVR/IMPACII data

# Incorporation of Sex/Gender in funded Admin. Supp. (Combined data of 6 yrs., FY 2013-2018)



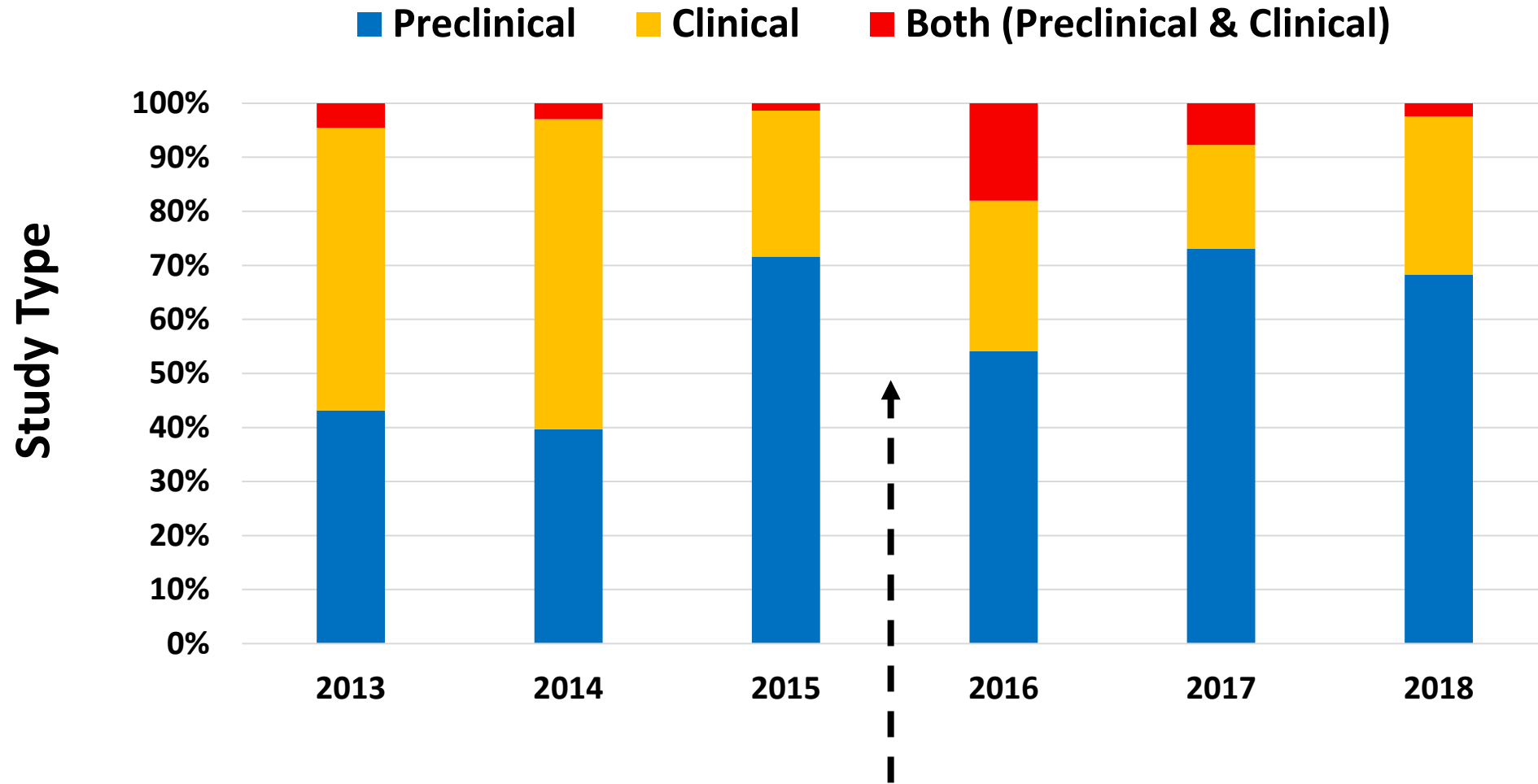
**Preclinical Research** includes - Cell line, Animal, Xenograft, or Non-human primates

**Clinical Research** includes - Human subjects or Human biospecimens

**Both Preclinical and Clinical Research** includes – as above, Patients derived xenografts



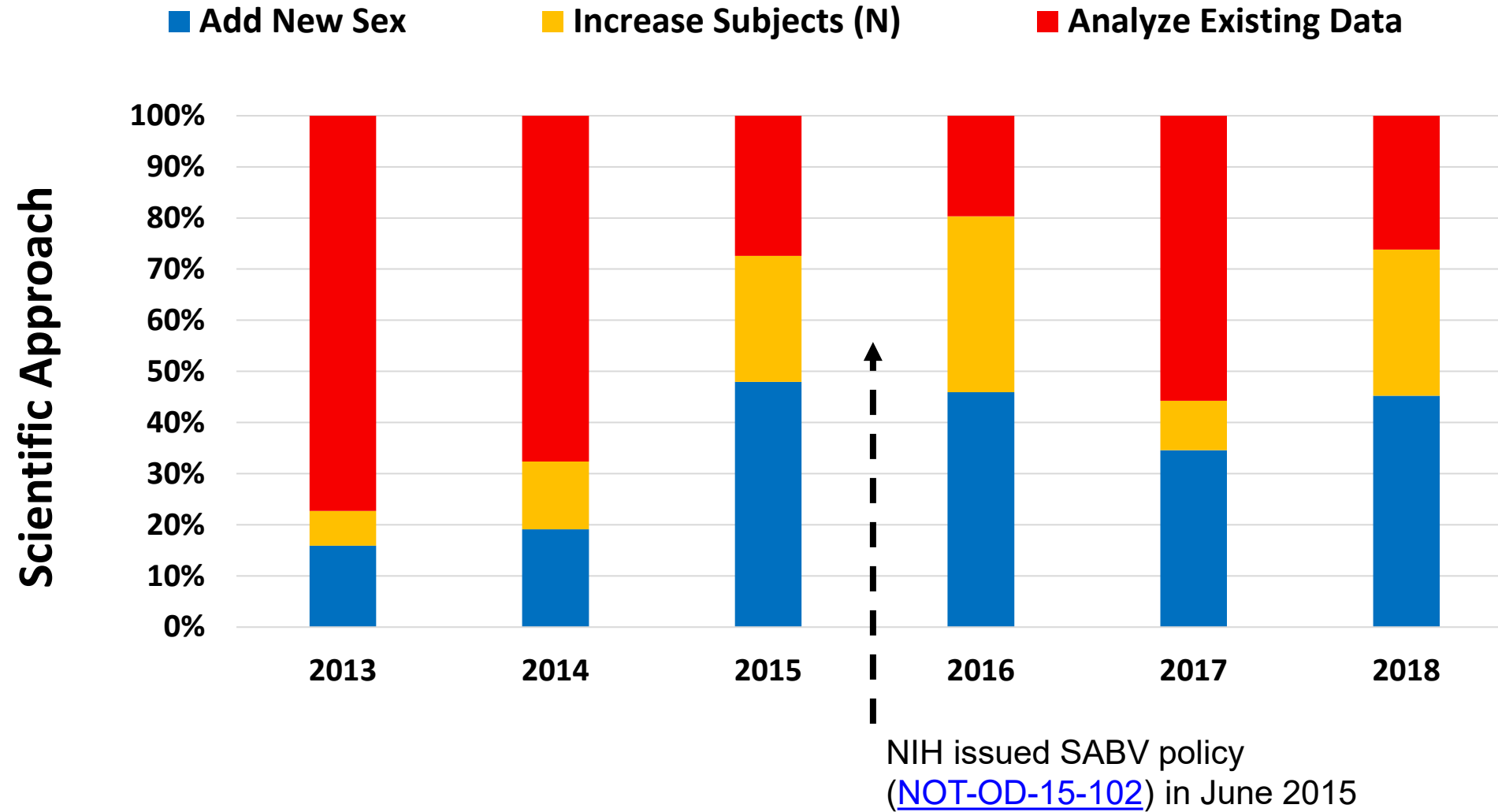
# Funded SAGE Admin. Supp. Apps – Study Types



**Preclinical Research** includes - Cell line, Animal, Xenograft, or Non-human primates  
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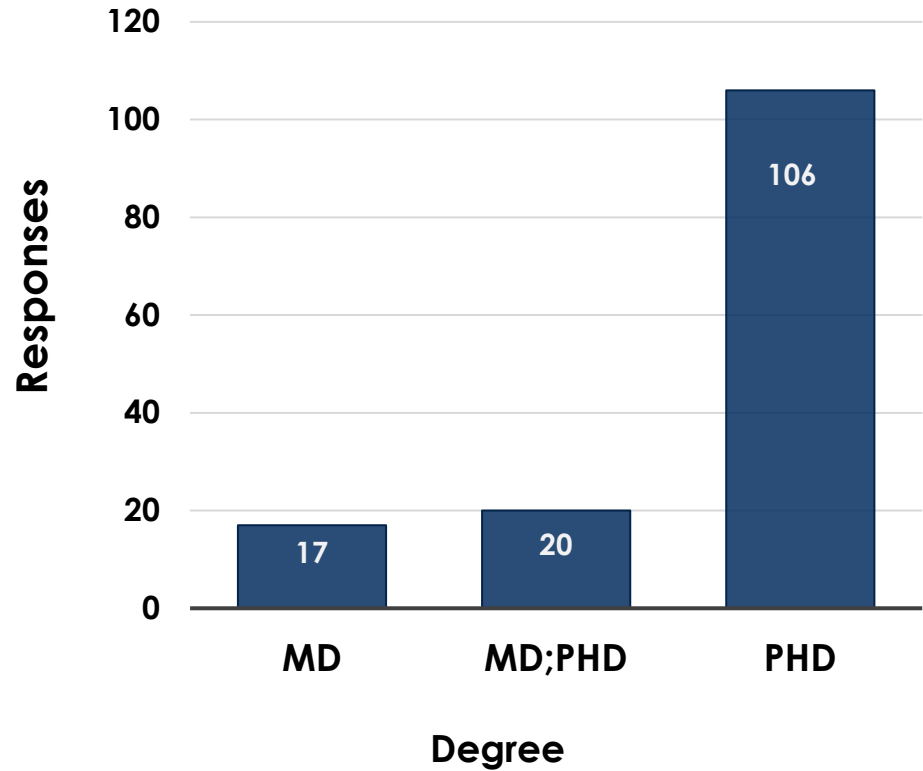
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# Funded SAGE Admin. Supp. Apps – Research Approach

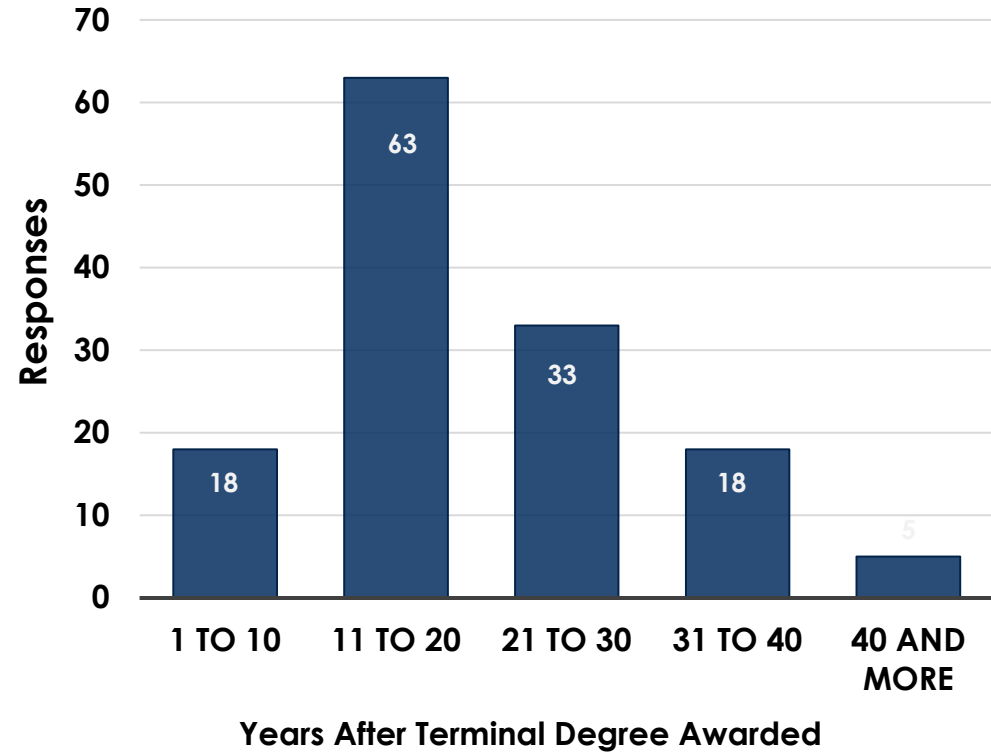




Q: What terminal degrees were held by SAGE recipients at time of award?

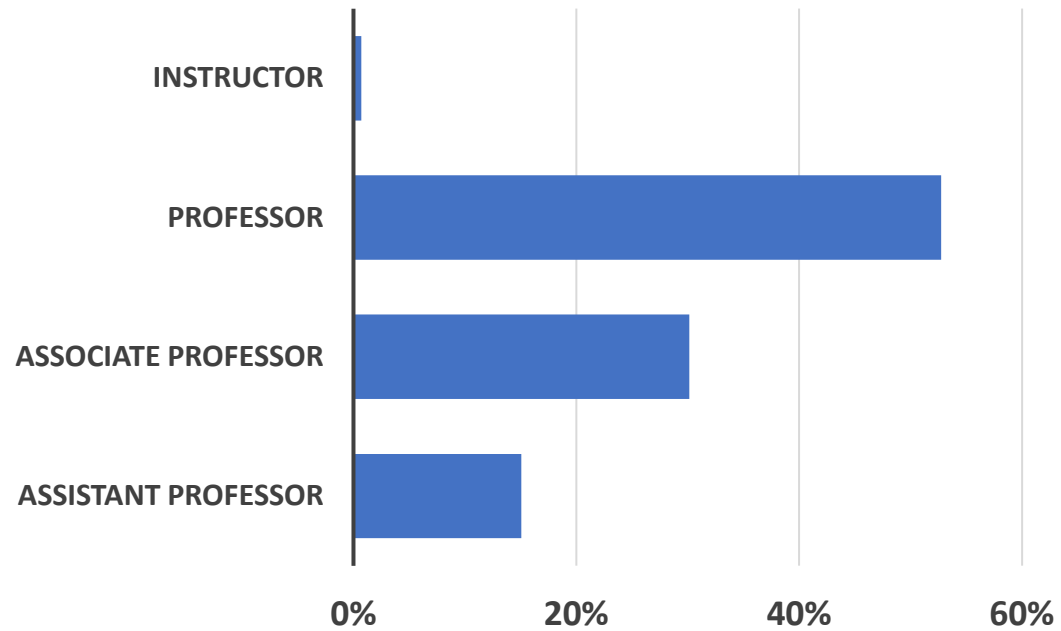


Q: How many years after your terminal degree did you become a SAGE supplement awardee?

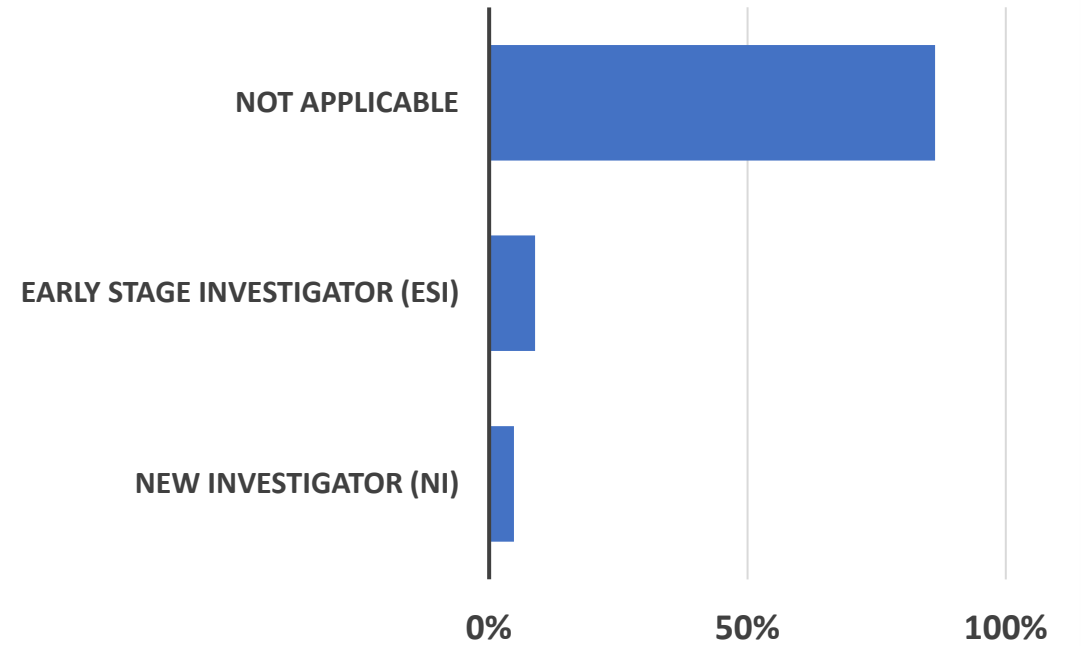




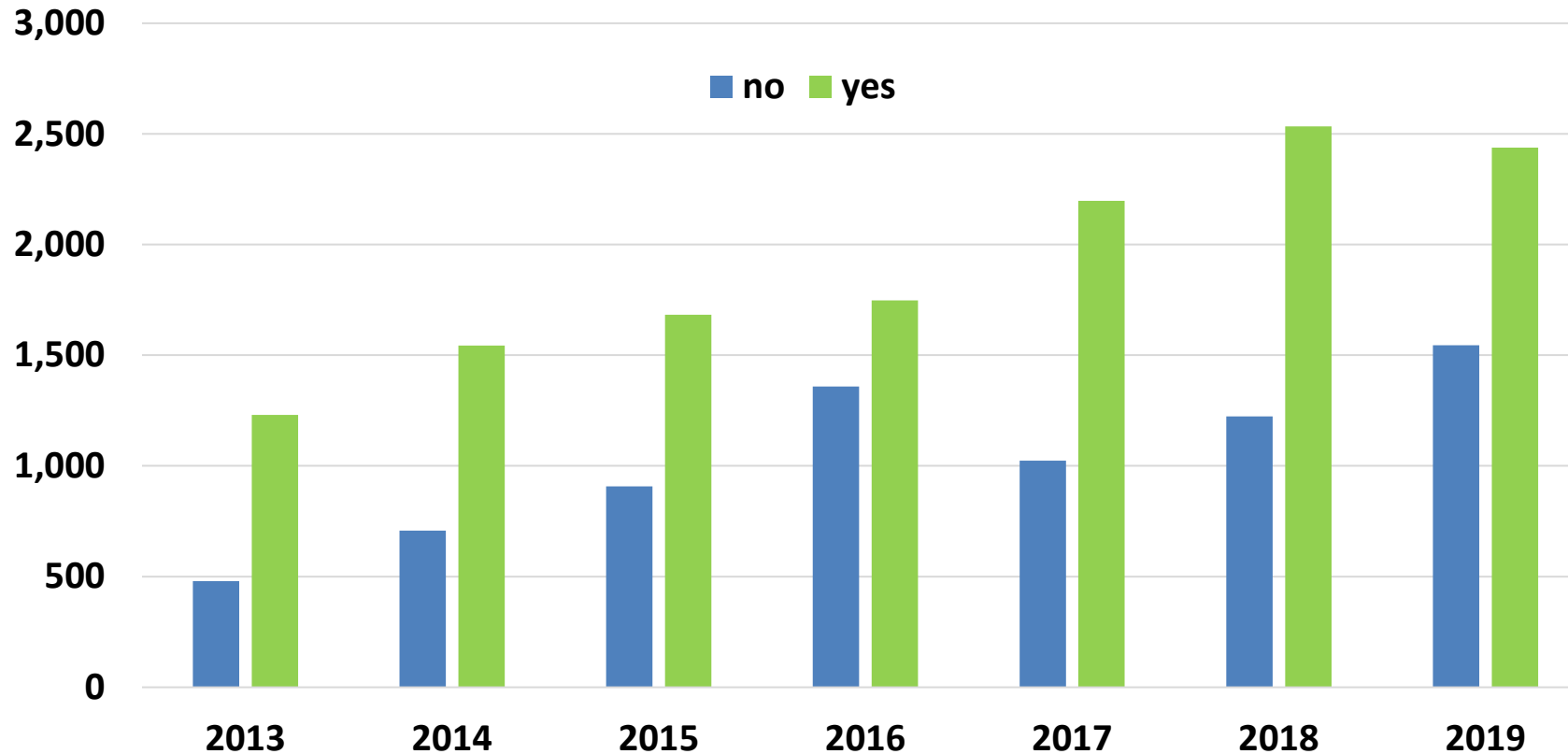
**Q: At the time you became a SAGE supplement awardee, what was your professional status?**



**Q: At the time you became SAGE supplement awardee, what stage investigator were you?**





# SAGE Pls' Publications by Fiscal Year FY'13 Cohort



## SABV Keywords Used:

- Biological variable
- Bisexual
- Bisexuality or homosexuality
- Female
- Gay
- Gender
- Gender difference
- Gender differences
- Gender disparities
- Gender disparity
- Gender identities
- Gender identity
- Gender inequalities
- Gender inequality
- Lesbian
- LGBT
- Male
- Man
- Men
- Queer
- SABV
- Sex
- Sex as a biological variable
- Sex characteristics
- Sex difference
- Sex differences
- Sex distribution
- Sex effect
- Sex effects
- Sex factors
- Sex ratio
- Sexism
- Sexual and gender minorities
- Sexual dimorphism
- Transgender
- Transgender persons
- Woman
- Women

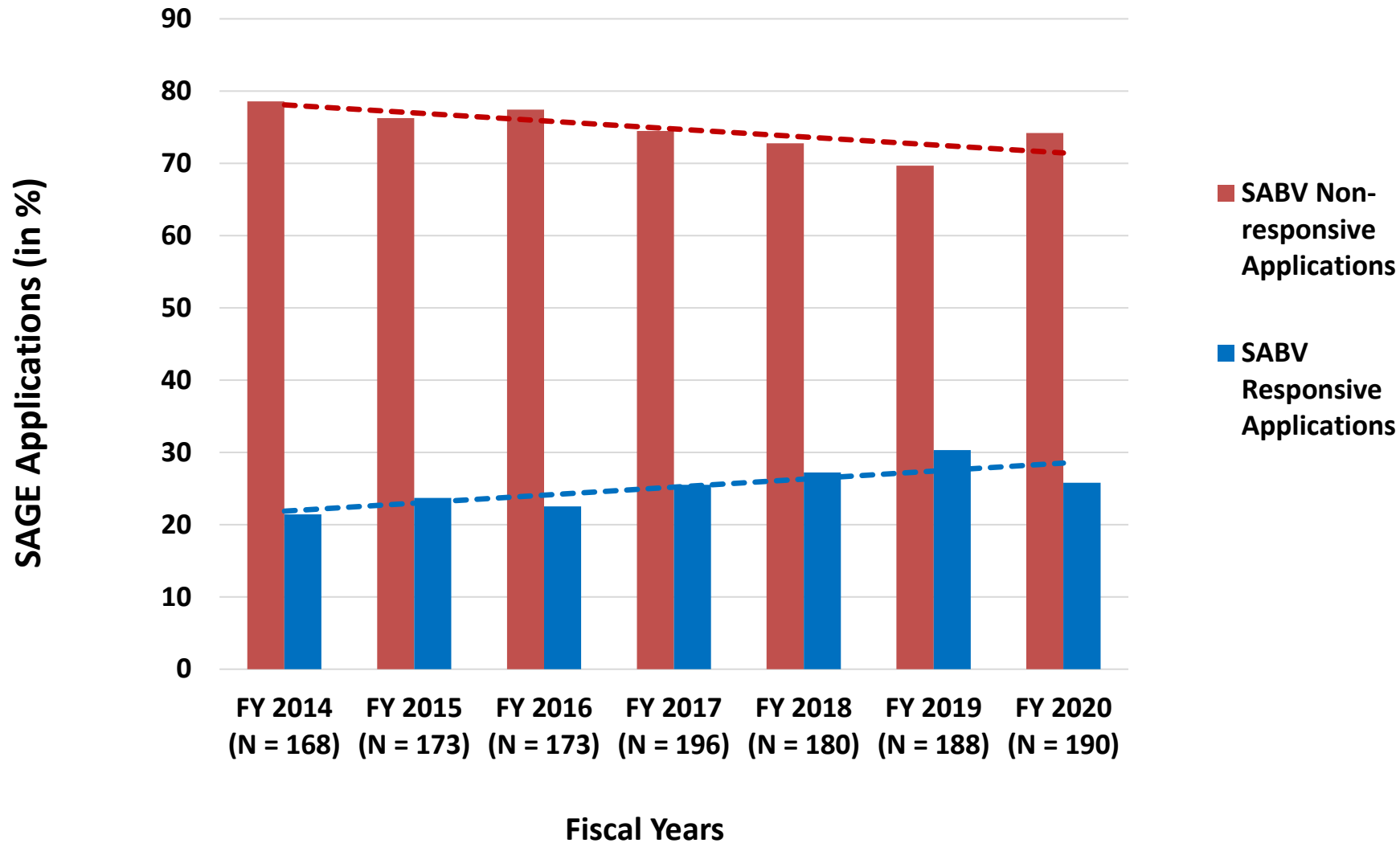
 Yes =Publications that contain keywords related to sex/gender and SABV

 No =Publications that DO NOT contain keywords related to sex/gender and SABV





# FY'13 Supplement Awardees: SABV Non-responsive and Responsive Applications

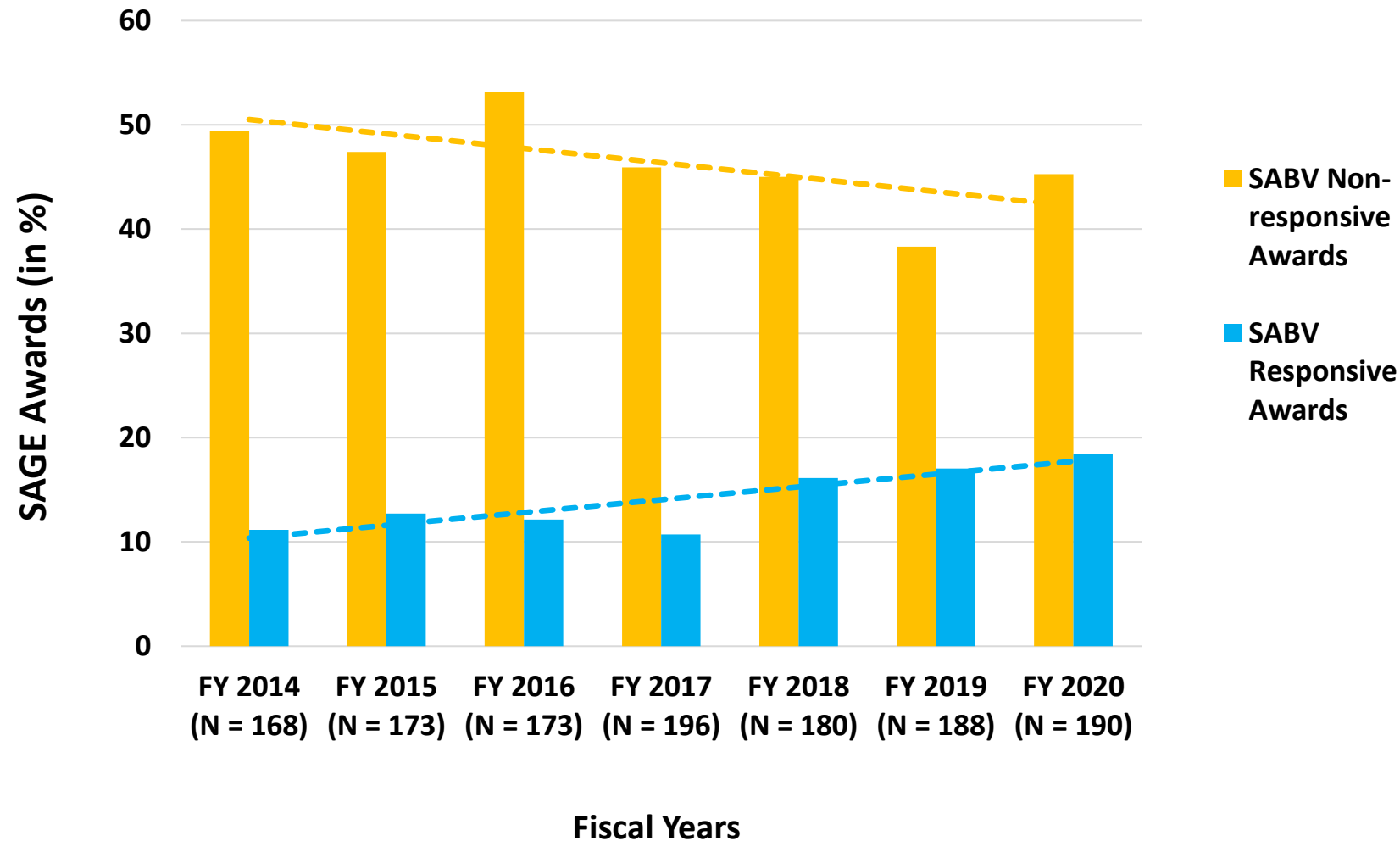


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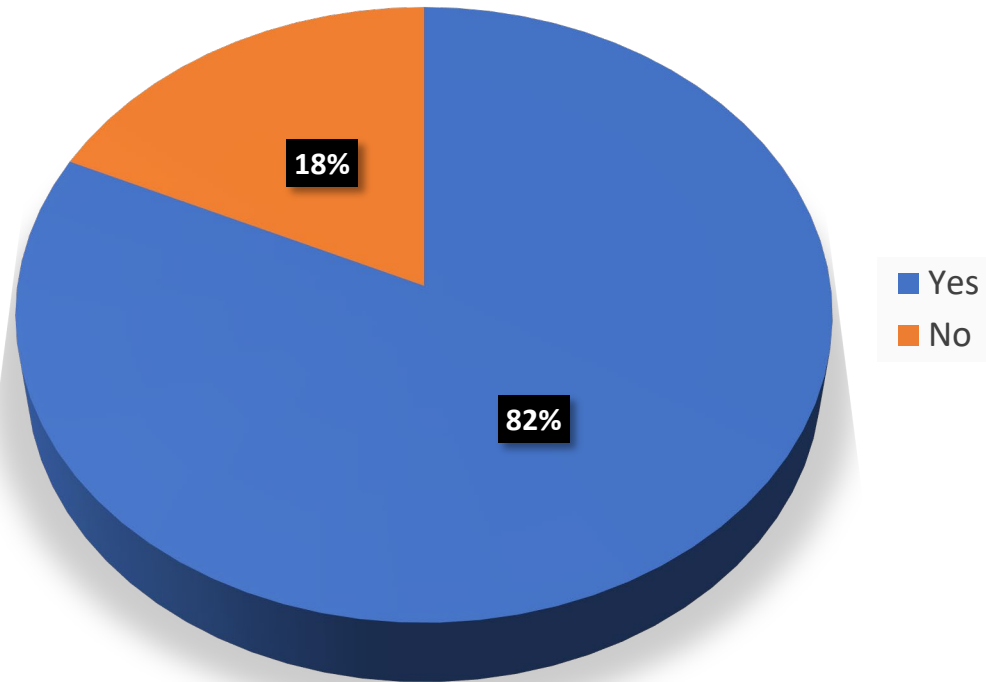


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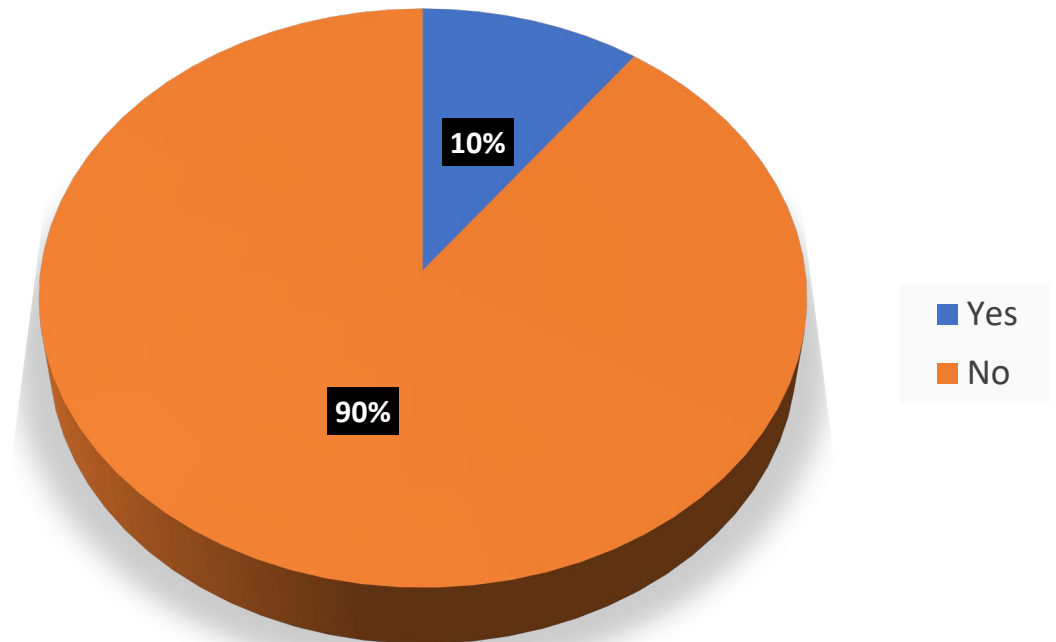
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**Q: Did you present any of the data from your SAGE supplement award at any national or international conferences?**

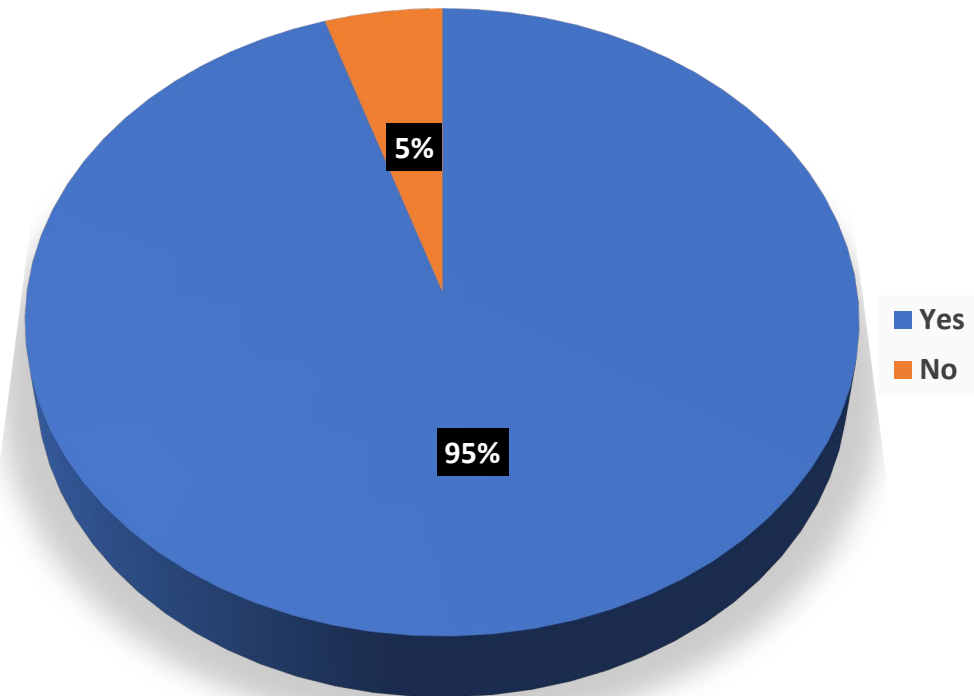


**Q: If you indicated that you presented your SAGE research at one or more national or international conferences, were the conference(s) specifically focused on sex and/or gender, or women's health?**

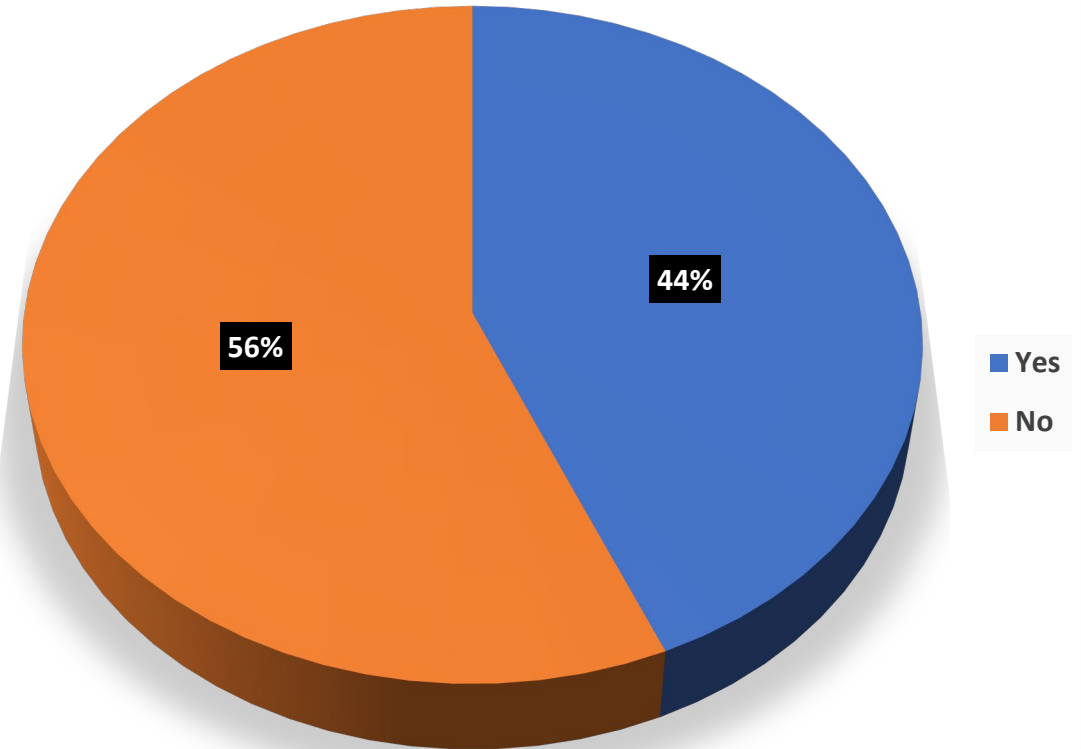




**Q: Do you feel that students, fellows, and other trainees in your lab/research group are better equipped to consider sex and/or gender in their research as a result of your SAGE supplement award?**



**Q: Do you feel that research in your field/discipline appropriately addresses sex and/or gender?**





## Q:How has obtaining a SAGE supplement award impacted your career path?



## Data Hidden in Plain Sight (FY 2016)



SPIE data analyses of FY 2016 identified a number of SPIE objectives that represented gaps in our portfolio. The 2017 ([PA-17-078](#)) and 2018 ([PA-18-658](#)) FOAs were modified accordingly.

In FY 2017, a new FOA ([PA-17-101](#)) was issued for SPIE 3.9 to target Under-studied, Under-represented and Under-reported (U3) women.

**So far, ORWH has funded 59 applicants and has invested >\$10 Million in U3 program**

**SPIE 3.9: Examine **health disparities** among women stemming from differences in such factors as race and ethnicity, socioeconomic status, gender identity, and urban-rural living, as they influence health, health behaviors, and access to screening and therapeutic interventions.**

# Sex As a Biological Variable Workshop, Oct 26-27, 2017, NIH



Keynote speaker: Dr. Virginia Miller

*Sex-specific risk for cardiovascular dysfunction and cognitive decline*



## Sessions:

- Sex Differences in Brain Function and Behavior
- How Sex Impacts Our Interactions with External Influences
- Sex Differences in Animal Models
- Sex Differences in Gene Expression
- Poster Session
- Panel Discussion on Applying SABV

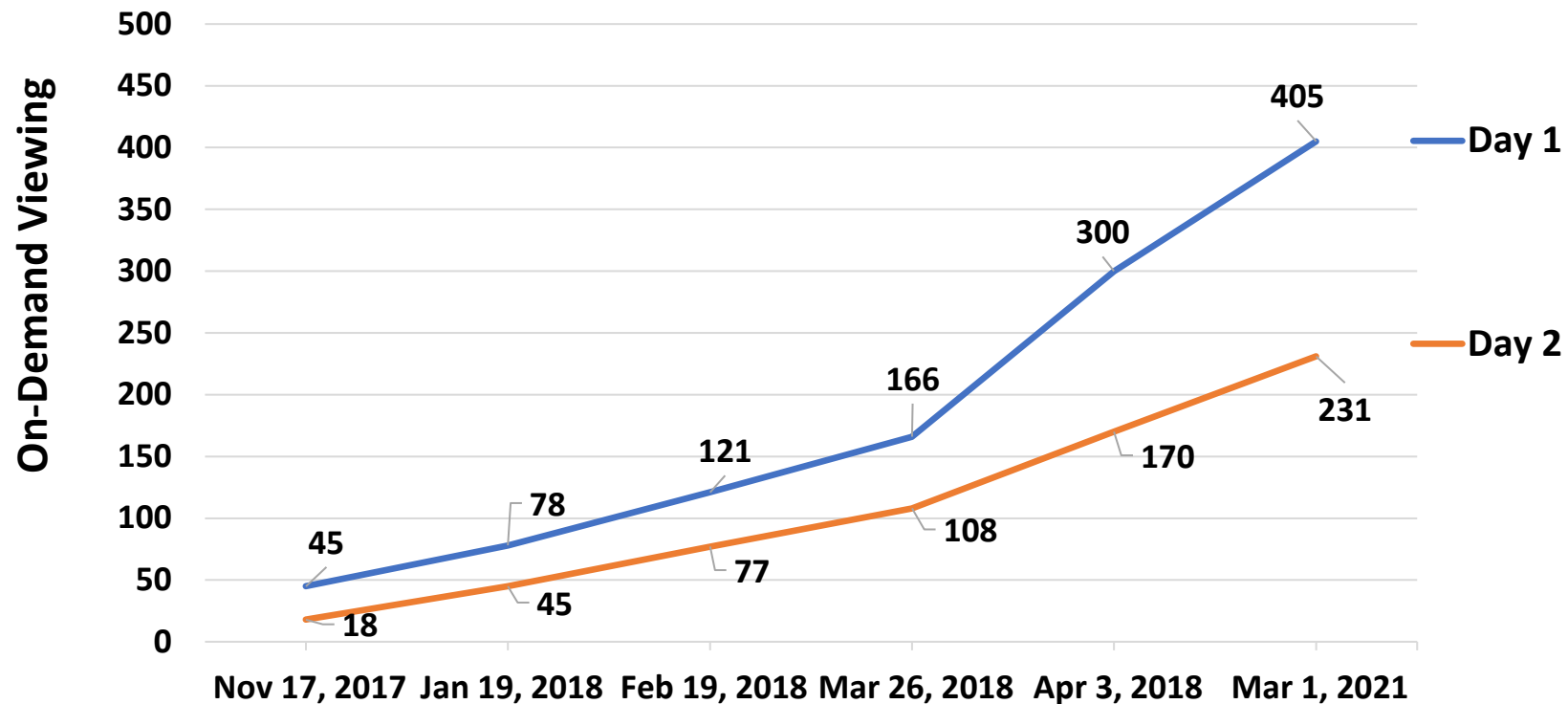
*SABV Workshop* was organized by ORWH and the Office Strategic Coordination (NIH Common Fund)

*Materials* (Agenda, Speaker Biographies, Oral Presentations, Poster Abstracts, and Participant list), **and videocast** of individual sessions are available online: <https://commonfund.nih.gov/sexdifferences/workshop>

# Stat - SABV Workshop



- Total Registered Guests – 206, and more than 150 guests attended the workshop in person
- Workshop had a live Videocast – **119 people (day 1)** and **53 people (day 2)** viewed in real-time
- Videocast is archived for on-demand viewing:
  - Day 1 (Thu. Oct. 26, 2017): <https://videocast.nih.gov/summary.asp?live=26050&bhcp=1>
  - Day 2 (Fri. Oct. 27, 2017): <https://videocast.nih.gov/summary.asp?live=26054&bhcp=1>







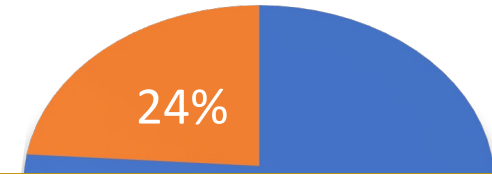
# Overall Summary

## Sex/Gender Administrative Supplement program

### ➤ Supported researchers to:

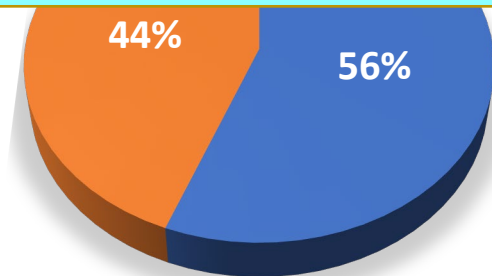
- ✓ Add the Opposite Sex/Gender

Q: Did your SAGE supplement award motivate you to seek additional funding related to sex and/or gender?



**Since the SAGE program has accomplished the intended objectives and beyond, there is an opportunity to address other gaps in the consideration of sex/gender in biomedical research.**

- ✓ 76% said their SAGE award motivated them to seek additional funding related to sex/gender
- ✓ ~60% submitted subsequent applications using data from the SAGE award



■ Yes  
■ No



# Research is needed to address Gaps related to Sex/Gender Influences on COVID-19 Pandemic

- ORWH published, [“Guiding Principles: Sex and gender influences in COVID-19 and the health of women”](#), which was developed in collaboration with CCRWH COVID-19 working group members.
  
- The Guiding Principles cover five major themes:
  - ✓ The Principles
  - ✓ SABV Policy Requirements and COVID-19
  - ✓ NIH Inclusion and COVID-19
  - ✓ COVID-19 and the Health of Women
  - ✓ Consequences of COVID-19 on the Biomedical Workforce

# Concept: COVID-19 and the Health of Women



- ❖ **A new Funding Opportunity Announcement (FOA) to support studies on the SARS-CoV-2 virus or COVID-19 disease in alignment with efforts across NIH to:**
  - **Develop and implement effective therapeutics and vaccines and**
  - **Accelerate research on technologies to validate and improve programs that will overcome barriers and increase uptake of effective therapeutics and vaccines at the point of care**
  
- ❖ **FOA research topics of interest could include, but are not limited to:**
  - **Sex and gender influences in the development and administration of effective therapeutics and vaccines**
  - **Investigations of sex and gender differences in access to care (e.g., admission, diagnosis, and treatment) of COVID-19 affected individuals**
  - **Investigation of sex and gender influences on the outcome of patient interactions with health care providers**
  - **The impact of sex and gender on mortality due to co-morbid conditions**



Thank you so much!

Any Comments or Feedback?