

# Addressing Researchers' Personal Financial & Institutional Conflicts of Interest

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## Presenters in order of presentation:

### Debra Thurley

Assist. V.P. for Research  
Penn State University



PennState

### Brian Smith

Chief Ethics & Compliance Officer  
Sr. Assoc. Vice Chancellor –  
Research Infrastructure & Operations  
University of California San Francisco



University of California  
San Francisco

### Stacy Pritt

Assoc. V.P. Research Support  
& Regulatory Mgmt.  
Assist. Professor  
UT Southwestern Medical Center

UTSouthwestern  
Medical Center

### Moderator:

**Kris West**, Director, Research Ethics & Compliance  
COGR

**COGR**

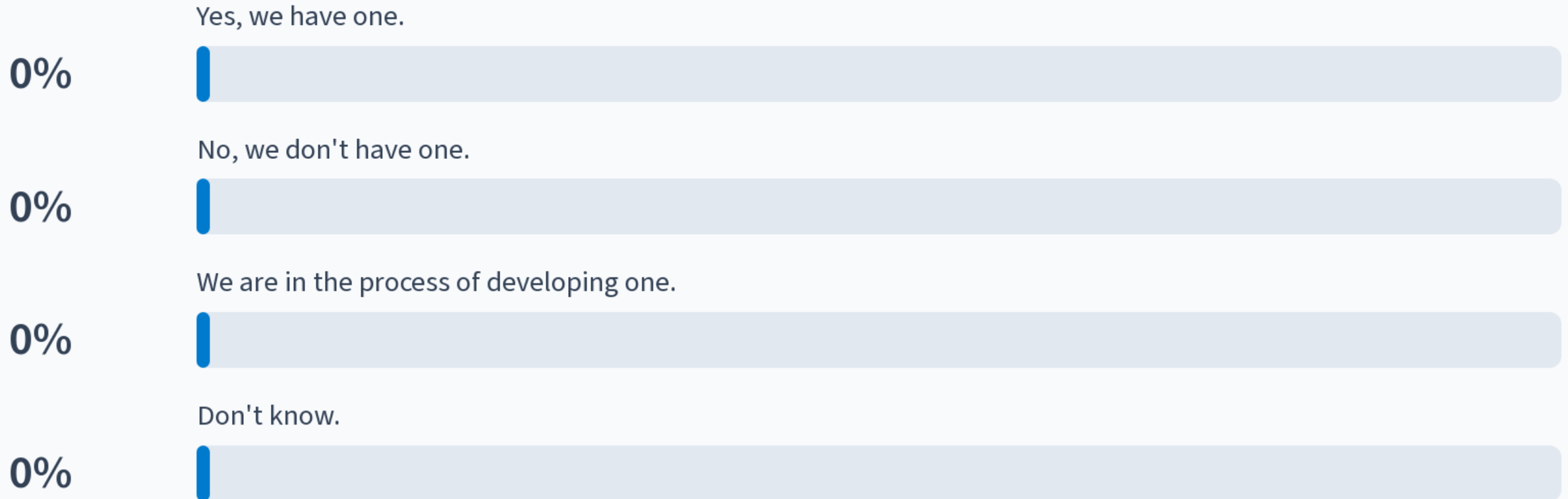
# Presentation Overview

- Overview of COGR's Recent Publication:
  - *Analyzing Personal Financial and Institutional Conflicts of Interest in Academic Research Contexts*
- Case Studies and Poll Questions
  - Questions and Answers during the discussion of each case study
- Get Poll Everywhere Ready!
- Slides posted [www.cogr.edu](http://www.cogr.edu)

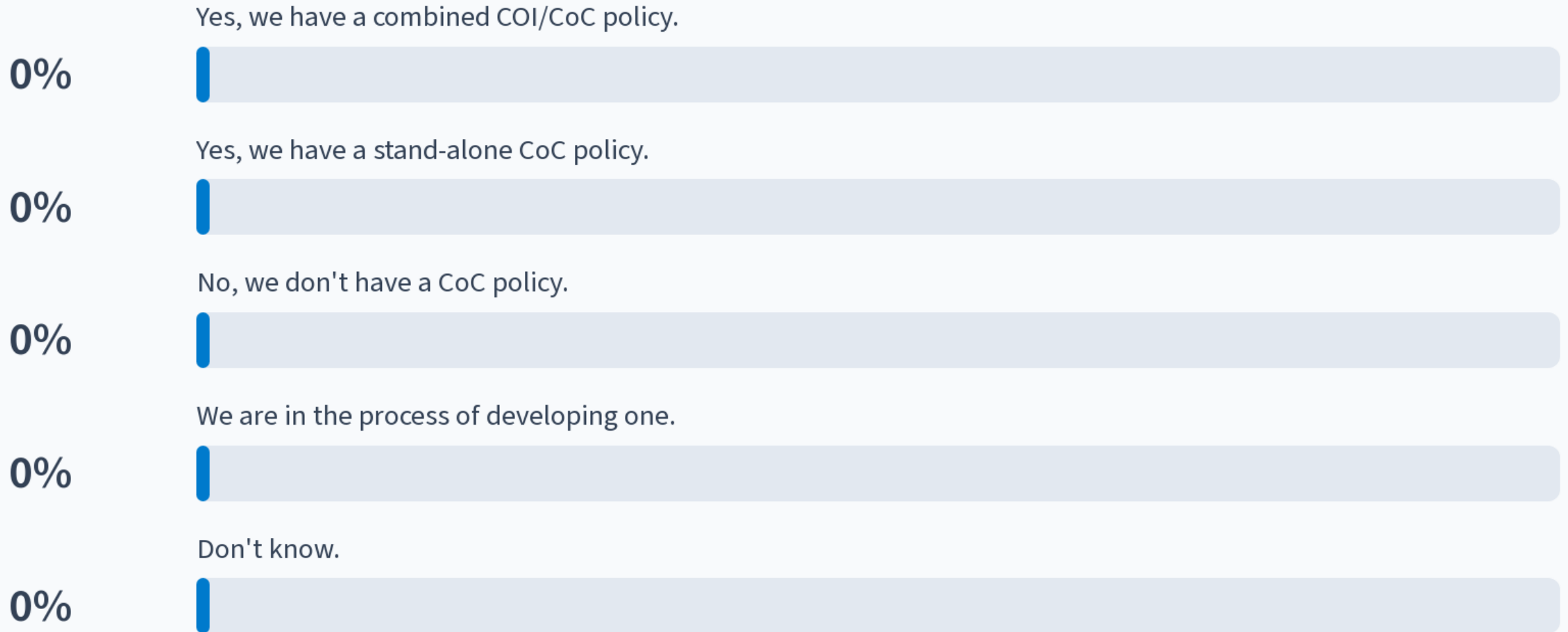
# Analyzing Personal Financial and Institutional Conflicts of Interest in Academic Research Contexts

- Overview of Types of COIs and Applicable Regulations
- COIs in the Context of Malign Foreign Influence
  - COIs vs. COCs
- Common Scenarios in which COIs Arise
  - Consulting
  - Licensing
  - Clinical Studies/Human Subjects Research
  - Mentoring
  - Procurement
- Case Study Scenarios

## Poll #1 Does your institution have an institutional COI Policy?



## Poll #2: Does your institution have a policy on conflicts of commitment (CoC)?



# On the Horizon

## Continued Fallout from [GAO Report](#)

- Are COCs a type of COI?
- Will new regulations take this approach?

## [NASA's Proposed COI & COC Policy](#)

- Different approach than that used by NSF or NIH

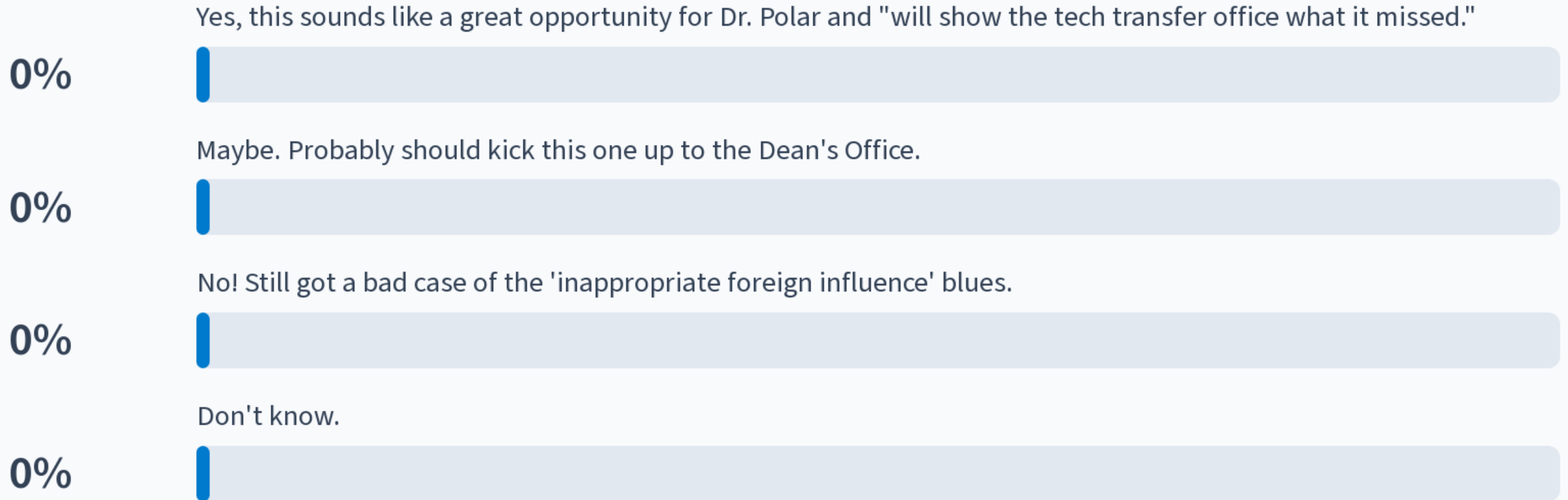
## Dept. of Energy Final COI/COC Policy

- Will it follow [interim policy](#) approach?

## *Case Study 1: The Case of the Summer Sabbatical*

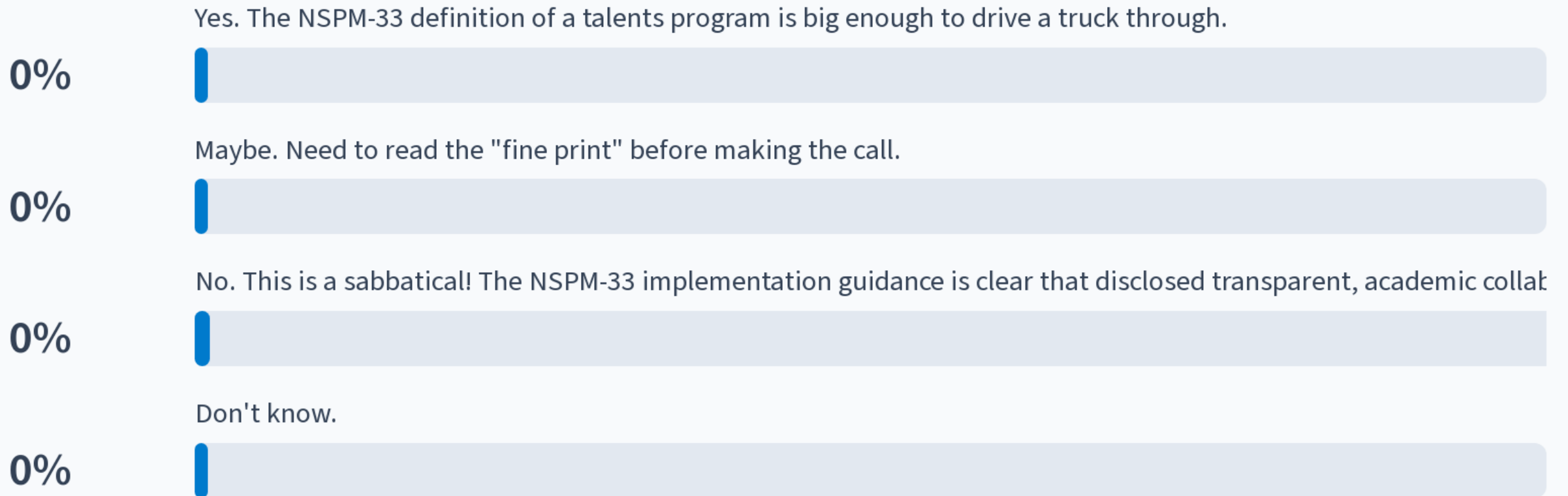
- Dr. Polar is a highly renowned NSF and NIH-funded researcher at State University. His research focuses on the use of AI to predict the risk of cardiovascular disease. Polar developed blood test and algorithm (“Invention”) to predict a patient’s one-year risk of having a coronary event. State U. reviewed the Invention and decided not to pursue a patent.
- Polar was contacted by Prestige University in Japan, which offered to host him for a summer sabbatical. Polar will not be compensated by Prestige, but he will have a lab where he can work and housing in the faculty housing complex. Polar will need to give lectures on his research and work with students in his lab. Prestige told Polar that they can help him patent the Invention in several Pacific rim countries and introduce him to companies in those countries that will be very interested in licensing the Invention. Prestige says it can also help him conduct any necessary clinical research.
- Polar knows that he is eligible for an unpaid sabbatical at State University and approaches his Chair about this “great opportunity.”

### Poll #3: Should the Chair approve this sabbatical?

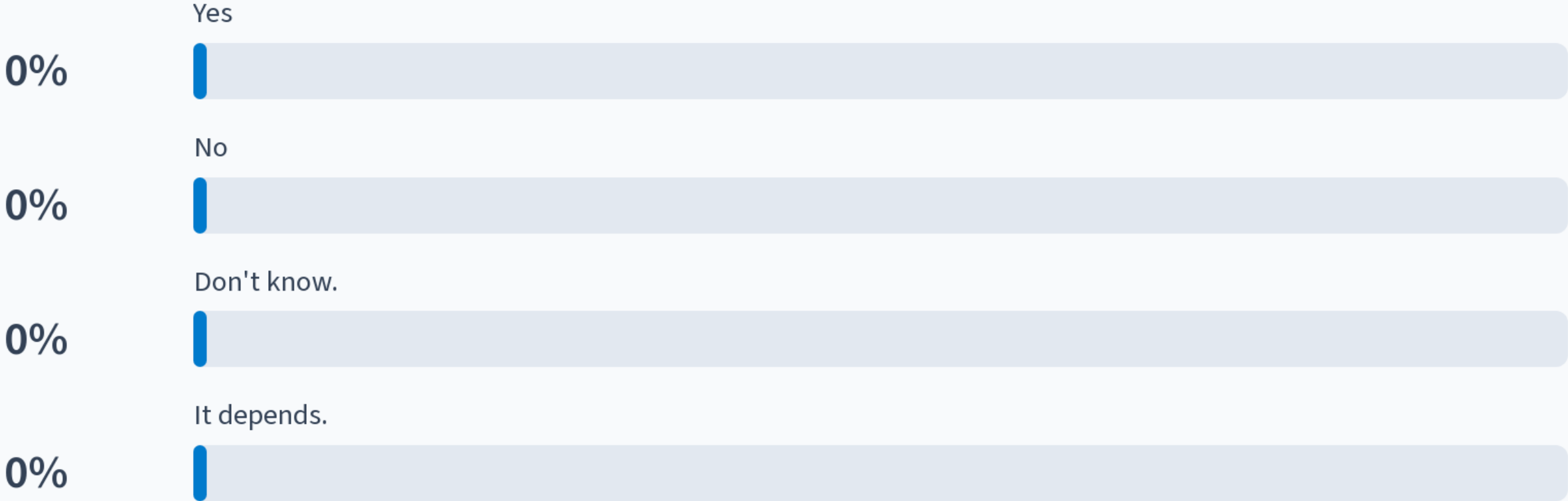




## Poll #4: Do you think that this sabbatical could be considered a "foreign talents program"?



# Poll #5 Does your institution require faculty members to provide for review a written agreement with the institution hosting their sabbatical?



## Key Issues & Questions

- Should Polar be able to conduct research on the Invention at Prestige?
- Should State U. have any role in reviewing COI issues concerning that research?
- What if Polar was licensing the Invention through his own start-up company?
- Should institutions have COI or inappropriate foreign influence “reviews” of sabbatical opportunities?

# Q & A

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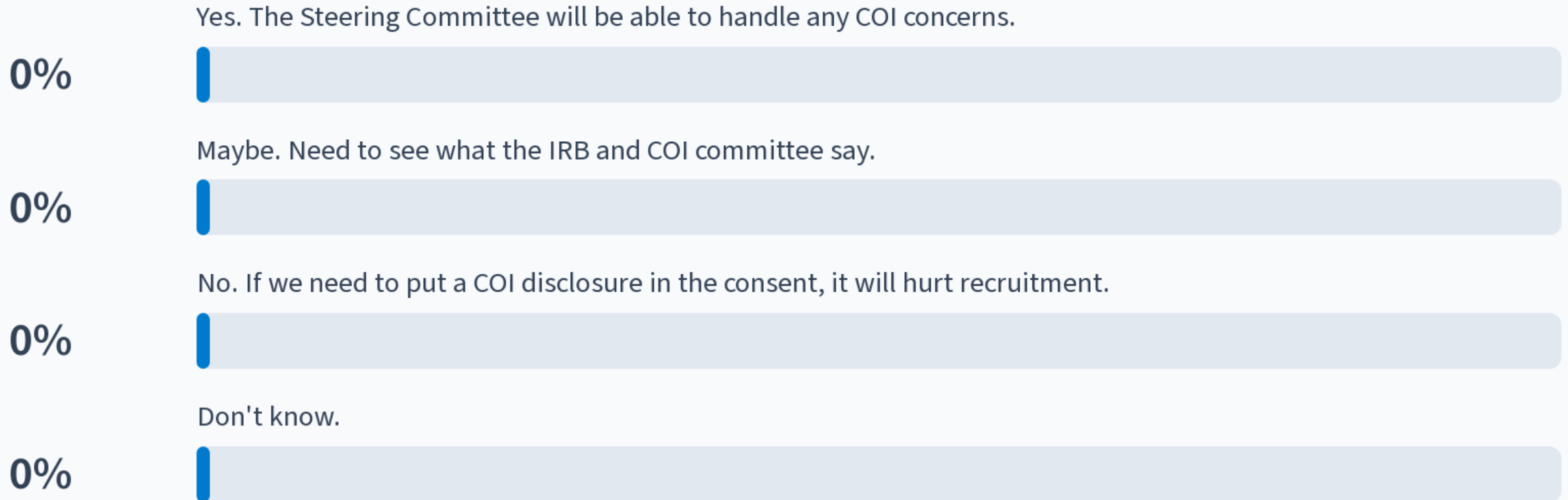
## Key Points

- **Consider how university policies & federal funding agency requirements may apply to sabbaticals.**
- **A PI's agreement can create university problems!**
- **Malign Foreign Talent Recruitment Programs can take many forms.**
- **Remember funding agency current & pending/other support disclosure requirements apply to in-kind contributions.**

## *Case Study 2: The Case of the Blockbuster Drug*

- Dr. Evian is a successful physician researcher at Top Scholar University's School of Medicine, and she also serves as the Top Scholar's Vice President of Research. She developed a new drug therapy for Alzheimer's (Allay) that Top Scholar patented and licensed to NeuroBioMed (NBM), an emerging biotechnology company focused on dementia-related treatments.
- As part of the licensing agreement, Top Scholar received a 5% equity stake in NBM, as well as the promise of two milestone payments – one when Allay is approved as a new drug in the United States and the other when Allay's U.S. sales total more than \$100 M. Dr. Evian receives personal licensing fees based on revenue from Allay, in perpetuity.
- Initial clinical trials were very successful, and NBM will now conduct a multi-site Phase 3 clinical trial that enrolls thousands of Alzheimer's patients across the US at major academic medical centers. NBM is managing the clinical trial. Dr. Evian will have a compensated position on NBM's Clinical Trial Steering Committee, and she will also be the site PI at Top Scholar.

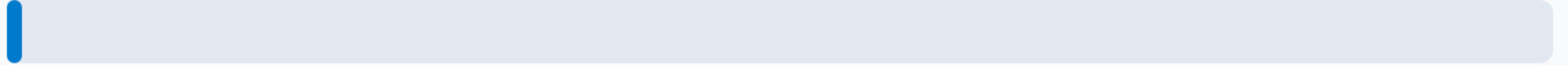
## Poll #6: Should Top Scholar serve as a site for the clinical trial?



## Poll #7: Should Dr. Evian serve on the Steering Committee for the trial?

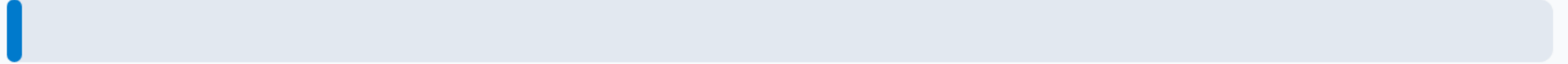
Yes. His expertise regarding the drug is essential for the Committee's functioning.

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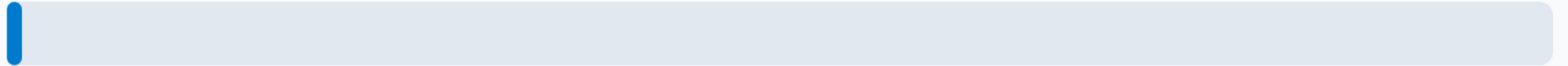
Maybe. Need to see what role the Steering Committee will play.

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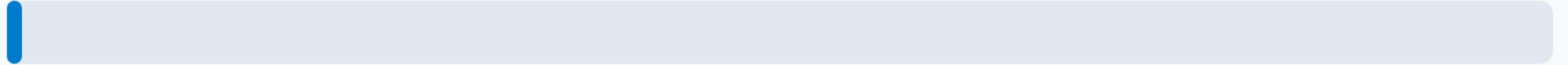
No. Even the appearance of a COI should be avoided.

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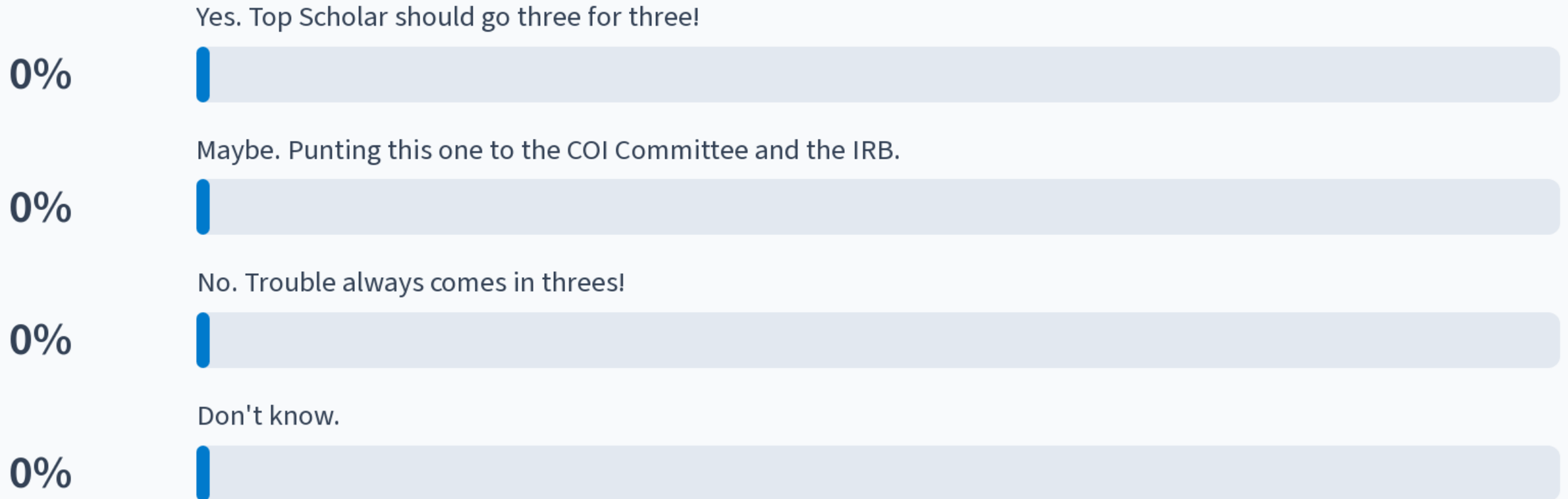
Don't know.

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## Poll #8 Should Dr. Evian serve as the site PI for the trial?



## Key Issues & Questions

- What are the potential institutional COI issues in this scenario?
- Would the assessment change if:
  - Top Scholar received licensing income instead of equity in NBM?
  - Allay was a treatment for a rare disease and Top Scholar had a sizable patient population because of Dr. Evian's expertise?
- What if NBM asks Top Scholar to appoint a university representative to sit on NBM's Board? With compensation?
- What if NBM announces it is going public?

# Q & A

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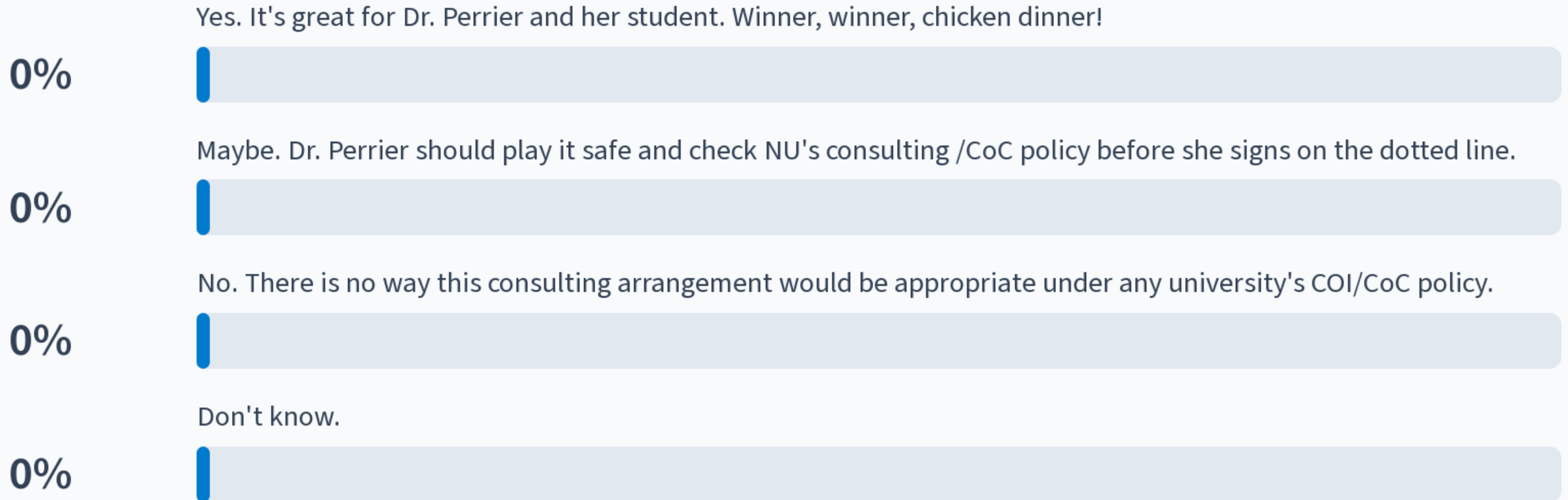
## Key Points

- COIs in the context of clinical trial require particular scrutiny because of concerns re. human subjects
- Institutions must carefully consider the conduct of trials at sites with interests in the test article/company.
- Consider policies regarding board membership by university officials.

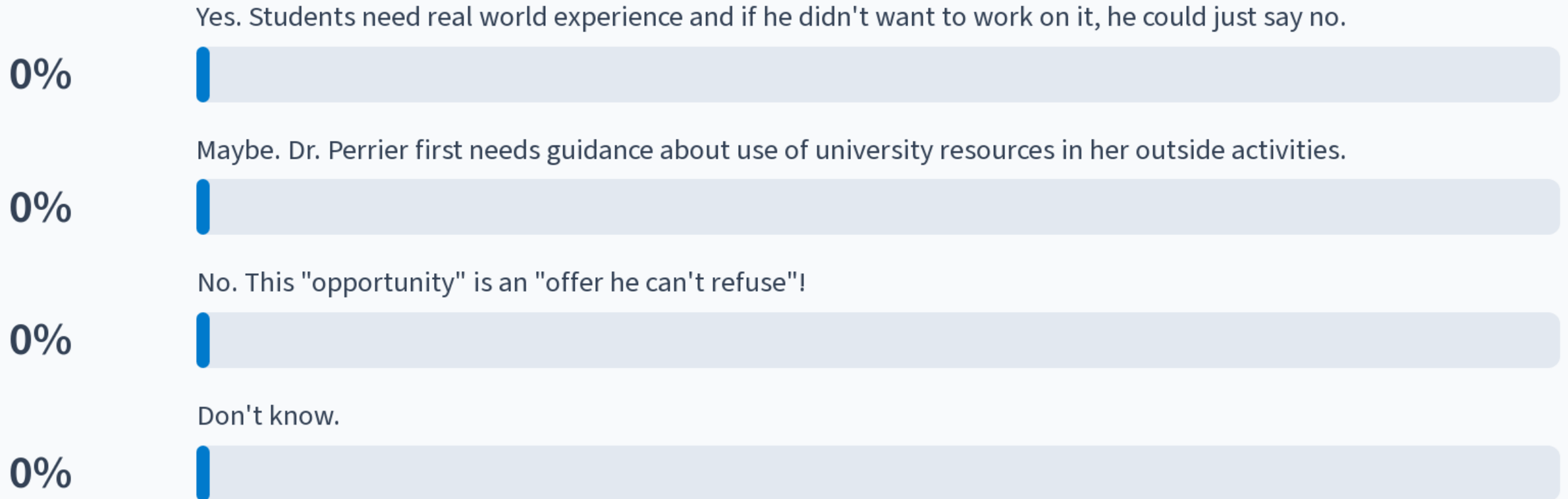
## *Case Study 3: The Case of the Mucky Mollusks*

- Dr. Jane Perrier is an assistant professor in the biology department at Nature University (“NU”). She has a promising research program funded by NSF to study adhesins, the molecules that help mollusks attach to surfaces. Red Water and Power (“RWP”) is a major electricity supplier to the five-state area that includes NU. RWP has a research program to study ways to eliminate zebra mussels infestations that clog water pipes at hydro-electric plants. RWP presents Dr. Perrier with a consulting agreement for her to advise RWP’s research team on zebra mussels project.
- The consulting agreement is with Dr. Perrier in her University capacity and has the following terms:
  - Generous compensation for Dr. Perrier
  - Confidentiality/non-disclosure provisions
  - Provision that any patentable inventions in Dr. Perrier’s field of expertise in adhesins will be owned by RWP
  - Commits Dr. Perrier to work with RWP team 10 days/month for next two years
- Dr. Perrier asks her graduate student to help her conduct some of the experiments in her NU lab on evenings and weekends because the student needs some real work experience to put on his CV.
- RWP decides to make a gift to NU for the benefit of Dr. Perrier’s adhesins research. Dr. Perrier thinks NU should let her decide how the gift will be used. She wants to use it to buy new equipment that she can be use for both her NSF funded work and her RWP weekend and evening consulting work.

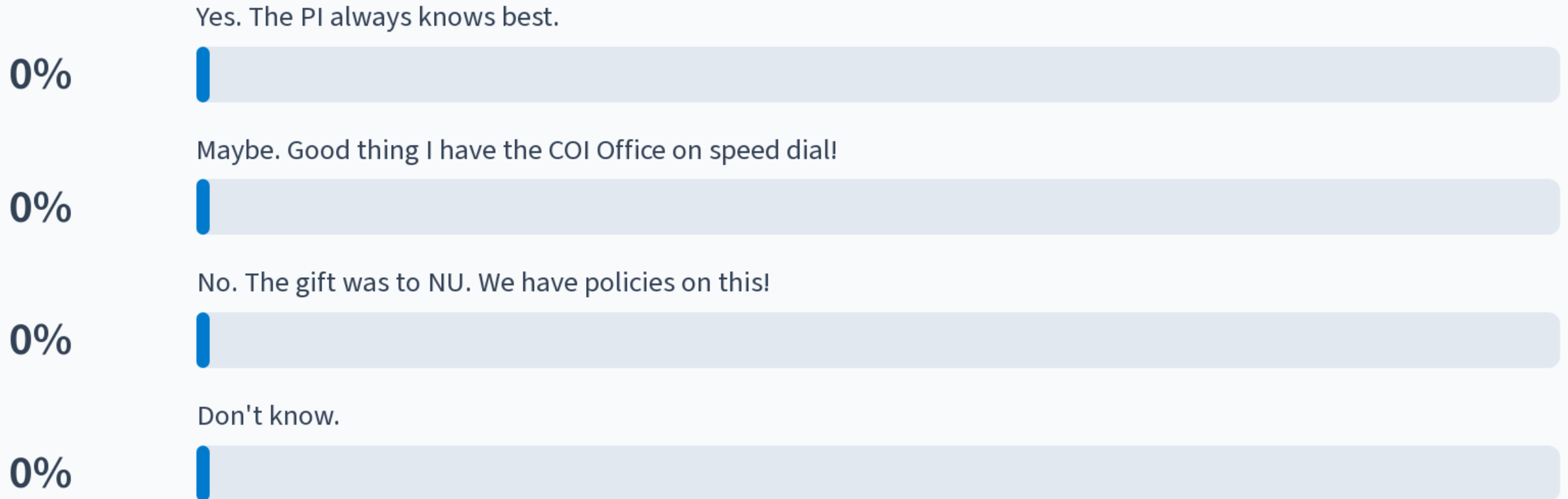
## Poll #9 Should Dr. Perrier have signed the Consulting Agreement?



## Poll #10: Should Dr. Perrier's graduate student be allowed to participate in her consulting work?



## Poll #11 Would your institution allow Dr. Perrier to determine how the gift should be used?





## Key Issues & Questions

- Would Dr. Perrier have been able to sign this consulting agreement under your institution's consulting/conflict of commitment policy? Would your institution review the agreement?
- What are the any potential individual COI issues in this scenario?
- Are there any conflict of commitment concerns you see in this scenario?
- What to do about that gift?!?!?
- What are some potential management strategies?

# Q & A

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## Key Points

- **Provide investigators with guidance on consulting agreement provisions that violate university policies or raise concerns under funding agency requirements, particularly if institutional review of such agreements is not required.**
- **Set clear expectations regarding use of university resources (equipment, lab space, graduate student time and efforts) for outside commitments.**
- **Beware of “gifts” that are *not* actually gifts.**



**Consider malign foreign influence  
when analyzing COI and COC situations**

**Keep COI and COC policies up-to-date**

**Develop processes for promoting  
consistency in decisions**

# Final Q & A

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# COGR Point of Contact

**Kris West, Director, Research Ethics & Compliance  
Research Ethics & Compliance Committee (REC)  
[kwest@cogr.edu](mailto:kwest@cogr.edu)**



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# Thank You

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