NIH's Guide Notice NOT-OD-21-073: Institutional Perspective

June 8, 2021

Moderator:

Kristin West, Director, Research Ethics & Compliance, COGR



Panelists (in order of presentation):

Naomi Schrag, Vice President of Research Compliance, Training and Policy, Columbia University



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Grace Fisher-Adams, Chief Research Compliance Officer, California Institute of Technology



Presentation Overview

- NIH <u>NOT-OD-21-073</u>, Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components
 - New Biosketch and Other Support format pages
 - Effective Date: May 25, 2020
 - NIH NOT-OD-21-110: New formats are not mandatory until January 25, 2022
- Presentation Focus Areas Considerations & Tools
- Summary of Requirements
- Positively promoting international collaborations in the current environment
- Consulting
- Clinical Trials
- Valuation
- Gifts
- Coordinating information from different units; controls
- Collaborations
- Training & Communication





Ironing Things Out

- Many institutions still working on policies and practices.
- Like other requirements, a certain degree of interpretation and institutional decisionmaking is required for implementation.
- One shot at training!

Positively Promoting International Collaborations

How to foster this:



When headlines look like this:

The New York Times

A Scientist Is Arrested, and Academics Push Back

times.com/2021/01/26/us/mit-scientist-charges.html



U.S. doubles down on protecting university research from China
https://www.reuters.com/world/china/us-doubles-down-protecting-university-research-china-2021-03-01/



Russia tried to hack coronavirus vaccine research, US, UK and Canada say

https://abcnews.go.com/International/us-uk-canada-claim-russia-hack-coronavirus-vaccine/story?id=71818654



Consulting

Requirement: Sr./Key Personnel must report consulting agreements as "Other Support" if they are "conducting research" as part of the consulting activities.

- Treatment of consulting activities that fall within institution's consulting guidelines (i.e., "one day a week").
- Pros and cons of reviewing consulting agreements.
 - Institutional review raises complex issues
 - Is it possible to train faculty to review them and certify they meet institutional standards? Does this approach decrease or increase potential for institutional liability?

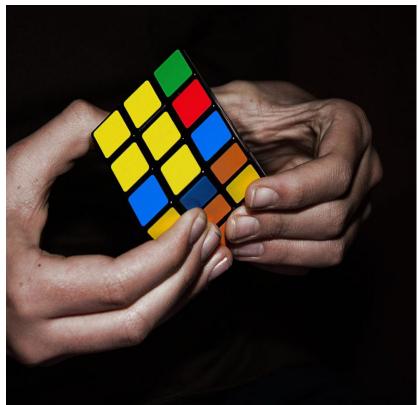


Consulting: The "Effort Conundrum"

- Under the Uniform Guidance, "effort" is based on Institutional Base Salary (IBS), which does not include external activities by definition and is not based on a particular number of hours per week or other metric. (see COGR's <u>Principles for Evaluating Conflict of Commitment Concerns in Academic Research</u> at 21)
- Uniform Guidance also provides that outside professional activity must be conducted in accordance with institutional policies (Sec. 200.430(c))
- Other Support instructions ask for "actual effort" on consulting that involves the conduct of research, in calendar months.



Consulting: The Effort Conundrum



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- Where the consulting engagement does not include an effort commitment in calendar months, is it possible to disclose an estimated number of days per year spent on the activity?
- "This project is professional activity outside of my institution, as defined in the Uniform Guidance, 2 CFR § 200.430(c), and carried out in accordance with institutional policy on outside activities. I spend approximately _____ days per quarter/year on this outside activity."



Clinical Trials: Effort and In-Kind Contributions

- Are industrysponsored clinical trials part of "research endeavors" or "clinical activities"?
- What about investigator-initiated clinical trials?
 - How should donated investigational items (drugs, devices) be treated?





Valuation

Requirements:

- In-Kind Other Support includes provision of "high-value" materials that are "not freely available" (e.g., biologics, chemicals, model systems, technology, etc.)
- Time commitment or dollar value of in-kind contributions (or reasonable estimate thereof) must be provided.

- Definition of "high-value."
- How to value items on which no value can be placed, e.g., human specimens?
- Who will determine values?



Gifts

<u>Requirements</u>: Reporting is not required for training awards, prizes or gifts (i.e., resources provided where there is no expectation of anything, e.g., time services, specific research activities, money, etc. in return).

- Gift v. grants policies.
- Coordination with institutional advancement/development offices.



Inter-Unit Coordination & Controls

<u>Requirements:</u> Institutions must "establish and maintain effective controls (e.g., policies and procedures)" to ensure Sr./Key Personnel fully disclose Other Support to institution as soon as it becomes known.

The Situation "On-the-Ground":

- Information is housed in different units.
- Units may have different IT systems that don't communicate.
- All institutions may not have university electronic signature systems.

- How to ensure consistency and alignment of information?
- How to promote cross-communications between units and systems?
- Testing? Validation?



Informing Researchers What to Report

 Penn State University Questionnaire on Other Support & Foreign Component Disclosures



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NIH Questionnaire for PSU Faculty (Other Support Forms and Foreign Component Disclosures):

NIH issued an important notice effective May 25, 2021 (NOT-OD-21-073), updating their expectations for disclosure of Other Support. In addition to disclosing all research activity administered through Penn State, Senior/Key Personnel are also expected to disclose all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at Penn State or received external to Penn State. NIH interprets Other Support to include the following:

Paid or unpaid appointment(s) at another institution. Please include all research collaboration(s) at another institution that directly benefit the investigator's research endeavors. Please also include any start-up funds provided by institutions other than PSU (amount currently available).
Financial support , including, but not limited to, selection to a foreign "talents" or similar-type program, or other foreign or domestic support. This includes research performed outside of a faculty member's appointment (e.g., a faculty member with a 9-month appointment at Penn State and a two-month appointment at another institution performed during the summer).
Financial support for laboratory personnel. Please include employees, post-docs, students, and visiting scholars who are paid a salary by their government or home institution. "If the time commitment or dollar value of the in-kind contribution is not readily ascertainable, the recipien must provide reasonable estimates."
In-kind contributions , e.g., office/laboratory space, equipment, supplies, and other "high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.)."
Outside Activities such as consulting where the researcher will be conducting research as part of the consulting activities. Private equity financing (e.g., in support of the SBIR/STTR program) and honoraria in support of an individual's research endeavors must be included.
Endowment(s), other PSU Unit/Department support, and retention funds provided in support of an investigator's research (amount currently available).
PSU Seed/internal grant (amount currently available).

Collaborations

Requirements: Report as Other Support collaborations with other scientists that directly benefit the reporter's research.

Considerations:

- Thresholds?
- Are all co-authors collaborators?

Tools:

 Caltech chart on collaborations: <u>https://researchcompliance.caltech.edu/documents/19335/Col</u> laboration Spectrum General-NIH ONLY FINAL.pdf



Collaboration Spectrum

No Need to Report

DOMESTIC OR FOREIGN

COLLABORATOR

General No shared resources (materials, Co-authorship/Acknowledgement (see NIH: Significant element of a project below); shared resources, financial or inperformed outside the US: experiments, facilities, equipment, or personnel), no Indicators direct or measurable benefit to my kind, including unique or high-value human or animal research, extensive data materials, facilities, equipment, or research, no collaborative analysis personnel; resources that benefit my experiments

research; collaborative experiments.

DOMESTIC OR FOREIGN

Report Support

Report Support OR

Consider Foreign Component

FOREIGN

Collaboration Spectrum

No Need to Report Support Report Support CR Consider Foreign Component

General	No shared resources (materials,	Co-authorship/Acknowledgement (see	NIH: Significant element of a project
Indicators	facilities, equipment, or personnel), no	below); shared resources, financial or in-	performed outside the US: experiments,
	direct or measurable benefit to my	kind, including unique or high-value	human or animal research, extensive data
	research, no collaborative	materials, facilities, equipment, or	analysis
	experiments	personnel; resources that benefit my	
		research; collaborative experiments.	
COLLABORATOR	DOMESTIC OR FOREIGN	DOMESTIC OR FOREIGN	FOREIGN
General	1. I had discussions with colleagues at a		
Scientific	Conference		
Discussions	Open discussions about research on		
Discussions	Zoom/phone call		
	3. I gave a research talk or seminar at		
	another university		
Sharing	I received data, materials, reagents, etc.	1. I received data, materials, reagents, results,	Unique materials, reagents, biological lines,
Resources	from my collaborator that <u>never</u> led to	etc. from the collaborator that	etc. were created in a collaborator's foreign
	publishable results or an	 benefits/benefited my research 	lab and provided to me for work on a
	acknowledgment or authorship in a	 led to a publication where I gave co- 	federally funded project
	publication	authorship or acknowledgment to the	Experiments were performed in a
	I received materials from my	collaborator	collaborator's foreign lab, and data or
	collaborator that were <u>not</u> "unique" or of	2. My collaborator visited my lab to perform	results were provided to me in support of a
	high value.	experiments	federally funded project
		3. My collaborator sponsors a postdoc or	Human or animal subject studies were
		graduate student in my lab	performed at a collaborator's foreign
			institution in support of a federally funded
1			project

Publishing/ Presenting Together	Dr. X is a co-author on a paper with me or is acknowledged on a paper where I am an author; HOWEVER: I have never had a direct scientific exchange with Dr. X, and Dr. X's contribution to the paper did not overlap with my research reported in the paper (e.g., we didn't design or perform experiments, Dr. X didn't contribute to the data analysis of my data), and Dr. X's contribution to the paper did not benefit my research reported in the paper (See publication example, below)	Dr. X is a co-author on a paper with me or is acknowledged on a paper where I am an author; AND Dr. X performed experiments in my lab, or Dr. X's contribution to the paper directly benefited my lab's research that is reported in the paper, or Dr. X contributed a key resource to my lab's research reported in the paper, or Dr. X performed extensive data analysis on my lab's research reported in the paper.	Dr. X is a co-author on a paper with me or is acknowledged on a paper where I am an author; the paper reports research sponsored by a federal sponsor, AND Dr. X performed experiments in her foreign lab Dr. X's contribution to the paper directly benefited my lab's research that is reported in the paper Dr. X contributed a key resource to my lab's research reported in the paper Dr. X performed extensive data analysis on my lab's research reported in the paper
Working together on my research project where my collaborator is outside the US	1. Dr. Yis my former postdoc. He was not funded by any outside entity while at the University. We finished all experiments on a paper, wrote the paper, and submitted it before Dr. Y left to set up his lab outside the US. The paper was accepted with only minor edits. Dr. Y helped me finish those edits while outside the US. 2. Dr. Z is a long-time colleague who is a professor outside of the US. We have monthly discussions about our research. I am a theorist, and Dr. Z is an experimentalist. We have not started or designed any experiments together.	Dr. Y is my former postdoc who left the University 2 years ago to set up a lab outside the US. I will publish a paper that includes experiments conducted by Dr. Y when he was at The University. Dr. Y will not perform other experiments outside the US but will help with some data analysis and writing the paper. The federal funding used to support Dr. Y when he was in the lab is still ongoing. Dr. Z is a long-time colleague who is a professor outside of the US. We have monthly discussions about our research. I am a theorist, and Dr. Z is an experimentalist. Dr. Z sends a postdoc to my lab at the university to run the experiments. No experiments will be run outside the US.	1. Dr. Y is my former postdoc who left The University a year ago to set up a lab outside the US. 1 will publish two papers with him, which include experiments conducted by Dr. Y when he was at the University. For the first, all of the initial experiments were conducted at The University, but the manuscript reviewers requested another experiment. Dr. Y will conduct the experiment in his lab. For the second, all of the experiments were conducted in the lab, but the manuscript reviewers have requested significant revisions to the paper, including extensive new data analysis. Dr. Y will perform the data analysis and edit the manuscript in the foreign country. The federal funding used to support Dr. Y when he was in the lab is still ongoing. Dr. Z is a long-time colleague who is a professor outside of the US. We have monthly discussions about our research. I am a theorist, and Dr. Z is an experimentalist. Dr. Z offers to set up and perform experiments in his lab in a foreign country.

Training and Communication

- Training for research administrators and faculty
- Keeping up with constantly changing requirements
- The advantage of training NDAA FY 2021



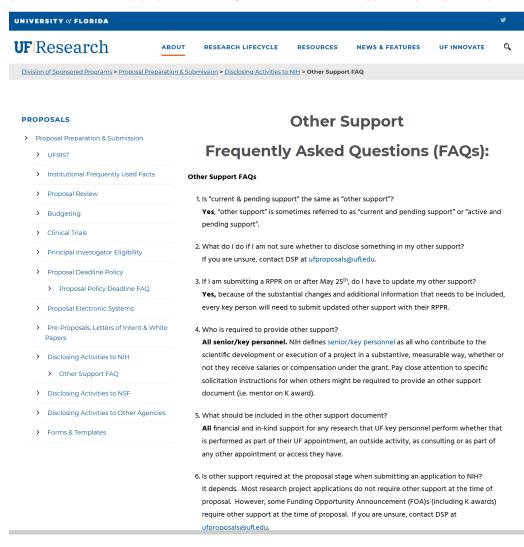
Tools that Summarize Notice's Requirements

- University of Florida Table re. Where to Report Items Other Support, Facilities
 & Resources, Budget
 - https://research.ufl.edu/dsp/proposals/disclosing-activities-to-nih/other-support-frequently-asked-questions.html
- University of Michigan Table re. Requirement Effective Dates
 - https://orsp.umich.edu/sites/default/files/implementation of not od 21 0
 73 changes to biosketch and other support.pdf
- Caltech website
 - https://researchcompliance.caltech.edu/international collaboration/federal-agency-requirements/nih compliance



UF Resources

https://research.ufl.edu/dsp/proposals/disclosing-activities-to-nih/other-support-frequently-asked-questions.html



Person, Equipment, Samples, Materials, etc.	Facilities & Resources	Other Support	Budget
Access to but not needed on this project		Χ	
Used on this project but not charged to this project	X		
Access to Core facilities or shared equipment	Χ		
Budgeted to charge to this project			Χ

UF webpage on Disclosing Activities to NIH

NIH webpage on Other Support

NIH FAQs



U. Michigan Resources

https://orsp.umich.edu/sites/default/files/implementation of not od 21 073 changes to biosketch and other support.pdf

Implementation of NOT-OD- 21-073 Changes to Biosketch and Other Support (as of May 18, 2021)				
Biosketch Changes	Effective May 25, 2021	Effective Jan. 25, 2022		
Use SciENcv to generate Biosketch	Not required but available for use	Not required (for now?)		
Follow format and provide requested information per NIH guidance in effect prior to release of NOT-OD-21-073	Required	Not allowed		
Follow new format and provide requested information per NIH guidance in NOT-OD-21-073	Not required but templates available	Required		
Add scientific appointments, paid and unpaid	Required	Required		
List positions, appointments, honors in reverse chronological order	Required	Required		
Highlight research projects within last 3 years in Section A. Personal Statement	Not required	Not required		
D. Research Support "removed"	N/A	N/A		
Other Support Changes	Effective May 25, 2021	Effective Jan. 25, 2022		
Disclose all sources of Other Support and related information, including outside activities (e.g. consulting, visiting professorships) if conducting research, In-Kind support, and gifts if donor expects anything in return (e.g. time, services, research).	Required	Required		
Use SciENcv to generate Other Support	Not required (optional when available this fall)	Not required (for now?)		
Follow new format	Not required (templates available)	Required		
Separate sections for Project/Proposal Support and In-Kind	Not required	Required		
Completed Support for the last 3 years	Not required	Required		
Submit copies of agreements for investigator's foreign appointment/ employment if listed as Other Support (translated and redacted as necessary)	Not required	Required		
When requested, submit copies of agreements for investigator's foreign appointment/ employment if listed as Other Support (translated and redacted as necessary)	Required	Required		
Each senior/key person electronically signs PDF of their Other Support	Not required	Required		
If Other Support signed, flatten PDF prior to submission	Required	Required		
Submit updated Other Support immediately upon learning a source of Other Support for an active NIH grant was not disclosed	Required	Required		



Caltech Website:

https://researchcompliance.caltech.edu/international_collaboration/federal-agency-requirements/nih_compliance

- Caltech Guidance for investigators by agency
- Tools to aid investigators in deciding what, when and where to disclose
- Recent Notices
- Training and FAQ



Research Compliance

Committe

Compliance

International Collaboration

Data & Facilities

Additional Resources COVID-19 and Research Q

Research Compliance / International Collaboration / Transparency in Research: Federal Agency Disclosure Requirements / NIH Compliance

NIH Compliance

INTERNATIONAL COLLABORATION

Who Can Help

Transparency in Research: Federal Agency Disclosure Requirements

NIH Compliance

DOD Compliance
DOE Compliance

NASA Compliance
Frequently Asked Questions

Contact Us:

Office of Research Compliance

PDF of NIH Checklist >

PDF of NIH RPPR Checklist >

UPDATED JUNE 6, 2021

Complying with National Institutes of Health Policy

May 17, 2021: Pls have asked for more guidance on reporting research collaborators as NIH
Other Support. Please review the Caltech guidance on when to report to the NIH, which includes
several examples

May 11, 2021: In response to concerns raised by the academic community, NIH is deferring implementation of its new Other Support and Biosketch formats and the other new requirements imposed in Notice NOT-OD-21-073 which was issued on March 12. The changes will now go into effect on January 25, 2022 instead of May 25, 2021.

You still must disclose **all** Other Support as described in that Notice and in Notice NOT-OD-19-114 in your just-in-time submissions and RPPRs. And you should contact OGC if you have any previously undisclosed other support.

For more details, please see the memo regarding the Update on NIH Requirements from the Vice Provost.

April 28, 2021: NIH issued a follow-up Notice: NOT-OD-21-110 regarding the May 25th deadline for reporting Other Support and biographical information on the Biosketch.

March 12, 2021: NIH issued Notice No. NOT-OD-21-073, which announced updated application forms and instructions intended to further promote transparency and full disclosure of all resources (both domestic and foreign) that directly support the individual's research endeavors. All proposal applications and Just-In-Time requests either submitted or with due dates on or after May 25, 2021, must comply with these new requirements.

Please review Notice No. NOT-OD-21-073, along with NIH's revised Biosketch Instructions and FAQs and Other Support Instructions and FAQs.

The information below is intended to guide users to complete the NIH Other Support, Biosketches, and Foreign Component information.

Grant Applications

Just-In-Time Submissions

Progress Report

Agency Communications

Complying with NIH Policy when Completing Grant Applications

Other Support, Biosketches and Facilities, Equipment and Other Resources

Other Support and Biosketches must be provided for all senior/key personnel and faculty associates. The term "senior/key personnel" includes:

(Co)Principal Investigator(s) - the individual(s) designated by the grantee and approved by NIH who will be responsible for the project's scientific or technical direction. If more than one, the first one listed will have primary responsibility for the project and the submission of reports.



Frequently Asked Questions

INTERNATIONAL COLLABORATION

Who Can Help

Transparency in Research: Federal
Agency Disclosure Requirements

Frequently Asked Questions

UPDATED APRIL 15, 2021

Below are answers to frequently asked questions. These will be added to as questions are submitted. If you have any other questions, please contact caltechcoi@caltech.edu.



Disclosure Foreign Engagements and Research Activities



Biosketch Information

Federal Agency FAQs related to foreign components:











DOE FAQs on Foreign Government Sponsored Activities

Additional Tools

Disclosure Tools for collecting Other Support and Biosketch Information

- Leveraging existing COI systems: Caltech
- Novel systems: Stanford External Activities Questionnaire
 - https://ora.stanford.edu/sites/g/files/sbiybj10141/f/sample_eaq.pdf

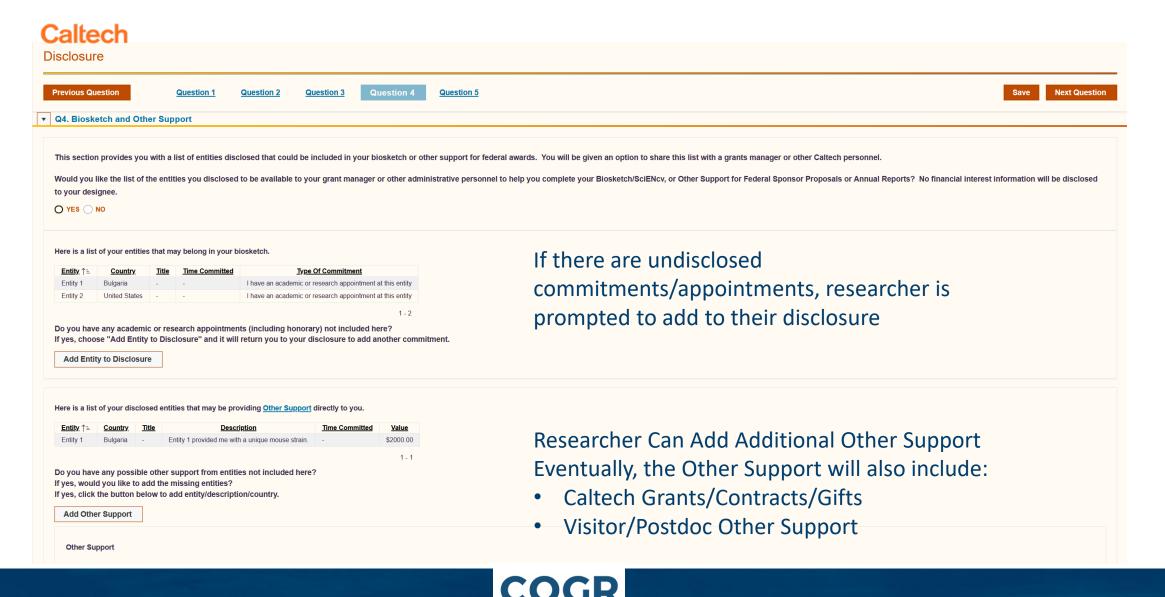


Caltech's Biosketch/Other Support Question

- COI/COC system redesigned to collect information regarding commitments and financial interests on an entity by entity basis
- All commitments disclosed will populate a page that can be shared with grant management personnel (Biosketch Information)
- For each entity, PI's are asked if the entity provided other support (financial or in-kind). If yes, the information will populate a page that can be shared with grant management personnel (Other Support)



Caltech Biosketch/Other Support:

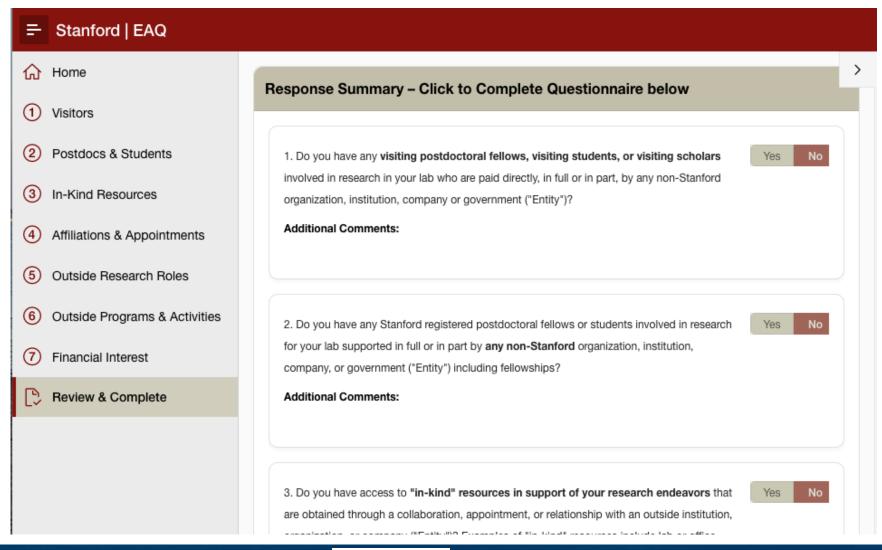


Stanford's External Activities Questionnaire (EAQ)

- 7 general questions designed to guide researchers to report details about their outside activities to meet new federal disclosure requirements
- all resources available for their research, no matter who is providing those resources (e.g., awards to perform research outside of Stanford)
- all appointments and affiliations with entities other than Stanford
- all "in-kind" research support, such as support for visiting researchers, space, equipment, "high-value" research materials (e.g., certain data sets or other materials)
- Connecting the dots:
 - Names (only) of outside entities from COI system are listed in the EAQ
 - Certain responses in EAQ will trigger a new disclosure in COI system
 - PI or Department Administrators can trigger an update of EAQ at any time



Stanford EAQ High Level View





Stanford EAQ – Question Level View

- Answering "yes" to a question returns names of the active entities in COI system; others entitles can be added
- EAQ collects details that enable administrators and PIs to complete federal forms

