

Convey

A Global Financial Interest Disclosure System

Heather H. Pierce, JD, MPH Senior Director, Science Policy Association of American Medical Colleges June 9, 2016 Learn Serve

Lead



OMB No. 0925-0613 Expiration Date: 03/31/2018 Journal of Clinical Oncology Anthor Co. Expiration Date: 0,031/05

Expiration Date: 0,03 Collection of this information is subteriord under 21 CFR 544. The use of this information is to dischare or entity information concentration of the classical interests of the classical interests of the classical interests introduced with climical studies. This information may be dischared concentration of the classical interests of the classi Fluince University School of Medicine
DIVISION OF CONTINUING MEDICAL EDUCATION ADDRESS OF THE STATE OF THE STA Submittees of this information is voluntary, however, in order for us to qualify you to conduct a study in accordance with the relevant, custost protected is, together and protected in the process of the conduct and the process of the conduct and the con Submissions of this information is volumently, however, in order for us to quanty you as second to all firstly complete all firstly complete representing bardons for this collection of information is estimated to average 5 minutes per response, including the public representing bardons for this collection of information is estimated to average 5 minutes per response, including the data sources, gathering data sources, gathering second in one of the second per se • Addi resear Have you or an immediate fami COAUTHOR DISCLOSURE FORM: of directors) in any for-Inform the core ABSTRACTS THAT REPORT ON CLINICAL TRIALS indicate that your obven dischium q CONFIDENTIAL FINANCIAL DISCLOSURE REPORT elon If you are This form is provided for use in collecting disclosure information from coauthors, it may not be submitted directly to ASCO by coauthors; it estimate or any other a MSC 7974, Bethrada, FOR SPECIAL GOVERNMENT EMPLOYEES This form is provided for use in collecting disclosure information from coauthors, it may not be submitted directly to ABOU by coauthors, it should be sent to the First Author, it is must enter disclosure information for all authors through the official Abstract Submitter program at Use the list of products/firms/issues in the cover memorandum to complete this form. Interests relating to these firms must be reported even if unrelated to products/indications listed, Please answer all questions below npilance with standards established by the Accreditation Council for Continuing Medical Education (ACCME), ASCO strives to promote you may have little or no person 3. OTHER INVOLVEMENTS (Other Kinds of Relationships) inpliance with standards established by the Accreditation Council for Continuing Medical Education (ALCME), ANCO strives to promote, independence, objectivity, and scientific viscos in all of its educational activities through the disclosure of financial interests and research grants in which you are n about the interest, and you have no NONE (If 'none," skip to Item 4.) Using the list of products/firms/issues in the cover memorandum, identify anything that would give an "appearance" of a which has not been disclosed above (e.g., involvement in a law suit, researcher initiated study, gift of research materials, etc.). hold a position (such as departme The FDA not personally involved as an invo could be helpful in preventing unin (see 21CI cts. The financial interests or relationships requiring disciosure are outlined in the or device 1. CURRENT FINANCIAL INTERESTS (Continued) cts, the thranscier interests or receivable processing electrical electrons are outlined in a disclose any relationships with commercial clinical i 1. CURRENT FINANCIAL INTEREST e. PATENTS / ROYALTIES / TRADEMARKS NONE (If 'none," skip to item 1.) Evaluati To your knowledge, do 1) you, you PRODUCTS / IF "YES," EXPLAIN BELOW AND INDICATE INCOME RECEIVED trustoe, general pertner or employee, 4. CERTIFICATION STATEMENT □yes □NO please enuployment have any current involv-The above information is true and complete to HONORARIA INVESTMENTS (e.g., stocks, born partnerships, sector funds, etc.) arrang my obligations as a special Government emplo Check yes if you or an immediate family member has been paid response contains __ pages. crees, year you or an immediate rating memory has been pero directly any honoraria (reasonable payments for specific speeches, YES NO seminar presentations, or appearances) at any point from two years prior to trial accrual through the present by an entity that YES NO has an investment, licensing, or other commercial interest in the holds PLEASE RETURNBY: To: COMMITTEE MANAGEMENT CO. subject matter under consideration in your abstract. f. EXPERT WITNESS (Last 12 months or under negotiation NONE (If 'none," skip to item g.) Yes, I have honoraria to disclose. ared for or against the following listed firm(s) / isque(s) ICMJE Form f PRODUCTS / INDICATIONS / ISSUE Select one:

Myself | Immediate Family Member AMOUNT RECEIVED IF "YER," EXPLAINBELOW b. EMPLOYMENT (Full or Part Time ☐ No, I do not have honoraria to disclose. TELEPHONE FIRM RESEARCH FUNDING ☐ YES ☐ NO Section 1. Check yes if at any time, beginning two years prior to accrual through the present, you or an immediate family member Title I of the Ethics in Government Act of 1978 conducted any research funded by the sponsor of any trial related YES NO 1. Given Name (Fir of the Office of Government Ethics regulations to the subject matter under consideration in your abstract. c. CONSULTANT / ADVISOR /Cu on this form is for review by Government official of interest laws and regulations. Additional disclo eal or Kermit the Yes, I have research funding to disclose. g. SPEAKING / WRITING (Last 12 months or under negotiation) NONE (If 'none," skip to item 2.) uticle. (1) to a Federal, State, or local law enfor potential violation of law or regulation; AMOUNT RECEIVED PRODUCTS / turers reanne or writing.

Select one:

Myself

Immediate Family Member 4. Are you the cor (2) to a court or party in a court or Fodon held comply with a subpoena;
(3) to a source when necessary to obtain info No, I do not have research funding to disclose. VES NO (4) to the National Archives and Record 5. Manuscript T management inspections: EXPERT TESTIMONY (5) to the Office of Maungement and Budget YES NO Check yes if you or an immediate family member has provided The effects of (6) in response to a request for disc expert testimony at any point from two years prior to trial accrual so that proceeding, if the information is relevant through the present where the testimony given relates to the A CONTRACTS / GRANTS / CRAF This confidential report will not be disclosed to: e facts. It YES NO Manuscript subject matter under consideration in your abstract. le bias in KF-34567 ☐ Yes, I have expert testimony to disclose. action by your employing agency or other appearance be reported may also subject you to criminal neo-2. PAST FINANCIAL INTERESTS Name of party on behalf of whom testimony was provided: a. To your knowledge, do any of the following persons have any past involvement with the meeting/task issues: You, your spouse, minor child, general partner, organization in which you serve as an officer, director, trustee, general partner or employee. Select one:

Myself
Immediate Family Member HONATURE OF REVIEWING OFFICIAL this is not YES . NO NOT TO MY KNOWLEDGE Select one:

Compensated Uncompensated b. If "Yes." describe involvement No, I do not have expert testimony to disclose. FINANCIAL INVOLVEMEN RELATED TO LISTED FIRM / PRODUCT COMMENTS OF REVIEWING OFFICIAL Did you or y Ves No OTHER REMUNERATION any aspect O FFER REMUNERALITY

Check yes if you or an immediate family member has received any statistical a check years you or an immediate rating manner real received any trips, travel, gifts, or other in-kind payments at any point from two YES NO years prior to trial accrual through the present from an entity Are there FORM FDA 3410 (1/95) (PAGE 1) years prior to trip occurs on output the processor in our an entropy having an investment, licensing, or other commercial interest in the If yes, ple neurog en investiment, insentaing, on beiner summerchen insentation in vour manuscript. You do not Excess rows can be reves l'Ino have to disclose payments that are directly related to research. Name of institution/Company Yes, I have other remuneration to disclose. IF MORE SPACE IS NEED YES NO his article. FORM FDA 3410 (1/95) (PAGE 3) Select one:

Myself | Immediate Family Member IF MORE SPACE IS NEEDED, COPY AND ATTACH AS ADDITIONAL PAGES Sunlight Stop, Inc. No, I do not have other remuneration to disclose. Date: FORM FDA 3410 (1/95) (PAGE 2) Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless or the companion with antition or described in the instructions. The end line for each position add or many lines account. Relevant financial activities outside the submitt Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardies) of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by Date: (3rd author): Signature: Date: (4th author): Signature: Date: (5th author): Signature: Date:



ICMJE Form for Disclosure of Potential Conflicts of Interest

Section 1. Identifying Information						
Given Name (First Name) Kermit the	2. Surnar Frog	me (Last Nar	ne)		3. Date 25-April-2013	
4. Are you the corresponding author?	Yes	✓ No	Correspond Miss Pigg	ding Author's y	Name	
5. Manuscript Title						
The effects of Sunstop on the function of	f sunlight	on frog sk	in slime			
6. Manuscript identifying Number (if you kn KF-34567	ow It)					
Section 2. The Work Un	dera	tion for P	ublication			
Did you or your institution at any time is symmetric services from a third party (government, commercial, private for any aspect of the submitted work (including our not limited to grants, data monitoring board, study design, manuscript protatistical analysis, etc.)?						
Are there any relevant conflicts of interest? 🗸 Yes 🔃 No						
If yes, please fill out the appropriate information below. If you have more than one entity press the "ADD" butt Excess rows can be removed by pressing the "X" button.						
Name of Institution/Company	Grant?	Personal Fees?	Non-Financial Support?	Other? C	Comments	
Sunlight Stop, Inc.	✓		/	Pro lot	ovided funds and the	ea

Pediatric Radiology

Conflict of Interest Disclosure Form

It is the policy of the journal Pediatric Radiology to ensure balance, independence, objectivity, and scientific rigor in the Journal. All authors are expected to disclose to the readers any real or apparent conflict(s) of interest that may have a direct bearing on the subject matter of the article. This pertains to relationships with pharmaceutical companies, biomedical device manufacturers or other corporations whose products or services may be related to the subject matter of the article or who have sponsored the study.

The intent of the policy is not to prevent authors with a potential conflict of interest from publication. It is merely intended that any potential conflict should be identified openly so that the readers may form their own judgement about the article with the full disclosure of the facts. It is for the readers to determine whether the authors' outside interest may reflect a possible bias in either the exposition of the conclusions presented.

All authors will complete and submit this form when submitting a manuscript to *Pediatric Radiology*. We prefer disclosures and signatures from all authors on one form. If this is not possible, however, separate forms will be accepted.

Please i d conflict of interest statement is published with each paper and must be inserted text document right before the reference list.

I/we certify that there is no actual or potential conflict of interest in relation to this article. (Please print names)

(1 st author): Signature:		Date:	
(2 nd author):	Signature:	Date:	
(3 rd author):	Signature:	Date:	
(4th author):	Signature:	Date:	
(5 th author):	Signature:	Date:	

Section 3.

Relevant financial activities outside the submitted work.

Place a check in the appropriate boxes in the table to indicate whether you have financial relationships (regardless of amount of compensation) with entities as described in the instructions. Use one line for each entity; add as many lines as you need by





Convey: The Goal

- To provide individuals with a web-based repository to enter and maintain records of financial interests and allow them to disclose directly to any organization.
- To build a streamlined, standardized system that sets and adopts national standards but allows organizations to tailor the disclosure process to get the information they need

The Creation of Convey

- Based on 2009 IOM recommendation
- Built on consensus data standards through MedBiquitous®
- Developed by the AAMC with the input of dozens of stakeholder organizations and individuals

Pilot Partners

- New England Journal of Medicine
- American Society of Clinical Oncology
- Cleveland Clinic
- Johns Hopkins



Convey: The Concept

First Disclosure

Second Disclosure

Create an Account





Find Subscribing Organization (or follow link)



Find Subscribing Organization (or follow link)



Review Organization's Requirements



Review proposed disclosure



Enter financial interest information to disclose



Enter additional financial interest information if needed

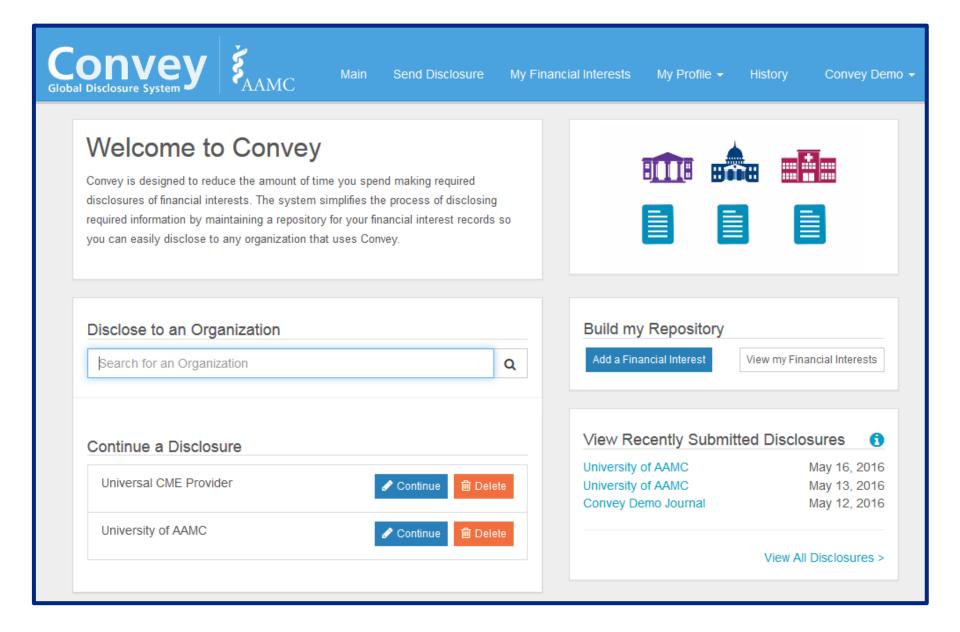


Review, certify, submit



Review, certify, submit

Discloser Homepage



Step 1: Organization Policy and Tailored Instructions

Sending Disclosure To: University of AAMC

Policy Details

Enter Interests

Additional Questions

Review and Send

Policy & Instructions

The University of AAMC Conflict of Interest Policy was developed to ensure integrity in research and patient care that occurs at our institution. All individuals who participate in research or clinical care activities are required to submit to the University a disclosure of all financial interests that relate to that person's institutional responsibilities, as well as those financial interests of the person's spouse or dependent children. Individuals disclosing to the University of AAMC are expected to disclose all required financial interests within the last 12 months and over a threshold of \$5000. See any additional criteria and details at our website.

The Discloser Identifier is unique to you and is used by the University of AAMC to match your disclosure to your institutional records. Please type your University of AAMC employee ID into the box for this disclosure. Contact the organization if you are unsure of your employee ID number.

The Disclosure Purpose is the reason that you are making the disclosure. Please type in 'General Annual' or 'Update' into the box to specify to the University of AAMC which type of disclosure you are making. Please contact the organization if you are unsure which to use.

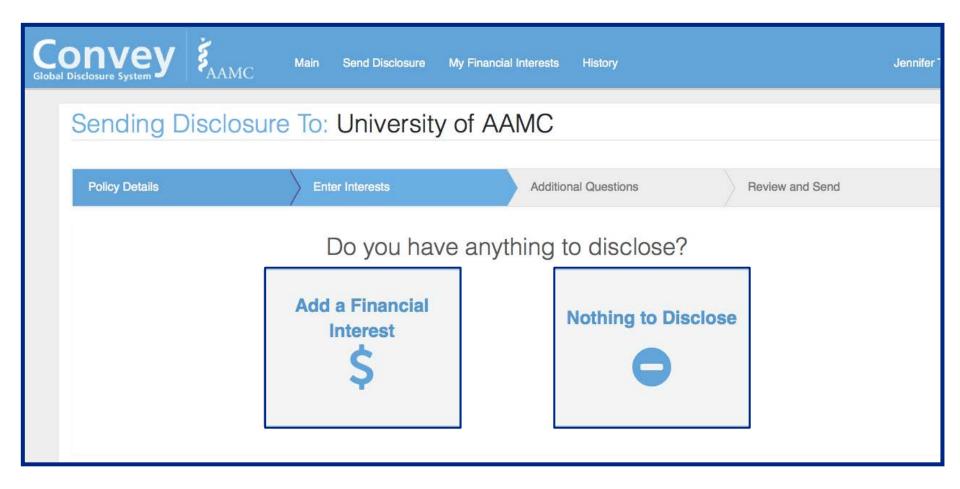
This organization accepts ORCID iD as your Discloser ID. If you already have an ORCID iD or would like to obtain one, you can retrieve or create it by clicking the ORCID icon above the Discloser ID field. If Convey has previously saved your ORCID iD, it has been used as your Discloser ID. To learn more about ORCID, visit http://orcid.org.

Disclosure Purpose

1234-5678

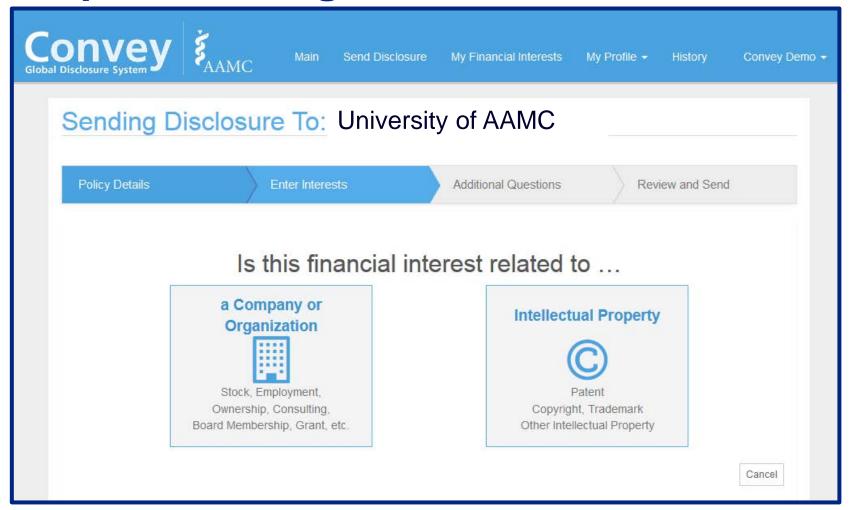
General Annual

Step 2: Entering Financial Interests



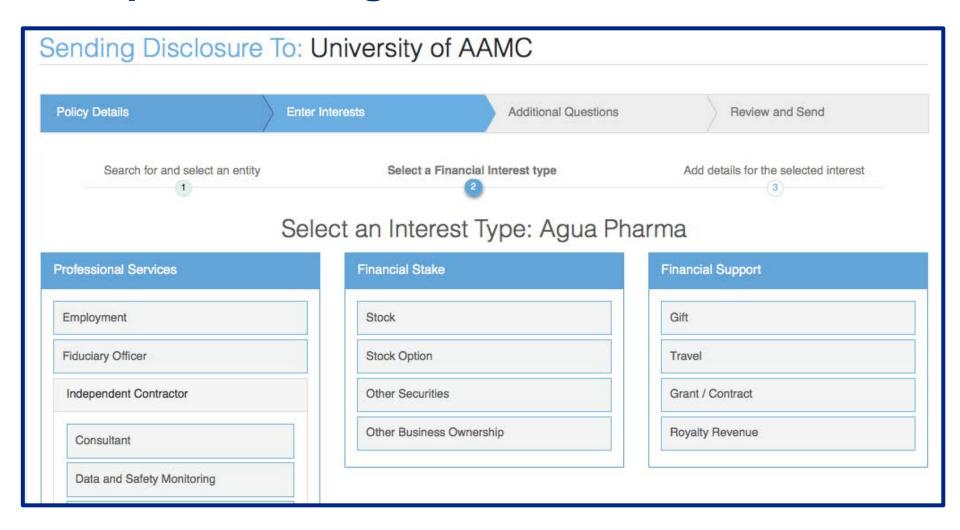


Step 2: Entering Financial Interests



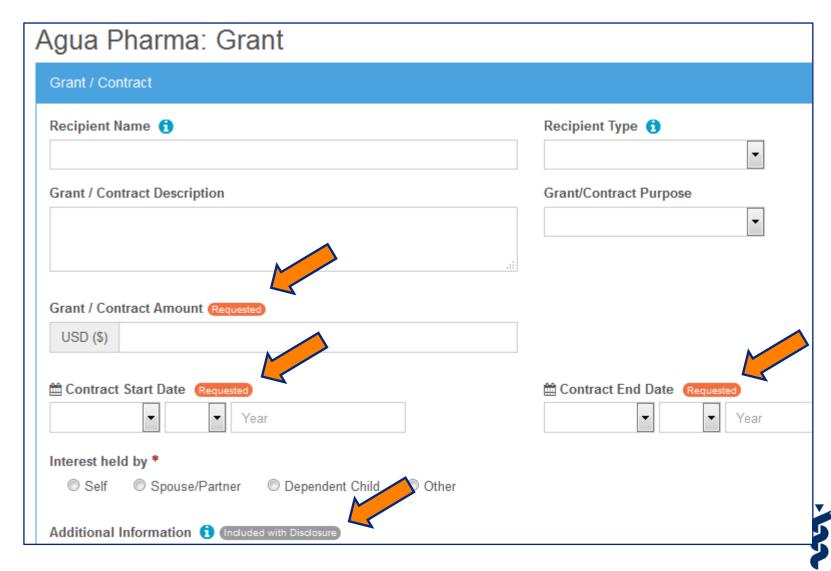


Step 2: Entering Financial Interests

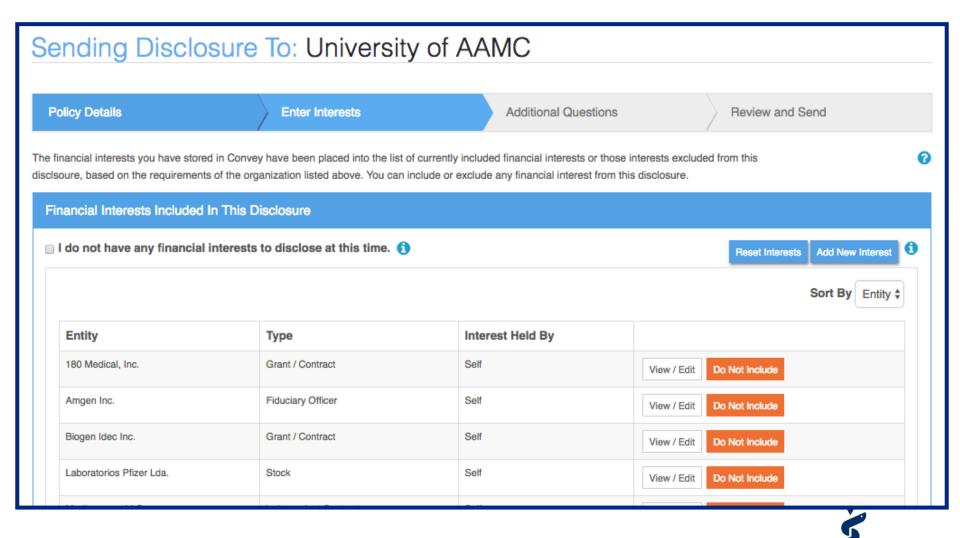




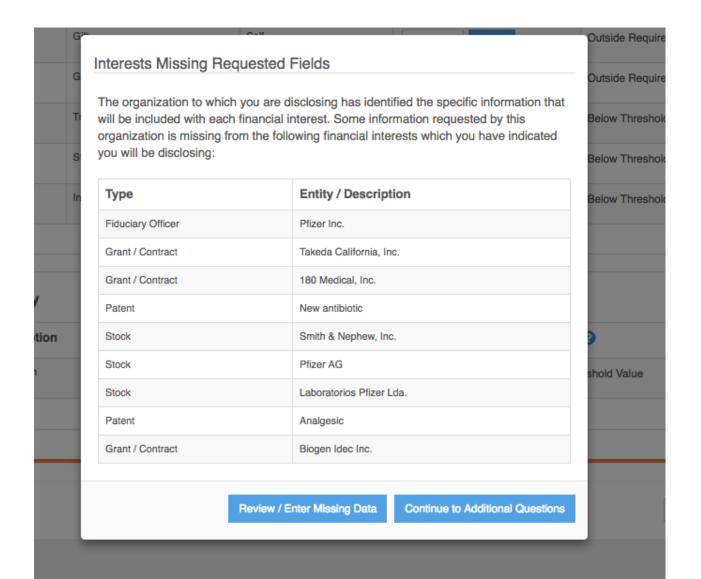
Step 2: Entering Financial Interests Requested fields are flagged



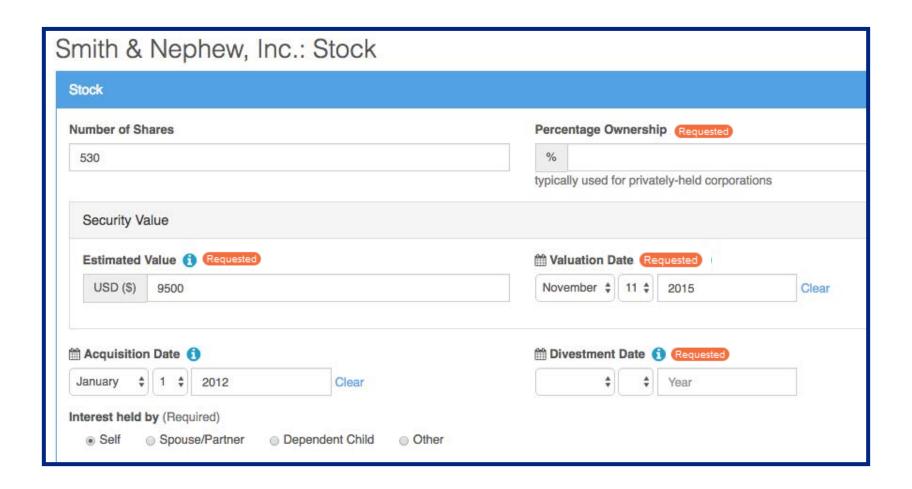
Step 2: Reviewing Financial Interests



Before Continuing, Individuals are Told Which Interests are Missing Requested Fields

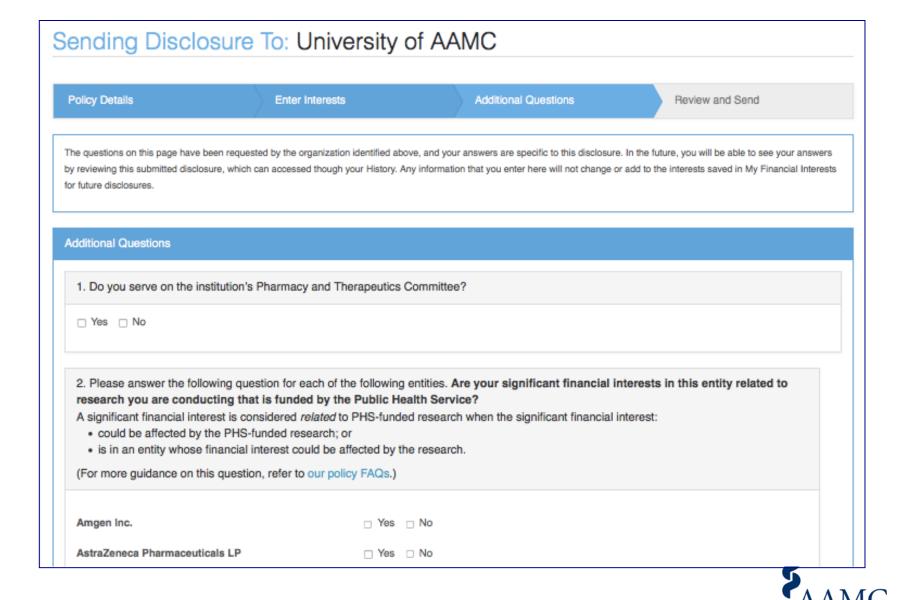








Step 3: Organization-Specific Additional Questions

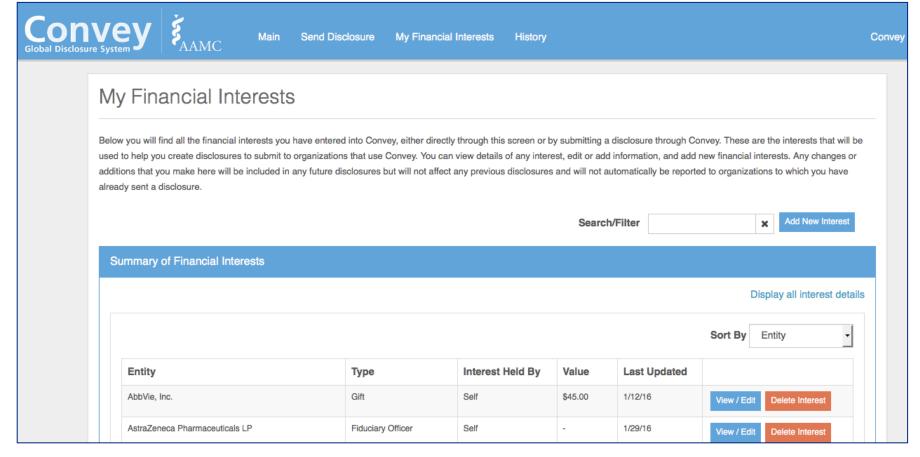


Step 4: Review, Certify, and Send

Sending Disclosure To: University of AAMC **Policy Details Enter Interests** Additional Questions Review and Send Review Disclosure Being Sent to: University of AAMC Please review carefully the information on this page that will be submitted to the organization identified at the top of the page. You can return to any step in this disclosure to make changes or click the Edit button next to any section on this page. The section entitled "Interests Not Included in this Disclosure" shows the financial interests that you have saved in Convey that will not be disclosed to this organization. Once you submit your disclosure, it cannot be modified or revoked. For questions about making changes to disclosure information after submitting a disclosure through Convey, please refer to the FAQ section. Discloser Email Discloser Name David Discloser csteele@aamc.org



Financial Interest Repository: Created and updated through the process of disclosing

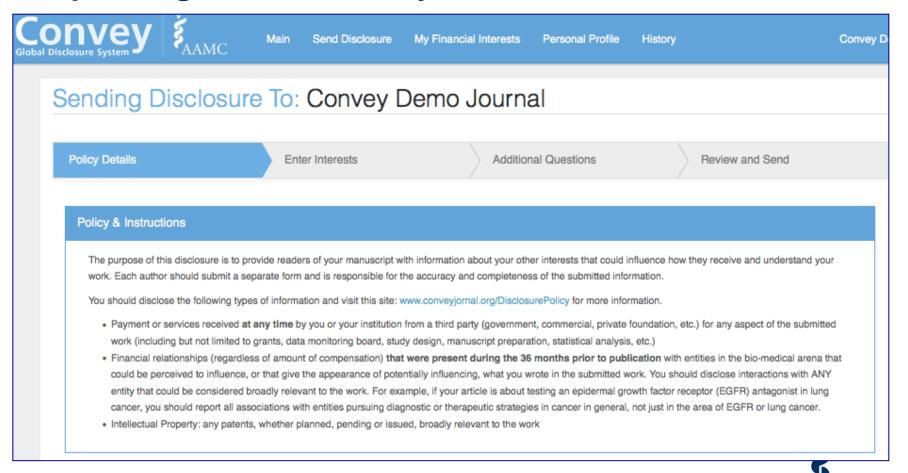




The Second Disclosure: Journal

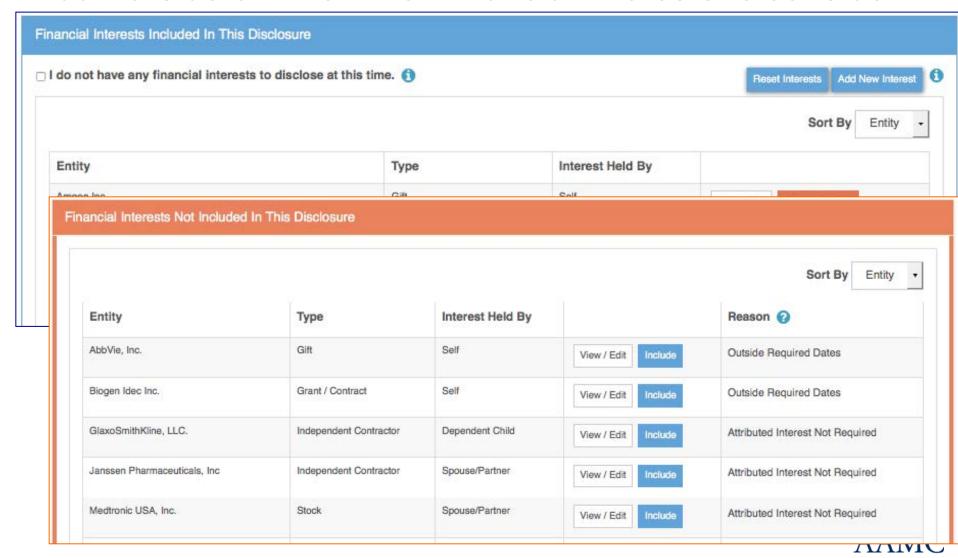
Same individual, same process New policy, new recipient

Step 1: Organization Policy and Tailored Instructions



Step 2: Review and update Financial Interests

Using the Organization's rules and policy, Convey helps authors determine which financial interests to consider

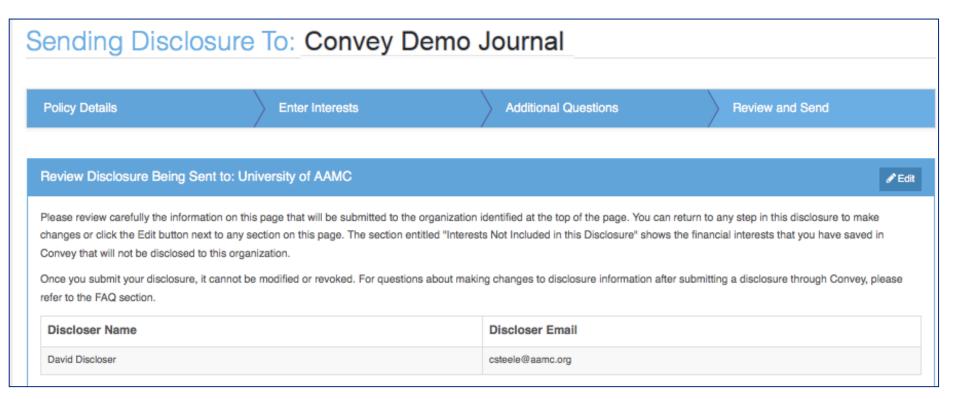


Step 3: Organization-Specific Additional Questions

Sending Disclosure To: Convey Demo Journal					
Policy Details	Enter Interests	Additional Questions	Review and Send		
Additional Questions					
What is the manuscript	1. What is the manuscript title?				
2. What is the manuscript Identifying Number (if you know it)?					
3. Are there other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing, what you wrote in the submitted work?					
□ Yes □ No					



Step 4: Review, Certify, and Send





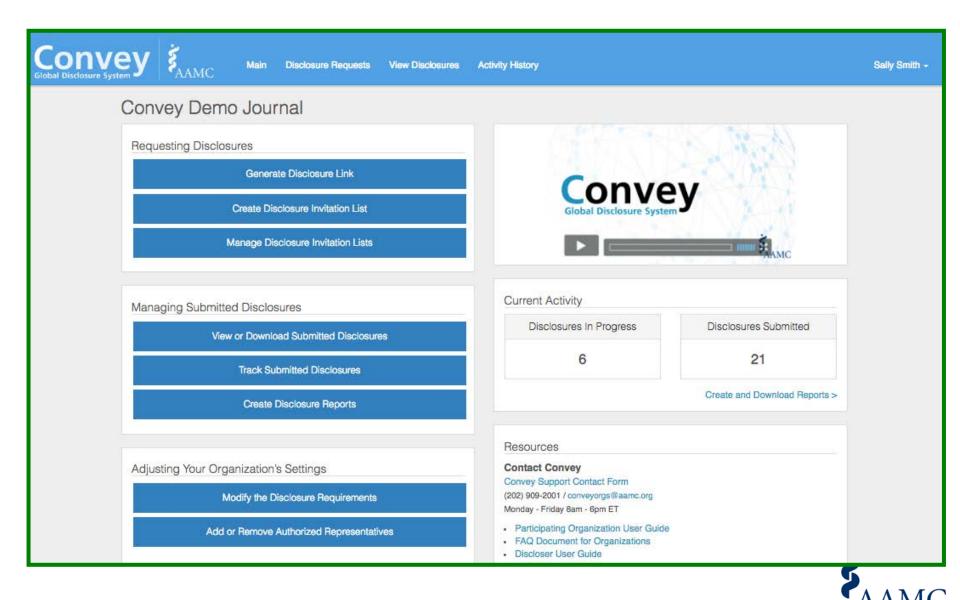
Convey: Subscriber Tools

From the subscriber-side interface, organizations can:

- Revise disclosure process text, rules, certification language, and additional questions
- Upload a list of individuals to invite through Convey
- Generate an organization-specific URL
- View and download any disclosure
- Manage disclosures and run reports on information submitted



Subscriber Interface



Subscriber Actions

Requesting Disclosures Generate Disclosure Link Create Disclosure Invitation List Manage Disclosure Invitation Lists



Subscriber Actions

Managing Submitted Disclosures

View or Download Submitted Disclosures

Track Submitted Disclosures

Create Disclosure Reports



Subscriber Actions

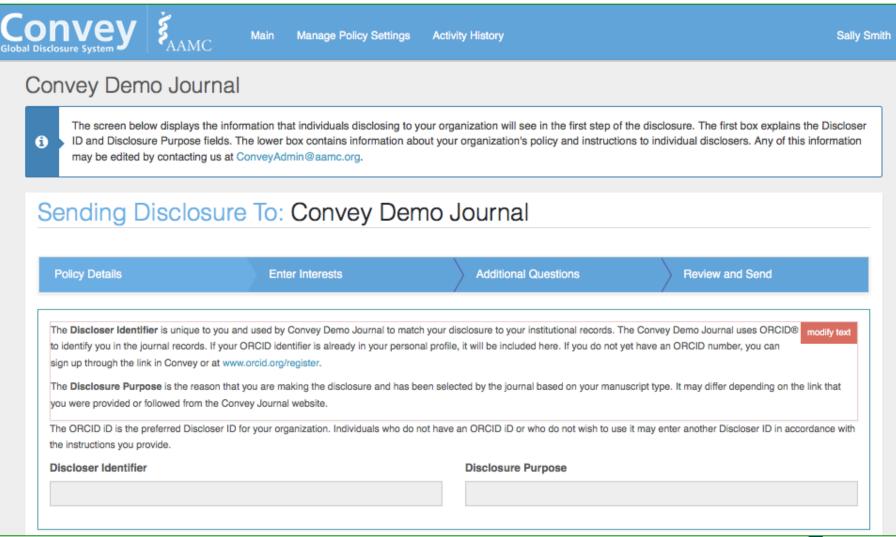
Adjusting Your Organization's Settings

Modify the Disclosure Requirements

Add or Remove Authorized Representatives

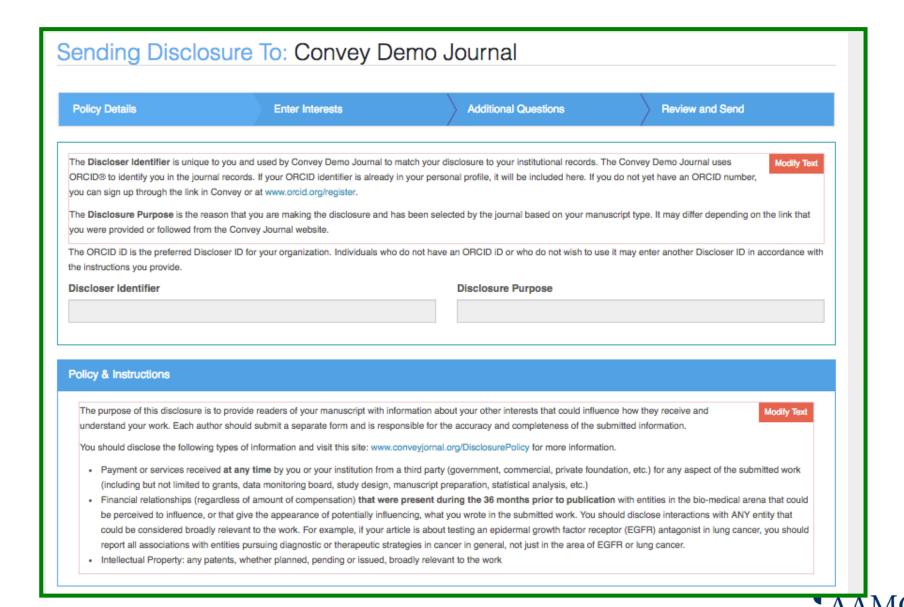


Subscriber Controls – Disclosure Process

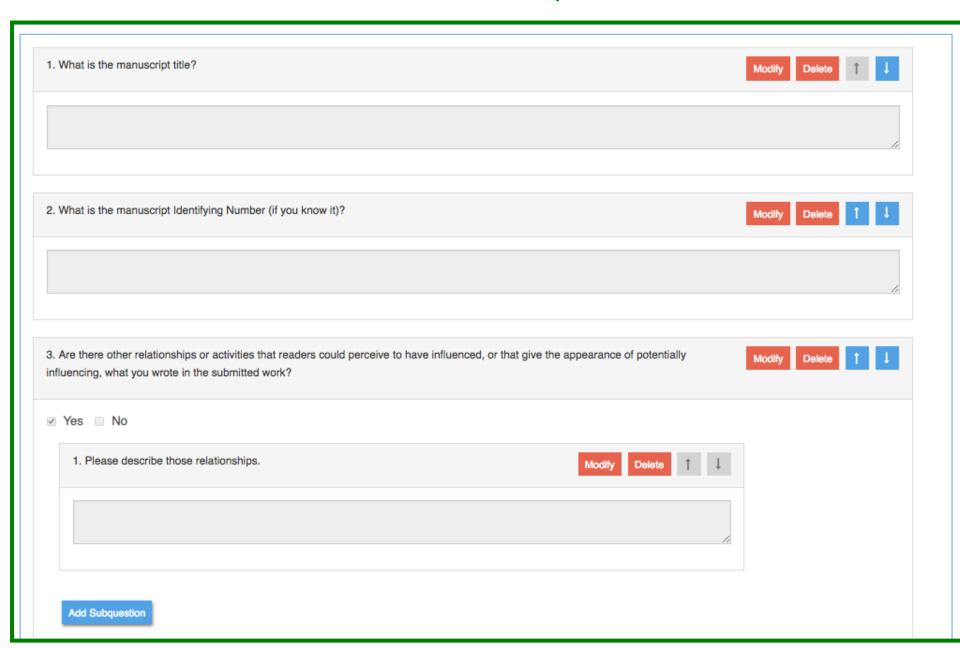




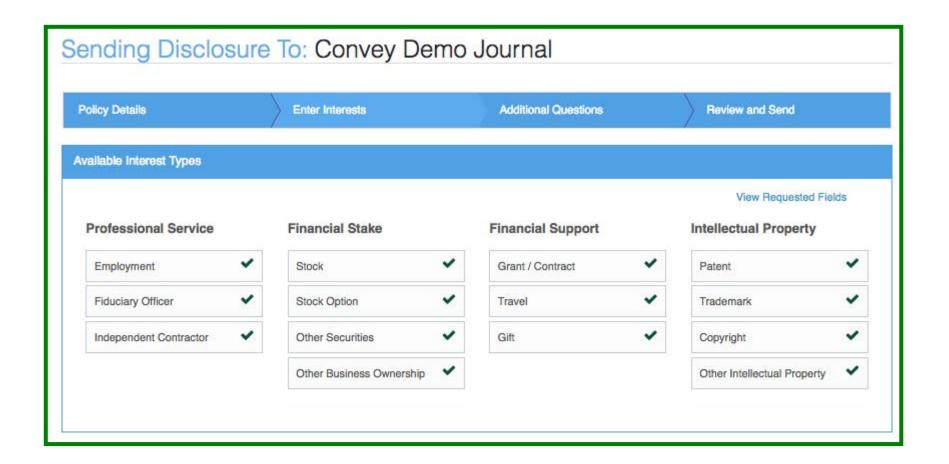
Modify the Policy and Instructions



Add or Edit Additional Questions

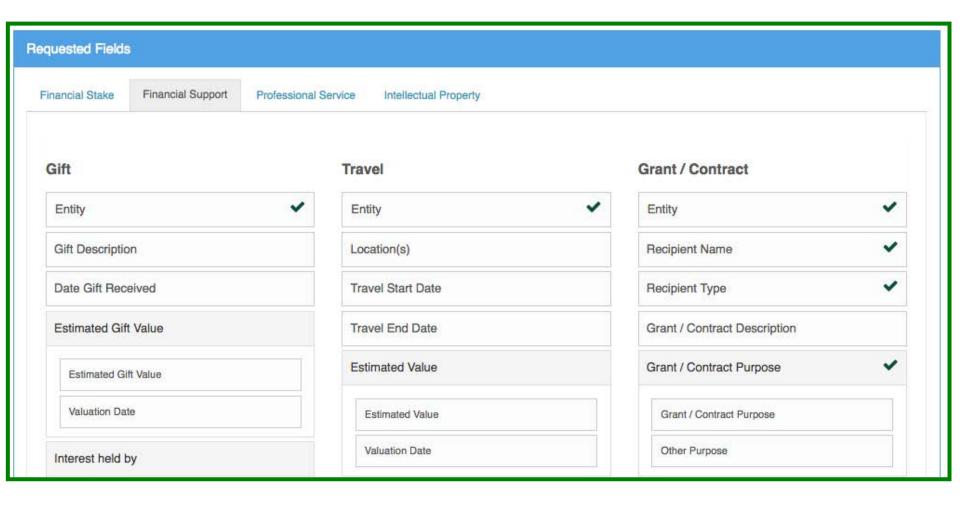


Subscriber Controls – Requested Fields





Subscriber Controls – Requested Fields





Subscriber Controls – Rules that guide disclosers to better disclosures

Attribution Rules

Your organization requires that individuals disclose financial interests attributed to the following individuals: **SELF** This attribution rule applies to all disclosed interest types.

Attribution

Value/Threshold Rules

Your organization requires that individuals disclose certain financial interests with a value equal to or greater than \$0. This Value Threshold rule applies to all interest types.

Value Threshold

Additionally, your organization has requested that if individuals have entered a value for a financial interest in Convey, this value will not be displayed in the disclosure and will not be transmitted to your organization.

Your organization has requested that individuals disclose certain financial interests regardless of the value of the interest and has not requested that the individuals disclose the value of those interests. If individuals have entered a value for a financial interest in Convey, this value will not be displayed in the disclosure and will not be transmitted to your organization.

Aggregation

Time(lookback)

Your organization requires that individuals disclose certain financial interests from the following time period:

The 36 month period from the date of disclosure.

Relevant Time Period

This rule applies to all interest types.



Next Steps

Convey is in late stage system testing

AAMC is currently engaging with the first organizations planning on using Convey as their disclosure source this year

Organizations working with AAMC now include:

- Academic institutions
- Health systems
- Journals and Peer review managers
- Government agencies
- CME Providers

How can you be involved? Contact us to:

- Have a WebEx demo for your institution
- Volunteer as a tester to provide input on the system
- Join the institutions engaged in technical conversations with AAMC about how information from Convey can integrate with their commercial or home-grown COI management systems



Email for more information or a demonstration:
convey@aamc.org
or visit www.aamc.org/convey