Conflict of Interest Module

Table of Contents

I: For a General Audience

The first section of the COI Manual contains information for all audiences.

Overview of the COI Module

Streamlyne's COI Module is designed to facilitate the institutional processes that ensure compliance with the federally-mandated regulations that promote objectivity in the design, conduct, and reporting of research by preventing bias due to the financial interests of an investigator. The financial COI module provides a place for researchers to report significant financial interests and disclose any financial interests that could pose a conflict with their research. Reviewers have access to COI disclosures online where their recommendations to manage, reduce, or eliminate conflicts and other comments are preserved. COI administrators have all the tools they need to track disclosures, coordinate reviews, maintain associated correspondence, properly administer disclosures, and manage any perceived conflicts of interest.

Section I Contents

Using This Guide

Please keep the following things in mind as you use this guide:

A Stepwise Approach

These guides are designed to facilitate immediate productivity for new users in a complex and unfamiliar system. To achieve this end, the processes are broken down into manageable sections with the steps to each process laid out sequentially.

By practicing the steps and experimenting in the application at the detail level, you will gain the knowledge you need to master your role or design high-level processes that meet your institution's unique needs.

Navigation and Common Elements

This guide assumes you are familiar with common features and basic navigation as presented in the **NEW USER MANUAL: Navigation, the Action List, and Common Document Elements**. Please use that manual as a companion to this one, as we have tried to eliminate redundancy wherever possible.

Every Installation Is Different

Streamlyne Research is highly configurable. If you are currently in the implementation process, it is likely your institution will perform some level of analysis to identify which features you would like to use, which values you would like to change to reflect your institution's terminology, and which features you will skip altogether.

Given this, the processes detailed in this document are representative of general Conflict of Interest practices and do not necessarily represent the exact manner in which your institution will choose to use the application.

Let's begin!

Searching with Conflict of Interest Lookups

To assist you in locating Financial Entities and Disclosures within Streamlyne Research, Conflict of Interest search windows, called lookups, are available from the Main Menu. Access to these lookups depends on the COI roles assigned to you in your Person record, or user profile. Most users at an institution will have Reporter permissions and will only be granted access to their own financial entities and disclosures. Some users will serve as Reviewers, who will only be allowed to access the disclosures assigned to them for review. COI Administrators will have access to all records necessary to complete their assigned administrative functions.

To search for items using Conflict of Interest lookups, simply navigate from the Main Menu to the corresponding Conflict of Interest Lookup as indicated below.

Reporter/Reviewer Lookups

The following lookups are specifically designed for users who are Reporters or Reviewers.
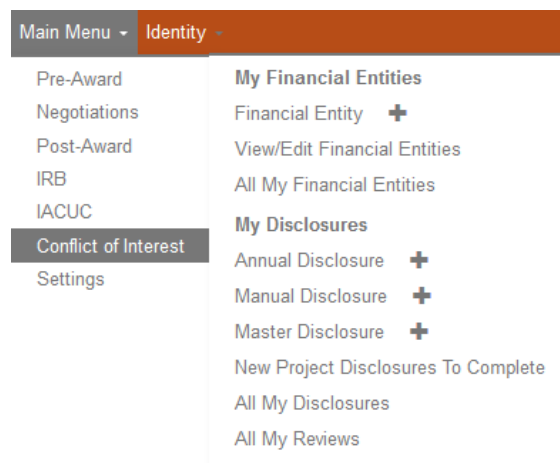
View/Edit Financial Entities

Navigation	Main Menu > Conflict of Interest > My Financial Entities > View/Edit Financial Entities

This lookup will generate a list of all of the financial entities that you have ever reported. Search results will include both Active and Inactive Financial Entities. From here, option buttons are made available to View, Edit, Deactivate, or View History of previously reported relationships.

All My Financial Entities

Navigation	**Main Menu > Conflict of Interest > My Financial Entities > All My Financial Entities**

This lookup is useful to those who wish to quickly search through all of their financial entities. Simply click the Search button to generate a list of all the financial entities that you have ever reported. If you wish to refine these results, enter further criteria in the Lookup fields and click the Search button.

New Project Disclosures to Complete

Navigation	**Main Menu > Conflict of Interest > My Disclosures > New Project Disclosures to Complete**

As configured by your institution, this lookup displays all of the reporter's projects within Streamlyne where a required COI disclosure submission remains outstanding. A proposal, award, IRB protocol, or IACUC protocol document generated within the Streamlyne suite would represent a project that could require a COI disclosure. Typically, all key personnel on a project will need to disclose potential conflicts of interest.

All My Disclosures

Navigation	Main Menu > Conflict of Interest > My Disclosures > All My Disclosures

This lookup allows reporters to quickly search for all of the disclosures they have started or submitted. If you wish to refine these results, enter further criteria in the Lookup fields and click the Search button

All My Reviews

Navigation	Main Menu > Conflict of Interest > My Disclosures > All My Reviews

This lookup is useful for reviewers assigned to review COI disclosures. The lookup returns all Disclosure documents assigned to the signed-on user. If you wish to refine these results, enter further criteria in the Lookup fields and click the Search button.

COI Administrator Lookups

The following lookups are specifically designed for users who are Conflict of Interest Administrators.

Main Menu ▾	Identity ▾	
Pre-Award	**Financial Entity Lookup**	
Negotiations	Financial Entities	
Post-Award	**Disclosure Lookups**	
IRB	Disclosures	
IACUC	Annual Disclosures	
Conflict of Interest	Project Disclosures	
Settings	Submitted Disclosures	
	Open and In Progress Disclosures	
	Unsubmitted Project Disclosures	

Financial Entities

Navigation	Main Menu > Conflict of Interest > Financial Entity Lookup > Financial Entities

This COI Administrator lookup will generate a list of all financial entity documents. If you wish to refine these results, enter further criteria in the Lookup fields and click the Search button.

Disclosures

Navigation	Main Menu > Conflict of Interest > Disclosure Lookups > Disclosures

This COI Administrator lookup will generate a list of all disclosure documents, including in-progress disclosures. If you wish to refine these results, enter further criteria in the Lookup fields and click the Search button.

Annual Disclosures

Navigation	Main Menu > Conflict of Interest > Disclosure Lookups > Annual Disclosures

This COI Administrator lookup will generate a list of all Annual Disclosures, regardless of the disclosure status. If you wish to refine these results, enter further criteria in the Lookup fields and click the Search button.

Project Disclosures

Navigation	Main Menu > Conflict of Interest > Disclosure Lookups > Project Disclosures

This COI Administrator lookup will generate a list of Project Disclosures, regardless of the disclosure status. If you wish to refine these results, enter further criteria in the Lookup fields and click the Search button.

Submitted Disclosures

Navigation	Main Menu > Conflict of Interest > Disclosure Lookups > Submitted Disclosures

This COI Administrator lookup will generate a list of all submitted disclosure documents, regardless of the disclosure status after submission. If you wish to refine these results, enter further criteria in the Lookup fields and click the Search button.

Open and In Progress Disclosures

Navigation	Main Menu > Conflict of Interest > Disclosure Lookups > Open and In Progress Disclosures

This COI Administrator lookup displays a dashboard of all Disclosure Reviews that have been assigned but not yet completed. The disclosure documents under review are grouped first by Review Status. Within each grouping, the system separates reviews with no Financial Entities (and therefore no conflict) from reviews with Financial Entities. Click the Show buttons to access the list of documents that fall within each subgrouping. Click the hyperlinked Document ID to open the Disclosure. You may also Print or Approve disclosures from within this lookup.

Unsubmitted Project Disclosures

Navigation	Main Menu > Conflict of Interest > Disclosure Lookups > Unsubmitted Project Disclosures

This COI Administrator lookup will generate a list of all Unsubmitted Project Disclosures, allowing the administrator to quickly assess all reporters who need to submit Project Disclosures, but have not done so. If you wish to refine these results, enter further criteria in the Lookup fields and click the Search button.

II. For COI Reporters

This second section provides a step-by-step guide for COI Reporters to 1) report relationships with Financial Entities and 2) prepare and submit COI Disclosures in Streamlyne Research.

Section II Contents

Reporting Relationships with Financial Entities

Streamlyne Research delivers functionality that allows users to self-report significant financial interests (SFIs) with any entity at any time via the Financial Entity document. The Financial Entity document is independent of the Disclosure documents available in Streamlyne Research. The Financial Entities document is designed to enable a user to disclose new financial relationships as those relationships form, or update and/or inactivate existing relationships as they evolve over time.

Active financial relationships documented on Financial Entities documents are automatically included on Disclosure documents, whether the disclosures are a part of the annual disclosure cycle or precipitated by a Proposal, Award, Protocol, travel, or other event.

Creating a New Financial Entity

Navigation	**Main Menu > Conflict of Interest > My Financial Entities > Financial Entity > +**

Follow these steps to create a new Financial Entity document:

1.   Access a new document via the following navigation:

Main Menu > Conflict of Interest > My Financial Entities > Financial Entity > **+**

Result   Streamlyne Research displays the document open to the Financial Entity tab.

Updating the Financial Entity Tab

Financial Entity Tab > Document Overview

Update the Document Overview section as detailed in the **NEW USER MANUAL: Navigation, the Action List, and Common Document Elements.**

Financial Entity Tab > Financial Entity Details

1.   The Financial Entity Details panel is used to record contact information for the financial entity. Before hand-keying the contact information for the new entity, check to make sure the data does not exist as a Sponsor record.

Click the magnifying glass 🔍 next to the **Sponsor Code** field to search for the name of the entity with which you have a financial relationship. If the entity exists as a Sponsor record, select the record to populate the entity's contact data to the document.

2.   If necessary, enter or correct the full legal name for the organization in the **Entity Name** field.

3.   Click the arrows next to the **Entity Type** field, and then select the most appropriate description of the entity's type from the dropdown list.

Note   The **Status Code** defaults to Active, indicating that your relationship with this financial entity is currently active. This is the appropriate setting for new records.

4.   If you selected a Sponsor record in Step 2, all fields containing entity contact data should have auto populated to the Financial Entities document. If so, and if the information appears to be correct, skip to the next process.

Otherwise, enter the entity's address information into one or more of the **Address Line** fields, beginning with **Address Line 1**.

5.   Select the entity's **State** from the dropdown list.

6.   Select the entity's **Country Code** from the dropdown list.

7.   Enter the entity's zip code into the **Postal Code** field.

8.   Enter the entity's **City** into the field provided.

9.   Enter the entity's web address into the **Website** field.

Note   Any data entry performed here, whether pertaining to new entities that do not exist as Sponsor records, or changes to an entity's contact data where a Sponsor record exists, will not be updated back to the Sponsor record.

10.   If **Entity Type** is Private For-profit, Public For-profit, Private Nonprofit, or Public Nonprofit AND **Country Code** is United States then the following question will be posed: **Is this entity a Domestic Subsidiary of a Foreign Entity?** Select Yes, No, or Not Sure from the dropdown list.

Financial Entity Tab > Questionnaire

The Questionnaire functionality in Streamlyne Research allows your institution to interview Reporters and capture specific information about their relationship with each financial entity. Mandatory Questionnaires can contain Questions where a response is required. Optional Questionnaires can contain Questions where a response is not necessarily required.

1. Click the header to expand the Questionnaire section.

2. Read through each question and answer truthfully.

    Some answers may require a Yes or No answer by clicking the corresponding radio button, while others may require that you hand-key your answer in a freeform text field.

Financial Entity Tab > Relationship Details

The exact nature of the reporter's relationship to the financial entity is defined in the Relationship Details section.

As you move through this section, keep in mind that the Relationship Details section is a completely configurable data matrix. Your institution will define all elements of this section, including:

- The Relationship Types that report (Self, Spouse, Dependent Child)
- The Relationship Categories for which data will be collected (Ownership Interests, Office & Positions, etc.)
- The kind of responses that should be collected from the reporter (checkbox, Yes/No radio button, custom dropdown list, freeform textbox.)

Sub Tab > Equity Interests

The Equity Interests subsection of the Relationship Details panel prompts for information regarding any equity interests that you, your spouse, or dependent child may have in the financial entity.

1. Click the section header to expand the Relationship Details section.

2. If you (**Self**), your **Spouse**, or **Dependent Child** have any ownership interest in the financial entity, click the dropdown arrow under the corresponding column(s) and then select the percentage range that best represents that person's ownership interest.

3. Enter any **Comments** relevant to Ownership Interest that should be preserved for future reference.

4. If you (**Self**), your **Spouse**, or **Dependent Child** have any stock in the financial entity, click the dropdown arrow under the corresponding column(s) and then select the range that best represents that person's amount of stock.

5. Enter any **Comments** relevant to Stock that should be preserved for future reference.

6. If you (**Self**), your **Spouse**, or **Dependent Child** have any stock options in the financial entity, click the dropdown arrow under the corresponding column(s) and then select the range that best represents that person's amount of stock options.

7. Enter any **Comments** relevant to Stock Options that should be preserved for future reference.

Sub Tab > Offices & Positions

The Offices & Positions subsection of the Relationship Details panel prompts for information on any title or position that you, your spouse, or dependent child may hold within the financial entity.

OFFICES & POSITIONS	Self	Spouse	Dependent Child
Partner	☐	☐	☐
Comments			
Executive	☐	☐	☐
Comments			
Employee	☐	☐	☐
Comments			
Board Member or Trustee	☐	☐	☐
Comments			
Scientific Advisory Committee	☐	☐	☐
Comments			

1.   If you (**Self**), your **Spouse,** or **Dependent Child** holds a Partner position within the financial entity, click the corresponding checkbox(es).

2.   If you indicated that someone holds a Partner position, enter further details in the **Comments** field.

3.   If you (**Self**), your **Spouse,** or **Dependent Child** is an Executive within the financial entity, click the corresponding checkbox(es).

4.   If you indicated that someone is an Executive within the financial entity, enter further details in the **Comments** field.

5.   If you (**Self**), your **Spouse,** or **Dependent Child** is an Employee of the financial entity, click the corresponding checkbox(es).

6.   If you indicated that someone is an Employee of the financial entity, enter further details in the **Comments** field.

7.   If you (**Self**), your **Spouse,** or **Dependent Child** is a Board Member or Trustee with the financial entity, click the corresponding checkbox(es).

8.   If you indicated that someone is a Board Member or Trustee with the financial entity, enter further details in the **Comments** field.

9.   If you (**Self**), your **Spouse,** or **Dependent Child** is on a Scientific Advisory Committee with the financial entity, click the corresponding checkbox(es).

10.   If you indicated that someone is on a Scientific Advisory Committee with the financial entity, enter further details in the **Comments** field.

Sub Tab > Compensation

The Compensation subsection of the Relationship Details panel prompts for information on any compensation that you, your spouse, or dependent child may have received from the entity.

1.   If you (**Self**), your **Spouse**, or **Dependent Child** have received financial compensation from the financial entity as Salary, Consulting Fees, Honoraria, or Paid Authorship, click the dropdown arrow under the corresponding column(s) and then select the range that best represents the amount of compensation received.

2.   If you indicated that someone received financial compensation, enter further details in the corresponding **Comments** field.

Sub Tab > Intellectual Property

The Intellectual Property subsection of the Relationship Details panel prompts for information on any intellectual property income or rights that you, your spouse, or dependent child may be entitled to from the new financial entity.

INTELLECTUAL PROPERTY	Self	Spouse	Dependent Child
Patent Income	select ▾	select ▾	select ▾
	Comments		
Copyright Income	select ▾	select ▾	select ▾
	Comments		
Other Licensing Income	select ▾	select ▾	select ▾
	Comments		
Intellectual Property Rights	☐	☐	☐
	Comments		

1. If you (**Self**), your **Spouse,** or **Dependent Child** have received Patent Income, Copyright Income, or Other Licensing Income from the financial entity, click the dropdown arrow under the corresponding column(s) and then select the range that best represents the amount of compensation received.

> select
> less than $1,000
> $1,000 - $2,999
> $3,000 - $4,999
> $5,000 - $9,999
> $10,000 or more

2. If you indicated that someone received Patent Income, Copyright Income, or Other Licensing Income from the financial entity, enter further details in the corresponding **Comments** field.

3. If you (**Self**), your **Spouse,** or **Dependent Child** have Intellectual Property Rights with the financial entity, click the corresponding checkbox(es).

4. If you indicated that someone has Intellectual Property Rights with the financial entity, enter further details in the **Comments** field.

Sub Tab > Other

The Other subsection of the Relationship Details panel prompts for information on miscellaneous relationships not covered in other sections that you, your spouse, or dependent child may be entitled to from the new financial entity.

OTHER INTERESTS	Self	Spouse	Dependent Child
Gifts	select ∨	select ∨	select ∨
	Comments		
Loans	select ∨	select ∨	select ∨
	Comments		
Paid Travel	select ∨	select ∨	select ∨
	Comments		
Entertainment	select ∨	select ∨	select ∨
	Comments		
Volunteered Time	select ∨	select ∨	select ∨
	Comments		
Other	select ∨	select ∨	select ∨
	Comments		

1. If you (**Self**), your **Spouse**, or **Dependent Child** has received financial benefits in the form of Gifts, Loans, Paid Travel, Entertainment or Other from the financial entity, click the dropdown arrow under the corresponding column(s) and then select the range that best represents the amount received.

> select
> less than $1,000
> $1,000 - $2,999
> $3,000 - $4,999
> $5,000 - $9,999
> $10,000 or more

2. If you indicated that someone has received financial benefits in the form of Gifts, Loans, Paid Travel, Entertainment or Other from the financial entity, enter further details in the corresponding **Comments** field.

3. If you (**Self**), your **Spouse**, or **Dependent Child** has Volunteered Time with the financial entity, click the dropdown arrow under the corresponding column(s) and then select the range that best represents the time volunteered.
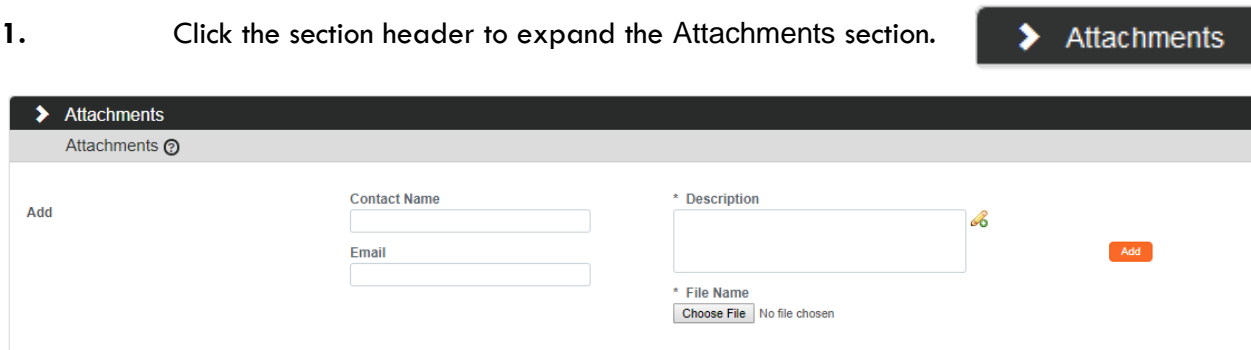
> select
> 1 - 12 hours (annual)
> 13 - 52 hours (annual)
> 53 hours or more (annual)

4. If you indicated someone Volunteered Time with the financial entity, enter further details in the **Comments** field.

Financial Entity Tab > Attachments

Any files that support or document the terms of the financial relationships reported in previous sections should be added in the Attachments section.

1.   Click the section header to expand the Attachments section.

2.   If the document to be attached pertains to an individual other than yourself, such as your spouse, child, student, or other relation, enter the individual's name in the **Contact Name** field.

3.   If the document to be attached pertains to an individual other than yourself, such as your spouse, child, student, or other relation, enter the individual's email address in the **Email** field.

4.   Enter a detailed description of the document's contents in the **Description** field.

5.   Click the Choose File button to locate and upload the attachment according to your operating system's prompts.

6.   Click the Add button to complete the attachment process.

7.   Repeat Steps 2 through 6 until all Attachments are uploaded to the Financial Entities document.

8.   Once attached, each document's details display within the Attachments panel.

If you choose, click the corresponding View button to open the attachment.

9.   If you choose, click the corresponding go-to icon to open the full Description of the attachment in a pop-up window.

10.   If you choose, click the corresponding Delete button to remove any documents that were uploaded in error.

11.   Click the Submit button at the bottom of the page. `Submit`

Result   The system will add the New Financial Entity to the database and return to a blank New Financial Entity screen. The new entity can be seen on the My Financial Entities tab. This may take some time.

Reporter Tab > Contact Information

To view Reporter Contact Information, select the Reporter Tab on the left.

👤 **Reporter**

❯ Reporter

Contact Information ⓘ

Full Name :	Biochemistry Professor	User Name :	bioprofessor
Email Address :	streamlyneuser@gmail.com	Office Phone :	102-456-1079
Primary Title :	Biochemistry Professor	Directory Title :	Biochemistry Professor
Home Unit :	105010	School :	Medicine University
NSF ID :		CITI User Name :	
eRA Commons User Name :		Fax :	102-456-2079
Pager :		Mobile :	
Office Location :	Suite 779	Secondary Office Location :	
Address Line 1 :	2020 Camino del Rio N.	Address Line 2 :	Suite 779
Address Line 3 :		City :	San Diego
County :	San Diego	State :	CA
Postal Code :	92108-1545	Country :	USA

The Contact Information subsection of the Reporter tab displays read-only data pulled from the Reporter's Person record. If the data in this section is incorrect, contact a Streamlyne Administrator.

Financial Entity Actions Tab

When the Financial Entity document is complete and all errors have been resolved, select the Financial Entity Actions Tab on the left.

⚡ **Financial Entity Actions**

Click the Submit button at the bottom of the page to finalize the document. `Submit`

Using the My Financial Entities Tab

The My Financial Entities tab lists all active relationships you have previously reported with other entities.   Here, you have the options to view, edit, deactivate, or view history of previously reported data.

You can also access this page directly at any time using this navigation:

Navigation	Main Menu > Conflict of Interest > My Financial Entities > View/Edit Financial Entities

Viewing & Comparing Previously Reported Information on a Financial Entity

1. Click the View button to open a read-only pop-up window with data reported for the corresponding financial entity. view

2.	Streamlyne Research displays the pop-up window with the most recent version displayed first.

	If more than one version exists, use the Previous and Next buttons in the upper right to scroll through all the iterations. Previous Next

3.	If more than one version exists, click the Show button to compare the record you are viewing to the previous version.

	Show
	Compare to Previous Version:
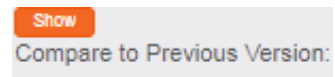
Result   Streamlyne Research will
highlight the changes from the
previous record in red.
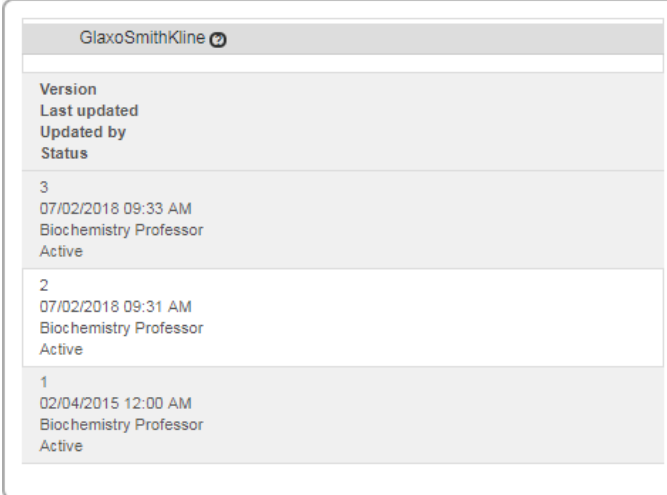
Amgen, Inc.

Last Updated
03/03/2017 05:00 PM
Updated by
Biochemistry Professor
Version
2 of 2

Previous   Next

Address
One Amgen Center Drive
Thousand Oaks
91320-1799
CA
USA
Sponsor
Amgen, Inc.

Sponsors Research
No
Status
Active

Ownership Type
Private

Details
Org Relation Description:
Entity is now a corporate sponsor for university basketball team

Entity Principal Business/Activity:
Key Note speaker at Annual Conference

Hide

Compare to Previous Version: 02/04/2015 12:00 AM - Biochemistry
Professor

4.   When done reviewing, click anywhere outside the pop-up window to close the
window.

Viewing the Audit History of a Financial Entity

1. Click the View History button to open a read-only pop-up window with the date, time, and username associated with each change made to the corresponding financial entity.

2. When done reviewing, click anywhere off of the pop-up window to close the window.

Deactivating a Relationship with a Financial Entity

Deactivate is used to indicate that your relationship with the entity has ended for the time being.

Follow these steps to perform this action directly from the shortcut on the My Financial Entities tab:

1. Click the corresponding Deactivate button for the entity with whom your financial relationship is no longer active.   Deactivate

2. Streamlyne Research will prompt you to confirm the deactivation.

Are you sure you want to deactivate this financial entity ?

* Please enter the reason below:

Yes   No

3.   Enter an explanation for the deactivation in the freeform text field and click the   `Yes`
        Yes button to proceed.

        Otherwise, click the No button to cancel the action and return to the previous   `No`
        screen.

Result   If you clicked Yes, Streamlyne Research will update the entity's **Status Code** to
        Inactive, and move the entry to the Inactive Financial Entities subsection of the My
        Financial Entities tab. The date and timestamp of the change will reflect in the View
        History section.

Editing an Existing Financial Entity

The system provides more than one path to access an existing entity record for editing. If you are
not already in the My Financial Entities tab, use the following navigation:

Navigation	Main Menu > Conflict of Interest > My Financial Entities > View/Edit Financial Entities

To edit an existing Financial Entity, follow these instructions:

1.   Click the corresponding Edit button for the entity whose details you wish to update.   `Edit`

2.   Streamlyne Research opens the entity's record for editing. The fields displayed are the
        same as those covered in Creating a New Financial Entity and New Financial Entity Tab
        > Relationship Details. Refer to those sections as you make necessary changes.

3.   If you have made changes but would like to resume editing at a later time, click the
        Save Edit button. `Save Edit`

        If your changes are complete, click the Submit Edit button. `Submit Edit`

Result   Once changes are submitted, Streamlyne Research will record date and timestamp of
        the change and this information will be reflected in the View History section.

Understanding Types of Disclosures & Common Elements

There are four types of COI Disclosure Documents in Streamlyne Research:

- Manual Disclosures – COI disclosures that are manually entered into the system, including those that report travel reimbursements
- Project Disclosures – COI disclosures that are automatically initiated by the system when a proposal, award, IRB protocol, or IACUC protocol document for a project is generated within the Streamlyne suite
- Annual Disclosures – COI disclosures that are generated on an annual basis and contain all manual disclosures and project disclosures reported by an investigator in the last year
- Master Disclosures – COI disclosures that are generated at any time to contain all manual disclosures and project disclosures reported by an investigator ever

While each is initiated under different conditions, the majority of the data collected or displayed on each document is the same.

This chapter will review the common elements of the Disclosure documents in the order in which you will encounter them. The individual Disclosure types will be covered in subsequent chapters with references back to this section to reduce repetition.

Updating Reporter & Screening Data

Disclosure > Reporter > Contact Information

The Contact Information subsection of the Reporter section displays read-only data pulled from the signed-on user's Person record. If the data in this section is incorrect, contact a Streamlyne Administrator.

Disclosure > Reporter > Unit Details

The Unit Details section displays the reporter's default Unit association. This default can be edited or updated here for the Disclosure only; changing the Unit association here will not change the defaults set in the reporter's Person record.

1. Scroll down to the Unit Details subsection if it is not already visible on the screen.

2. Streamlyne Research displays all Units that the user is associated with as indicated on his or her Person record. The user's Lead Unit is marked as such in the **Lead** column.

    If this information is correct and complete, skip to the next process.

    If this is not the correct Lead Unit, or if the user is working with an additional Unit that is not included here, click the magnifying glass in the **Unit Name** column on the **Add:** line to search for and select the desired Unit.

3. Click the Add button to record the new information on the Disclosure document.

4. Repeat Steps 2 and 3 until all new Units are included on the Disclosure document.

5. If the Lead Unit is not correctly marked in the **Lead** column, resolve the problem by unchecking the corresponding checkbox for the incorrect Unit and checking the corresponding checkbox for the correct Lead Unit.

Note Adding, editing, or deleting Unit information on the Disclosure document will not update the same information on the corresponding Person record.

If you edited Unit information in Steps 2 through 4, contact your Streamlyne Administrator to update the same information in the corresponding Person record.

Disclosure > Screening Questionnaire

The Screening Questionnaire section contains standard interview questions used to screen for potential conflicts of interest. These questions are standard across all Disclosure documents regardless of the Event Type that precipitated the disclosure.

Note that the sample language in the screen shot does not necessarily represent the language your institution will choose to implement in this section.

1.   Click the header to expand the Screening Questionnaire section.

2.   Read through each question and truthfully answer Yes or No by clicking the corresponding radio button.

    The Screening Questionnaire contains built in logic that looks for any Yes answer. If any one of the screening questions is answered Yes, then you will not be able to submit the corresponding disclosure without also adding a Financial Entity. To add a Financial Entity, see Creating a New Financial Entity.

Disclosure > Questionnaire

The Questionnaire section contains custom interview questions that appear dynamically when certain conditions are met. These questions may be driven by data selections further along in the process, for example, the Event Type selected in the Manual Event and Financial Entities section. For this reason, it is important to complete the majority of the Disclosure document before completing the Questionnaire section.

The system requires this section be complete before the disclosure can be submitted into workflow.

3.   Click the header to expand the Questionnaire section.

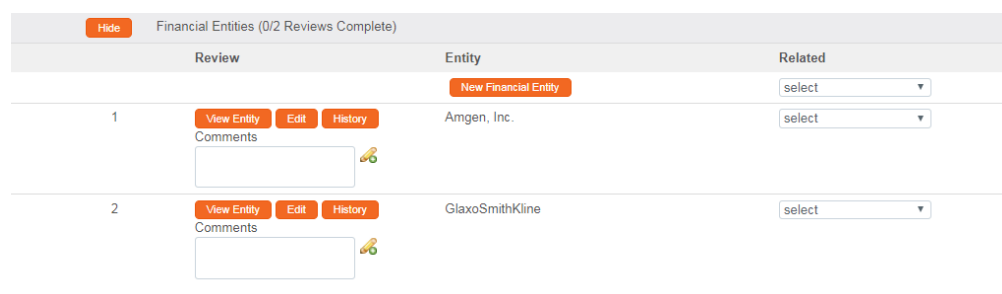4.   Read through each question and answer truthfully.

    Some answers may require a Yes or No answer by clicking the corresponding radio button, while others may require that you hand-key your answer in a freeform text field.
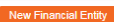
5.   See Adding Notes & Attachments to complete the Notes & Attachments section of the document.

Financial Entities

The Financial Entities section is found in the Project/Event section of the Disclosure document.

For Manual Disclosures, this section will not appear until you click the Add button [Add] in the Manual Events subsection.
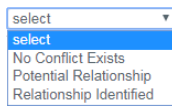
Note that any financial entities that you have previously reported are automatically included in this section providing those relationships are still active. Any deactivated relationships with financial entities are excluded. Refer to Deactivating a Relationship with a Financial Entity for more information on this action.

Follow these steps to disclose relationships with financial entities on a Disclosure:

1.   If you need to report a relationship with a new financial entity or a not yet entered Financial Entity, click the New Financial Entity button. [New Financial Entity]

If all your existing relationships with financial entities are already listed in this subsection, skip to Step 7.

2.   Streamlyne Research will open a new Financial Entities document on a new page. Return to Creating a New Financial Entity and follow the steps in this section to report this new relationship. Once you submit the new Financial Entity, you will then be redirected back to the Disclosure document. The Financial Entity you added will now appear.

3.   For each entity listed, click the arrow next to the corresponding **Related** field, and then select an option that best represents the entity's conflict-of-interest status relative to the event disclosed on this document.

4.   Click the Save button at the bottom of the page to save the changes.

5.   If you are working on a Manual Disclosure, be sure to return to the Questionnaire section to complete any interview questions that may have appeared based on your entries in this section.

6. To view read-only data previously reported for an entity listed in this section, click the View Entity button to access a pop-up window. [View Entity]

Otherwise, proceed to Step 7.

7. To review the history of entries for an entity, click the History button. [History]

Otherwise, proceed to Step 8.

8. To make changes to an existing entity click the Edit button to open the applicable Financial Entities document on a new page. [Edit]

See Editing an Existing Financial Entity and follow the steps in this section to edit the information on this Entity. Once you submit the edits to the Financial Entity, you will then be redirected back to the Disclosure document. The Financial Entity you edited will now appear and will reflect the changes made.
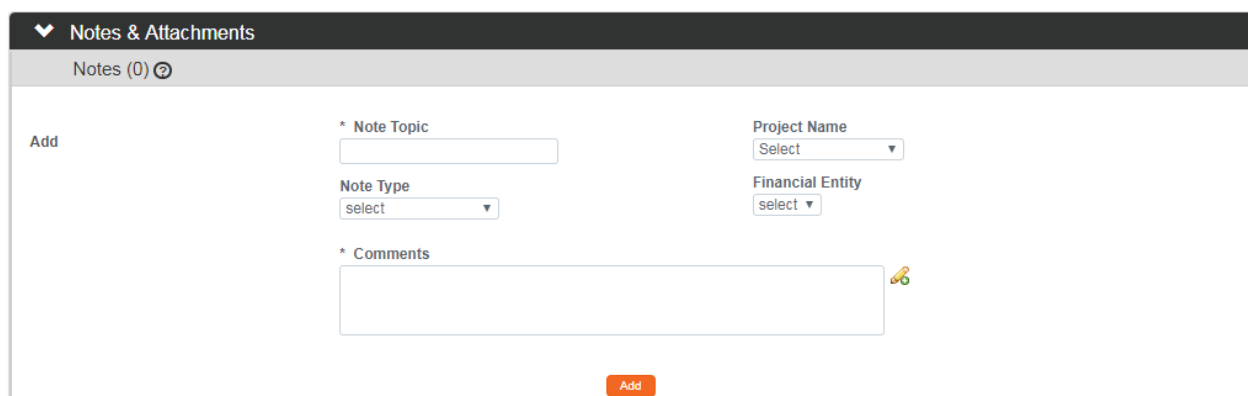
The electronic documents in Streamlyne Research share common elements across most modules, though exceptions are noted. The following information about Notes and Attachments is one such exception. Please refer to the **NEW USER MANUAL: Navigation, the Action List, and Common Document Elements** for other common elements.
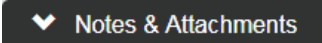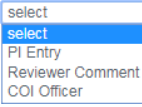
Adding Notes & Attachments
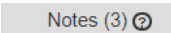
Notes and Attachments can be uploaded to the system at various points in the disclosure processes. The instructions that follow apply to every electronic document supported by the Conflict of Interest module. The content of the documents attached in the Notes & Attachments section will depend on the Project/Event Type that precipitated the disclosure as well as your institution's policies and procedures.

Attaching Notes to the Disclosure

Follow these steps to add a note to the Project Disclosure.
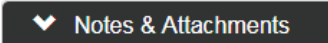
1. Click the header to expand the Notes & Attachments section.   ❯ **Notes & Attachments**

2. Enter a short description of the note in the **Note Topic** field.

3. Click the arrow next to the **Note Type** field and select the appropriate option from the dropdown list.

   ```
   select                ▾
   select
   PI Entry
   Reviewer Comment
   COI Officer
   ```

4. If the note refers to a specific project, identify this project by clicking the arrow next to the **Project Name** field and selecting the appropriate project from the dropdown list.

5. If the note refers to a specific **Financial Entity,** identify the entity by clicking the arrow next to the field and selecting the entity name from the dropdown list.

6. Enter the note itself in the **Comments** field.

   You may do this by hand keying the text directly into the freeform text field, by copying and pasting from a source document, or by clicking the pencil icon ✏ to open a text editor in a pop-up window.

7. Click the Add button to attach the note.   **Add**

Result Once you have attached a note, the contents will be displayed in the Notes subsection and the total number of notes attached to the document will be reflected in the subheader title bar within parentheses.   Notes (3) ⓘ

Editing or Deleting an Existing Note

1	Created By	Note Topic possible issue	Project Name Proposal Example
		Note Type Reviewer Comment	Financial Entity Amgen, Inc.
	Updated By Reviewer, Rachel 05/29/2015 12:00 AM	Comments Possible conflict with keynote speaker--topics may overlap with project ➦	

Follow these steps to edit a note:

1. If it is not already open, click the header to expand the Notes & Attachments section.   ❯ **Notes & Attachments**

2. Click the Edit button that corresponds to the note you wish to edit.   **Edit**

3. The system will open all the note fields for you to change.

   Make any changes as necessary.

4. Click the Save button at the bottom of the page to save the changes.   **Save**

Result Once saved, the fields will return to read-only status and the Updated By information will reflect the username and the date/timestamp of the change.

Follow these steps to delete a note:

1. If it is not already open, click the header to expand the Notes & Attachments section.

2. Click the Delete button that corresponds to the note you wish to delete.

3. The system will prompt you to confirm the action.

Click the Yes button to proceed or click the No button to cancel.

Uploading a New Attachment

Follow these steps to upload a new attachment to the disclosure:

1. If it is not already open, click the header to expand the Notes & Attachments section.

2. Working in the New Attachment subsection, click the arrow next to the **Attachment Type** field and select the appropriate value from the dropdown list.

3. Enter the name of the person uploading the attachment in the **Contact Name** field if other than the reporter/PI.

4. Click the arrow next to the **Project** field to select the project name from the dropdown list if applicable.

5. Click the arrow next to the **Financial Entity** field to select the entity's name from the dropdown list if applicable.

6. Enter contact information in the **Email** and/or **Phone** fields if someone other than the PI uploaded the attachment.

7. Enter optional **Comments** to be preserved for future reference.

8. Enter a summary or description of the attachment's contents in the **Description** field.

9. To upload the file, click the Choose File button next to **File Name**. Complete this action by following your operating system's prompts.

10. Click the Add button to attach the file to the Disclosure.

Result The system will append an Attached Items subsection to the section with the total number of attachments reflected within parentheses on the title bar.
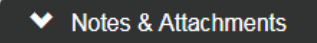
Filtering, Viewing, Editing, Replacing or Deleting Attachments

Streamlyne Research provides filtering options to manage the way attachments are displayed.

Follow these steps to filter the attachment list:

1. If it is not already open, click the header to expand to the Notes & Attachments section.

2. Working within the Attached Items subsection, click the arrow next to the **Sort By** field and select the filtering option from the dropdown list.

3. Click the Filter button to sort the list of attachments according to your selection.

Note Streamlyne Research displays each attachment's details as a collapsed subsection with the attachment's details displayed in the title bar according to the following naming convention: Description: File Name: Updated By: username.

Follow these steps to view an attachment:

1.   Click the Show button that corresponds to the attachment you wish to view.   Show

2.   Streamlyne Research displays the attachment's details. These fields may or may not be editable based on your permissions.

Click the View button.   view

3.   Save or open the download by following your browser's prompts.

Follow these steps to edit an attachment's details:

1.   If you haven't already done do, click the Show button that corresponds to the attachment you wish to edit.   Show

2.   Streamlyne Research displays the attachment's details. These fields may or may not be editable based on your permissions.

If these fields are editable, make changes to the data as necessary.

3.   Click the Save button at the bottom of the page to save the changes.   Save

Follow these steps to replace an attached file with a new version:

1. If you haven't already done do, click the Show button that corresponds to the attachment you wish to replace. [Show]

2. Streamlyne Research displays the attachment's details.

Click the Replace button. [replace]

Note Clicking the Replace button effectively deletes the existing attachment without warning. Take care not to click the Replace button without preserving the existing attachment if necessary.

3. Streamlyne Research makes the Choose File button available next to the **File Name** field.

4. To upload the file, click the Choose File button next to **File Name**. Complete this action by following your operating system's prompts.

5. Click the Save button at the very bottom of the page to save the replacement file to the existing attachment record. [Save]

Follow these steps to delete an attachment:

1. If you haven't already done do, click the Show button that corresponds to the attachment you wish to replace. [Show]

2. Streamlyne Research displays the attachment's details.

Click the Delete button. [Delete]

3. Are you sure you would like to delete the following attachment: itinerary for conference travel itinerary for conference travel.pdf?
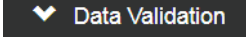
[Yes] [No]

The system will prompt you to confirm the action.
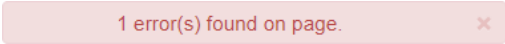
Click the Yes button to proceed or click the No button to cancel.

Validating, Certifying and Submitting

Validating the Disclosure Data

The validation feature helps to ensure your data is complete and correct. Follow these steps:

1.   Click the header to expand the Data Validation section.   `⌄ Data Validation`

2.   Click the Turn On Validation button.   `Turn On Validation`

3.   Streamlyne Research will run a series of validation steps to make sure all fields are populated correctly and that field entries do not conflict wherever possible.

If errors are found, the system will display a red error message at the top of the page, and   `1 error(s) found on page.    ✕`

append any Validation Errors, Warnings, Unit Business Rules Errors, and/or Unit Business Rules Warnings found to the Data Validation section.

All errors must be resolved before submission, though warnings will not hamper submission if left unaddressed.

If errors exist, click the Fix button next to the first listed error.   `Fix`

4.   Streamlyne Research will note where the problem resides.

Make your corrections and save the updated document.

5.   Repeat Steps 3 and 4 as many times as necessary to resolve all errors.

Note   This same validation routine is automatically run each time you submit the Disclosure into workflow. If it is the case that your submission is interrupted because of errors, you must recertify and resubmit the document by following the steps outlined in the next process.

Certifying and Submitting the Disclosure

With all details added to the document, you are ready to complete the certification step. The certification step essentially serves as your formal acknowledgment of the related policies set forth by your institution as documented in this section. This acknowledgement is legally binding.

Note that the terminology included in the screenshot is sample language that may not reflect your institution's current policies.

Follow these steps to certify your disclosure:

1. Click the header to expand to the Certification section.

2. Read the certification language presented here.

3. Click the checkbox next to the statement of acknowledgment.

4. When the box is checked, the system makes the Submit button available.

Click the Submit button to enter the Disclosure into workflow.

Result Streamlyne Research will display a success message upon submission, and your COI administrator will receive an APP item on his or her action list, prompting a disclosure review.
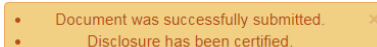
Note   The Disclosure may be sent to other approval points per your institutions workflow business practices.

Recalling a Disclosure

This action can only be performed by a Reporter after a document has been submitted into workflow and there are other users who need to approve a disclosure before it is received by the COI Office. This action will deliver the document back into the Action List of the Reporter. The Reporter can then make edits and submit the document back into workflow. If your Disclosure has been submitted and you would like to recall the submission, follow these instructions to recall the document.

Note   Recall is used for instances in which you would like a disclosure back for further edits before approvals and subsequent COI Office review.

1.   Within the Disclosure that you wish to Recall, scroll to bottom of the page and click the Recall button. ▭ Recall

Are you sure you want to recall this document to the action list?

* Please enter the reason below:

[Yes] [Return to Document]

2.   Enter an explanation in the field provided.

3.   If you are satisfied with your explanation, continue to the next Step. Otherwise, click the Return to Document button to cancel the recall action.

4.   Click the Yes button. [Yes]

Note   The Disclosure Status will be updated to Recalled in Routing.

Document Number : 26452	Disclosure Number : 1000018992
Disclosure Status : Recalled in Routing	Review Status : Submitted For Review
COI Disposition : Submitted for Review	Reporter : bioprofessor

Completing Manual Disclosures

Manual Disclosures may be used in various ways and allow an institution to create institution specific disclosures that are not captured in the other Disclosures within Streamlyne Research. This allows institutions to create their own pre-configured form(s). This manual will cover two of the most common Manual Disclosures delivered as part of the standard platform.

In addition, the fields that populate within each event or Manual Disclosure type may vary as these fields are highly configurable and may change per your institutions business practices.

However, the most common ways an institution may use Manual Disclosures are:

- To report reimbursed travel for compliance with National Institute of Health. Travel Disclosures are manually initiated in all cases.

- To disclose for projects at institutions where the corresponding project or event (Proposal, Award, Institutional Proposal, IRB, IACUC) is not maintained in the Streamlyne Research application and must therefore be manually initiated as a Manual Disclosure.

Initiating a Manual Disclosure

All Manual Disclosure documents are initiated the same way regardless of the disclosure's purpose.

Navigation	Main Menu > Conflict of Interest > Manual Disclosure > +

Follow these steps to begin:

1. Streamlyne Research displays the Manual Disclosure document open to the Disclosure tab with the Document Overview section expanded.

   Complete the Document Overview section. For more information on this common element, refer to the **NEW USER MANUAL: Navigation, the Action List, and Common Document Elements.**

2. Proceed to the next process.

Updating Reporter & Screening Data

Disclosure > Reporter > Contact Information

The Contact Information subsection of the Reporter section displays read-only data pulled from the signed-on user's Person record. If the data in this section is incorrect, contact a Streamlyne Administrator.

Disclosure > Reporter > Unit Details

If you find that you need to edit the defaulted Unit data, refer to Disclosure > Reporter > Unit Details.

Disclosure > Screening Questionnaire

For more information on the use of this common element, refer to Disclosure > Screening Questionnaire.

Disclosure > Questionnaire

The content of the Questionnaire section is driven by data selections further along in the process, for example, the Event Type selected in the Manual Event and Financial Entities section. For this reason, it is important to complete the majority of the Manual Disclosure document before completing the Questionnaire section.
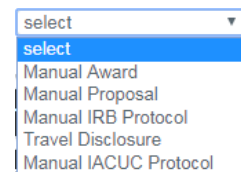
You will be prompted to return to this process. The system requires this section be complete before the Manual Disclosure can be submitted into workflow. For more information on the use of this common element, refer to Disclosure > Questionnaire

Updating Manual Events

The fields available to you in the Manual Events and Financial Entities section will depend on the **Event Type** that precipitated the Manual Disclosure.

1.   Click the header to expand the Manual Events and Financial Entities section.

> Manual Event and Financial Entities

2.   Click the arrow next to the **Event Type** field and choose the correct Event Type.
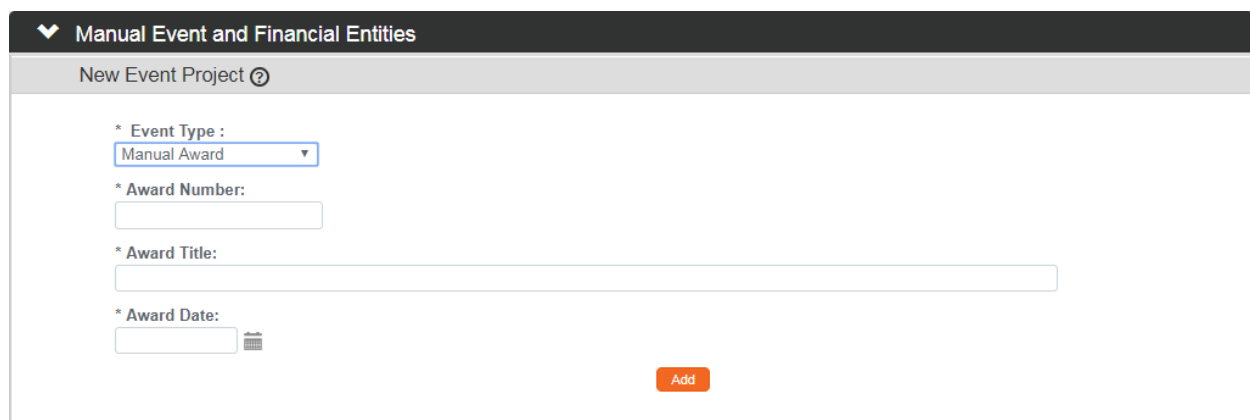
select
select
Manual Award
Manual Proposal
Manual IRB Protocol
Travel Disclosure
Manual IACUC Protocol

3.   Skip to the corresponding instructions listed here:

- Manually Disclosing Conflict of Interest for a New Award
- Manually Disclosing Conflict of Interest for a New Proposal
- Manually Disclosing Conflict of Interest for a New IRB Protocol
- Manually Disclosing Conflict of Interest for a New IACUC Protocol
- Manually Disclosing Travel

Manually Disclosing Conflict of Interest for a New Award

The Manual Award **Event Type** is used at institutions where the Streamlyne Research Award & Award Budget module is not in use.

Manual Event and Financial Entities

New Event Project

* Event Type :
Manual Award

* Award Number:

* Award Title:

* Award Date:

Add

1.   Streamlyne Research will automatically update the page based on your **Event Type** selection of Manual Award.

Enter the **Award Number** related to this disclosure.

2.   Enter the full title of the related Award in the **Award Title** field.

3.   Enter the **Award Date** in MM/DD/YYYY format or click the calendar icon 📅 to select the date.

4.   Click the Add button to complete this section.

Result   The system will update the page with a Financial Entities subsection listing your Financial Entities.

5.   Complete the Financial Entities subsection.

For more information on this common element, refer to Financial Entities.

Manually Disclosing Conflict of Interest for a New Proposal

The Manual Proposal **Event Type** is used at institutions where the Streamlyne Research Proposal Development and Budget module is not in use.

Manual Event and Financial Entities

New Event Project ⓘ

* Event Type :
Manual Proposal ▼

* Project Id:

* Project Title:

* Sponsor:

* Project Role:

* Project Funding Amount:

* Project Start Date:

* Project End Date:

* Project Type:
select ▼

Add

1. Streamlyne Research will automatically update the page based on your **Event Type** selection of Manual Proposal.

    Enter the **Project ID** for the proposal related to this disclosure.

2. Enter the full title of the related project in the **Project Title** field.

3. Enter an identifier for the **Sponsor** according to your institution's convention.

4. In the **Project Role** field, enter your role in the project or your title according to your institution's convention.

5. Enter the total dollar amount requested on the proposal in the **Project Funding Amount** field.

6. Enter the **Project Start Date** in MM/DD/YYYY format or click the calendar icon 📅 to select the date.

7. Enter the **Project End Date** in MM/DD/YYYY format or click the calendar icon 📅 to select the date.

8. Click the arrow next to the **Project Type** field and select the proposal type from the dropdown list.

    select
    New
    Resubmission
    Renewal
    Continuation
    Revision
    Task Order

9. Click the Add button to complete this section.   Add

Result The system will update the page with a Financial Entities subsection listing your Financial Entities.

10. Complete the Financial Entities subsection.

For more information on this common element, refer to [Financial Entities](#).

Manually Disclosing Conflict of Interest for a New IRB Protocol

The Manual IRB Protocol **Event Type** is used at institutions where the Streamlyne Research IRB Protocol module is not in use.

1. Streamlyne Research will automatically update the page based on your **Event Type** selection.

Enter the **Protocol Number** for the IRB protocol related to this disclosure.

2. Enter the full title of the related project in the **Protocol Name** field.

3. Click the arrow next to the **Protocol Type** field and select the type from the dropdown list.

4. Click the Add button to complete this section. Add

Result The system will update the page with a Financial Entities subsection listing your Financial Entities.

5. Complete the Financial Entities subsection.

For more information on this common element, refer to [Financial Entities](#).

Manually Disclosing Conflict of Interest for a New IACUC Protocol

The Manual IACUC Protocol **Event Type** is used at institutions where the Streamlyne Research IACUC Protocol module is not in use.
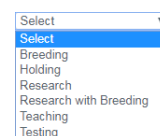
1. Streamlyne Research will automatically update the page based on your **Event Type** selection of Manual IACUC Protocol.

Enter the **IACUC Protocol Number** for the IACUC protocol related to this disclosure.

2. Enter the full title of the related project in the **Protocol Name** field.

3. Click the arrow next to the **Protocol Type** field and select the type from the dropdown list.
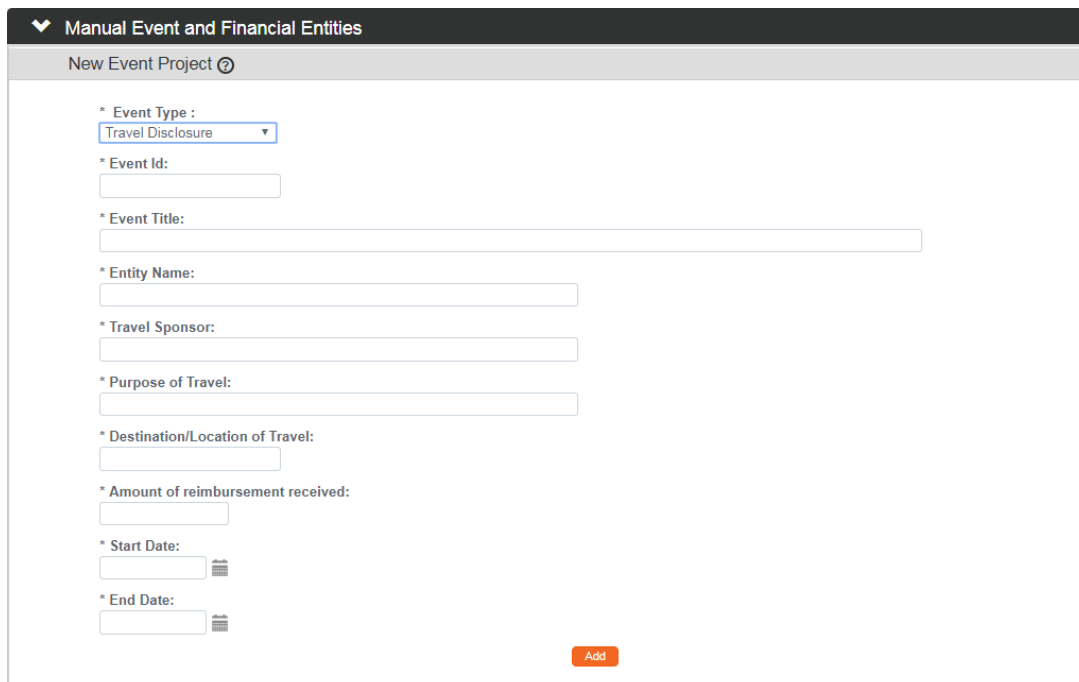
4.   Click the Add button to complete this section.   [Add]

5.   Complete the Financial Entities subsection.

For more information on this common element, refer to <u>Financial Entities</u>.

Manually Disclosing Travel

The Travel Disclosure **Event Type** is the only **Event Type** that is triggered manually in every case.

Follow these steps to complete a Travel Disclosure:

1.   Streamlyne Research will automatically update the page based on your **Event Type** selection of Travel Disclosure.

Enter the **Event ID** according to your institution's numbering convention.

2.   Enter the title of the event you will be traveling to in the **Event Title** field.

3.   Enter the name of the organization sponsoring the event you will be traveling to in the **Entity Name** field.

4.   Enter the name of the organization paying your travel expenses in the **Travel Sponsor** field.

5.   Enter a short description of the reason you are traveling in the **Purpose of Travel** field.

6.	Enter the city and country of your destination in the **Destination/Location of Travel** field.

7.	Enter the dollar value of the reimbursement you will receive for the travel in the **Amount of Reimbursement Received** field.

8.	Enter your departure date in the **Start Date** field in MM/DD/YYYY format or click the calendar icon 🗓 to select the date.

9.	Enter your return date in the **End Date** field in MM/DD/YYYY format or click the calendar icon 🗓 to select the date.

10.	Click the Add button to complete this section. [Add]

Result	The system will update the page with a Financial Entities subsection listing your Financial Entities.

11.	Complete the Financial Entities subsection.

	For more information on this common element, refer to [Financial Entities](#).

Adding Notes & Attachments

For more information on the use of these common elements, refer to [Adding Notes & Attachments](#).

Validating, Certifying and Submitting

For more information on the use of these common elements, refer to [Validating, Certifying and Submitting](#).

Completing Project Disclosures

Process Overview

Project Disclosures are very similar in functionality to Manual Disclosures. The primary difference is that the system will automatically initiate a Project Disclosure based on a set of triggering criteria if that particular module/project is being maintained in Streamlyne Research at your institution.

Triggering a Project Disclosure

Triggering criteria are determined during the analysis phase of your project and configured at the time of installation. Triggering events can include any combination of the following:

- When new Proposal Development documents are first saved to the database and the Proposal Development Document Status is In Progress.
- When existing Proposal Development documents are first submitted into workflow and the Proposal Development Document Status is Approval Pending.
- When existing Proposal Development documents are submitted to the sponsoring agency and the Proposal Development Document Status is Approved and Submitted or Approved Post-Submission.
- When Institutional Proposal documents are first saved to the database and the Institutional Proposal Document Status is Pending.
- When Awards are first saved to the database and the Award Document Status is Pending.
- When Awards are finalized, and the Award Document Status is Final.
- When new IRB and IACUC Protocol documents are first saved to the database and the respective Document Status is Pending/In Progress.
- When IRB and IACUC Protocol documents are first submitted into workflow and the respective Document Status is Submitted to IRB/IACUC.
- When IRB and IACUC Protocol documents are approved and the respective Document Status is Active.

These triggering events generate a COI Project Disclosure document to be completed by each member of the team named in the Key Personnel section of the project: the Principal Investigator, the Co-Investigator, and the Key Persons. If the Key Personnel are changed after Disclosures are first triggered, the system will recognize the change and generate additional Disclosures for new team members when downstream triggering events occur.

Completing Triggered Project Disclosures

When disclosures are triggered and generated for each member of the team named on the Key Personnel section of the project, the system makes an entry on each reporter's New Project Disclosures to Complete Lookup. This Lookup takes the reporter directly to his or her list of unsubmitted project disclosures in order to facilitate easy submission. For more information on this Lookup, refer to New Project Disclosures to Complete.

Once the reporter accesses a Disclosure document, he or she must complete two main tasks: identify any and all significant financial interests (SFIs) and identify the status of any potential conflict of interest that this SFI may or may not generate relative to the project that triggered the Disclosure. This work is reduced if the reporter has chosen to report new SFIs or changes to existing SFIs by keeping his or her Financial Entities documents up to date in Streamlyne Research. When the Financial Entities documents are up to date, the system automatically populates the details of the SFIs, if any, to the Project Disclosure document. When this occurs, the reporter need only specify the nature of the conflict of interest, if any, generated between the SFI and the reporter's role on the project.

Process Diagrams

Delivered Project/Event Triggers for COI Disclosures
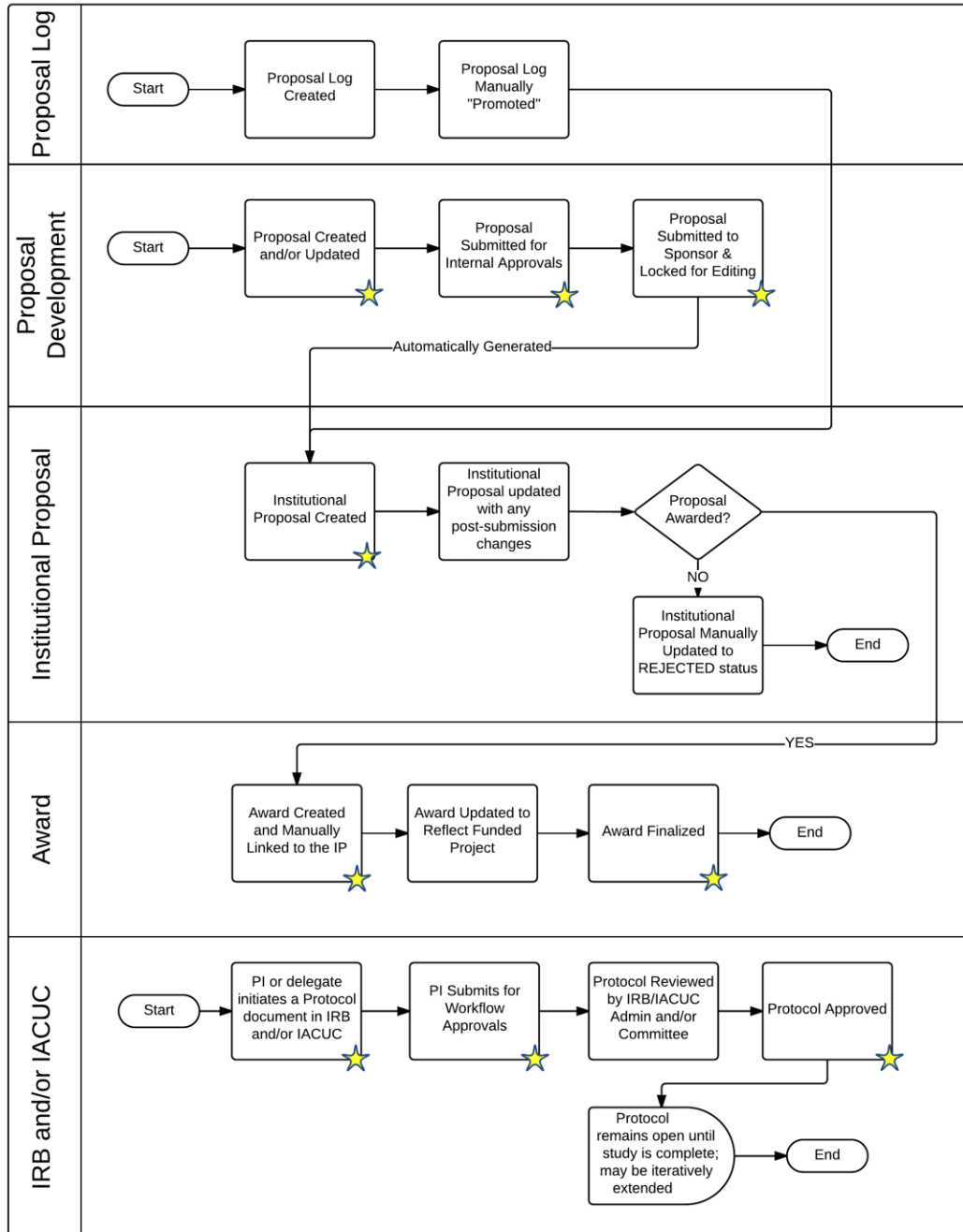
Streamlyne COI Project Disclosure Generation & Submission Processes

Streamlyne Automation

Triggering Event → Does a project disclosure doc exist for each named person? → YES → End

NO ↓

Creates COI Project Disclosure per person → Adds to each Disclosure any/all active SFI's reported on Financial Entities → Adds entry to New Project Disclosures To Complete lookup for each reporter → End

Reporter's Financial Entities

Start → New SFI or changes to exising? → YES → Creates or updates Financial Entity Record for each SFI → Updating as part of Disclosure process? → YES

NO ↓ (from New SFI) → End

NO ↓ (from Updating as part) → End

Reporter's Project Disclosure

Start → Accesses Project Disclosure via New Project Disclosures to Complete lookup → Any SF additions or updates?

YES ↑ (to Creates or updates Financial Entity Record)

NO ↓ → Completes Disclosure: answer COI screening questions and assess potential conflicts → Submits Disclosure to COI Admin → End

Completing Pending Project Disclosures

Navigation	Main Menu > Conflict of Interest > My Disclosures > New Project Disclosures to Complete

Follow these steps to identify and complete any pending Project Disclosures:

1. Streamlyne Research will display all projects with disclosures pending for the signed-on user, grouped together by Event Type.

Click the Report COI button next to the project for which you wish to submit a Project Disclosure.

2. The system will open a document for the selected project with all relevant project data automatically populated. The Project Disclosure will be open to the Disclosure tab.

Complete the Document Overview section. For more information on this common element, refer to the **NEW USER MANUAL: Navigation, the Action List, and Common Document Elements.**

Note The Event Type that precipitated the disclosure will be reflected in the title on the header, as shown here for a Proposal Development document:

Updating Reporter & Screening Data

Disclosure > Reporter > Contact Information

The Contact Information subsection of the Reporter section displays read-only data pulled from the signed-on user's Person record. If the data in this section is incorrect, contact a Streamlyne Administrator.

Disclosure > Reporter > Unit Details

If you find that you need to edit the defaulted Unit data, refer to Disclosure > Reporter > Unit Details.

Disclosure > Screening Questionnaire

For more information on the use of this common element, refer to Disclosure > Screening Questionnaire.

Disclosure > Questionnaire

For more information on the use of this common element, refer to Disclosure > Questionnaire.

Updating Project & Financial Entity Relationships

1. Click the header to expand the Project & Financial Entity Relationships section.

Note The identifying information for the project (the Proposal, Award, or Protocol) that triggered the disclosure is displayed first. This data is not editable.

All previously reported financial entities are automatically included in this section as well, providing those relationships are still active. Any deactivated relationships with financial entities are excluded. Refer to Deactivating a Relationship with a Financial Entity for more information on this action.

2. If you need to report a new relationship with a financial entity, click the New Financial Entity button.

If all your existing relationships with financial entities are already listed in this subsection, skip to Step 4.

3. Streamlyne Research will open a new Financial Entities document on a new page. Return to Adding a New Financial Entity and follow the steps in this section to report this new relationship. Once you submit the new Financial Entity, you will then be redirected back to the Disclosure document. The Financial Entity you added will now appear.

4. Click the header to expand the Project & Financial Entity Relationships section.

5. For each entity listed, click the arrows next to the corresponding **Related** field, and then select an option that best represents the entity's conflict-of-interest status relative to the project that triggered the disclosure.

6. Click the Save button at the bottom of the page to save the changes.

7. To view read-only data previously reported for an entity listed in this section, click the View Entity button   to access a pop-up window.

    Otherwise, proceed to Step 8.

8. To review the history of entries for an entity, click the History button.   History

    Otherwise, proceed to Step 9.

9. To make changes to an existing entity click the Edit button to open the applicable Financial Entities document on a new page.   Edit

    See Editing an Existing Financial Entity and follow the steps in this section to edit the information on this Entity. Once you submit the edits to the Financial Entity, you will then be redirected back to the Disclosure document. The Financial Entity you edited will now appear and will reflect the changes made.

Adding Notes & Attachments

For more information on the use of these common elements, refer to Adding Notes & Attachments.

Validating, Certifying and Submitting

For more information on the use of these common elements, refer to Validating, Certifying and Submitting.

Completing Annual Disclosures

The Annual Disclosure document can be used in lieu of Project and Manual/Travel Disclosures or in conjunction with them. For institutions that do not require project/event-based disclosures, Annual Disclosures are used to collect conflicts of interest data from all or part of the faculty on an annually scheduled basis.

Streamlyne COI can be configured to accommodate a variety of institutional preferences for sending out Annual COI Disclosure due date reminders that fall into four general scenarios:

Reminder notifications may be sent to investigators for Annual COI Disclosures due:

1. on one specific date set by the institution each year;
2. on initial hire dates and on one specific date set by the institution each year;
3. on a specific date set individually by each departmental unit each year; or
4. on initial hire dates and on a specific date set individually by each departmental unit each year.

Configurations are detailed in the **Annual COI Disclosure Reminder Documentation**.

For institutions that do require project/event-based disclosures, the Annual Disclosure document aggregates all Project and Manual/Travel disclosures submitted from any given reporter within the last 365 days, providing an opportunity for the reporter to verify or update the information previously submitted. Annual Disclosure documents can also be used to catch conflicts of interest from reporters who may not have had any active projects within the last rolling calendar year.

The process for completing an Annual Disclosure is very similar to a Manual or Project Disclosure. Consequently, the instructions that follow may seem repetitive in places.

Initiating an Annual Disclosure

Navigation	**Main Menu > Conflict of Interest > My Disclosures > Annual Disclosure > +**

Follow these steps to initiate an Annual Disclosure:

1.   Streamlyne Research will open a document for the selected project with all active Project/Event Disclosure data automatically populated. The Annual Disclosure will be open to the Disclosure tab.

Complete the Document Overview section. For more information on this common element, refer to the **NEW USER MANUAL: Navigation, the Action List, and Common Document Elements.**

Updating Reporter & Screening Data

Disclosure > Reporter > Contact Information

The Contact Information subsection of the Reporter section displays read-only data pulled from the signed-on user's Person record. If the data in this section is incorrect, contact a Streamlyne Administrator.

Disclosure > Reporter > Unit Details

If you find that you need to edit the defaulted Unit data, refer to Disclosure > Reporter > Unit Details.

Disclosure > Screening Questionnaire

For more information on the use of this common element, refer to Disclosure > Screening Questionnaire.

Disclosure > Questionnaire

For more information on the use of this common element, refer to Disclosure Questionnaire.

Updating Disclosed Projects

Reviewing & Updating Existing Disclosed Project Data

The Disclosed Projects section contains all Manual and Project Disclosures generated for the reporter.

1. Click the header to expand the Disclosed Projects section.

Note The identifying information for each project or event (Proposal, Award, Protocol or Travel Disclosure) submitted by the reporter is grouped into collapsed subsections. The identifying information for the project or event is not editable.

If you prefer to view this information grouped by linked Financial Entities, click the Group by Financial Entities button.

Once here, if you would prefer to return to the defaulted page view, click the Group by Projects button.

2. Click the Show button to access the first Project/Event Disclosure.

3. Streamlyne Research displays additional details from the Project/Event Disclosure document, along with collapsed subsections containing the completed Questionnaire and linked Financial Entities data.

If you wish to review or update the Questionnaire responses for this Project/Event Disclosure, click the Show button next to the Questionnaire subsection.

Otherwise, skip to Step 6.

4.   Make any changes to the responses.

5.   Click the Save button at the bottom of the page to save the changes.   `Save`

6.   Click the Show button to access the linked Financial Entities for this Project/Event Disclosure.   `Show` Financial Entities

	Review		Entity	Related
	Hide	Financial Entities		
1	View Entity	History	Amgen, Inc.	Awaiting Additional Information
2	View Entity	History	GlaxoSmithKline	Awaiting Additional Information

7.   The system displays the Financial Entity data reported on the original Project Disclosure.

For each entity listed, click the arrow next to the corresponding **Related** field, and then select an option that best represents the entity's conflict-of-interest status relative to the project.

> select
> No Conflict Exists
> Potential Relationship
> Relationship Identified

Note   If you need to report a new financial interest with a previously unreported entity, click the New Financial Entity button and refer to [Creating a New Financial Entity](#).

8.   Click the Save button at the bottom of the page to save the changes.   `Save`

9.   To view read-only data previously reported for an entity listed in this section, click the View Entity button to access a pop-up window.   `View Entity`

Otherwise, proceed to Step 10.

10.   To review the history of entries for an entity, click the History button.   `History`

Otherwise, proceed to Step 11.

11.   To make changes to an existing entity click the Edit button to open the applicable Financial Entities document on a new page.   `Edit`

See [Editing an Existing Financial Entity](#) and follow the steps in this section to edit the information on this Entity. Once you submit the edits to the Financial Entity, you will then be redirected back to the Disclosure document. The Financial Entity you edited will now appear and will reflect the changes made.

Adding a New Financial Entity to the Disclosed Project Section

1.   If you have not already done so, click the header to expand the Disclosed Projects section.   ❯ Disclosed Projects

2.   If you have not already done so, click the Show button to access the Project/Event Disclosure to which you wish to add a Financial Entity.

	Event
Show	Travel Disclosure
Show	Proposal

3.   Click the New Financial Entity button.   `New Financial Entity`

4.   Streamlyne Research will open a new Financial Entities document on a new page. Return to <u>Creating a New Financial Entity</u> and follow the steps in this section to report this new relationship. Once you submit the new Financial Entity, you will then be redirected back to the Disclosure document. The Financial Entity you added will now appear.

5.   Return to <u>Reviewing & Updating Existing Disclosed Project Data</u> and complete the steps outlined in this section.

Adding Notes & Attachments

For more information on the use of these common elements, refer to <u>Adding Notes & Attachments</u>.

Validating, Certifying and Submitting

For more information on the use of these common elements, refer to <u>Validating, Certifying and Submitting</u>.

Completing Master Disclosures

While Annual Disclosures aggregate all active Project/Event and Manual Disclosures from the last rolling calendar year, Master Disclosure documents aggregate all conflict data ever recorded for any given reporter on Manual and Project/Event Disclosures into a single document regardless of active/inactive status and submission date.

Some institutions may choose not to require faculty to review and update Master Disclosures when employees routinely submit Annual Disclosures. Other institutions may not use Annual Disclosures and therefore may use Master Disclosures to update or verify conflict of interest data before releasing funding for a project for the next funding cycle. Therefore, Master Disclosures can be used any time an institution may have a need for employees to verify and update their conflict of interest data that was previously reported.

Accessing the Master Disclosure

Navigation	Main Menu > Conflict of Interest > My Disclosures > Master Disclosure > +

1. Streamlyne Research will open a document for the signed-on user with all previously submitted Project/Event Disclosure data automatically populated, regardless of whether the Project/Event is still active. The Master Disclosure will be open to the Disclosure tab.

   Complete the Document Overview section. For more information on this common element, refer to the **NEW USER MANUAL: Navigation, the Action List, and Common Document Elements**.

Updating Reporter & Screening Data

Disclosure > Reporter > Contact Information

The Contact Information subsection of the Reporter section displays read-only data pulled from the signed-on user's Person record. If the data in this section is incorrect, contact a Streamlyne Administrator.

Disclosure > Reporter > Unit Details

If you find that you need to edit the defaulted Unit data, refer to [Disclosure > Reporter > Unit Details](#).

Disclosure > Screening Questionnaire

For more information on the use of this common element, refer to [Disclosure > Screening Questionnaire](#).

Disclosure > Questionnaire

For more information on the use of this common element, refer to [Disclosure > Questionnaire.](#)

Updating Disclosed Projects

Reviewing & Updating Existing Disclosed Project Data

The Disclosed Projects section contains all Manual and Project Disclosures previously submitted by the reporter.

1.   Click the header to expand the Disclosed Projects section.

Note   The identifying information for each project or event (Proposal, Award, Protocol or Travel Disclosure) submitted by the reporter is grouped into collapsed subsections. The identifying information for the project or event is not editable.

If you prefer to view this information grouped by linked Financial Entities, click the Group by Financial Entities button.

Once here, if you would prefer to return to the defaulted page view, click the Group by Projects button.

2.   Click the Show button to access the first Project/Event Disclosure.

Hide	Travel Disclosure	5	Travel to San Diego	Awaiting Additional Information	Approved

Event Id: 5 ⊙   Disposition: Awaiting Additional Information

Event Title:	Travel to San Diego	Entity Name:	Amgen
Destination/Location of Travel:	San Diego, CA	Travel Sponsor:	Amgen
Purpose of Travel:	Keynote Speaker	Amount of reimbursement received:	2000.00
Start Date:	04/01/02015	End Date:	04/03/02015

3. Streamlyne Research displays additional details from the Project/Event Disclosure document, along with collapsed subsections containing the completed Questionnaire and linked Financial Entities data.

If you wish to review or update the Questionnaire responses for this Project Disclosure, click the Show button next to the Questionnaire subsection.

`Show` Additional Questions for Travel Disclosure (Complete)

Otherwise, skip to Step 6.

4. Make any changes to the responses.

5. Click the Save button at the bottom of the page to save the changes. `Save`

6. Click the Show button to access the linked Financial Entities for this Project/Event Disclosure.

`Show` Financial Entities

	Review		Entity	Related
	Financial Entities			
1	View Entity	History	Amgen, Inc.	Awaiting Additional Information
2	View Entity	History	GlaxoSmithKline	Awaiting Additional Information

7. The system displays the Financial Entity data reported on the original Project Disclosure.

For each entity listed, click the arrows next to the corresponding **Related** field, and then select an option that best represents the entity's conflict-of-interest status relative to the project.

select ▾
select
No Conflict Exists
Potential Relationship
Relationship Identified

Note If you need to report a new financial interest with a previously unreported entity, skip to Adding a New Financial Entity to the Disclosed Project Section.

8. Click the Save button at the bottom of the page to save the changes. `Save`

9. To view read-only data previously reported for an entity listed in this section, click the View Entity button to access a pop-up window. `View Entity`

Otherwise, proceed to Step 10.

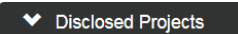**10.** To review the history of entries for an entity, click the History button. `History`

Otherwise, proceed to Step 11.

11. To make changes to an existing entity click the Edit button to open the applicable Financial Entities document on a new page. `Edit`

See Editing an Existing Financial Entity and follow the steps in this section to edit the information on this Entity. Once you submit the edits to the Financial Entity, you will then be redirected back to the Disclosure document. The Financial Entity you edited will now appear and will reflect the changes made.

Adding a New Financial Entity to the Disclosed Project Section

1. If you have not already done so, click the header to expand the Disclosed Projects section.

2. If you have not already done so, click the Show button to access the Project/Event Disclosure to which you wish to add a Financial Entity.

3. Click the New Financial Entity button. `New Financial Entity`

4. Streamlyne Research will open a new Financial Entities document on a new page. Return to Updating Adding a New Financial Entity and follow the steps in this section to report this new relationship. Once you submit the new Financial Entity, you will then be redirected back to the Disclosure document. The Financial Entity you added will now appear.

5. Return to Reviewing & Updating Existing Disclosed Project Data and complete the steps outlined in this section.

Adding Notes & Attachments

For more information on the use of these common elements, refer to Adding Notes & Attachments.

Validating, Certifying and Submitting

For more information on the use of these common elements, refer to Validating, Certifying and Submitting.

III. For Departmental Reviewers & Approvers

Based on your institution's specific Policies & Procedures, Principal Investigators, Department Chairs, College Deans, administrators, or other institutional officials may be required to review COI disclosures in a hierarchy prior to final submission to the COI Office. To facilitate this process, Streamlyne Research routes submitted disclosures to the appropriate Action Lists of those specified in your institution's COI workflow configuration for review and approval.
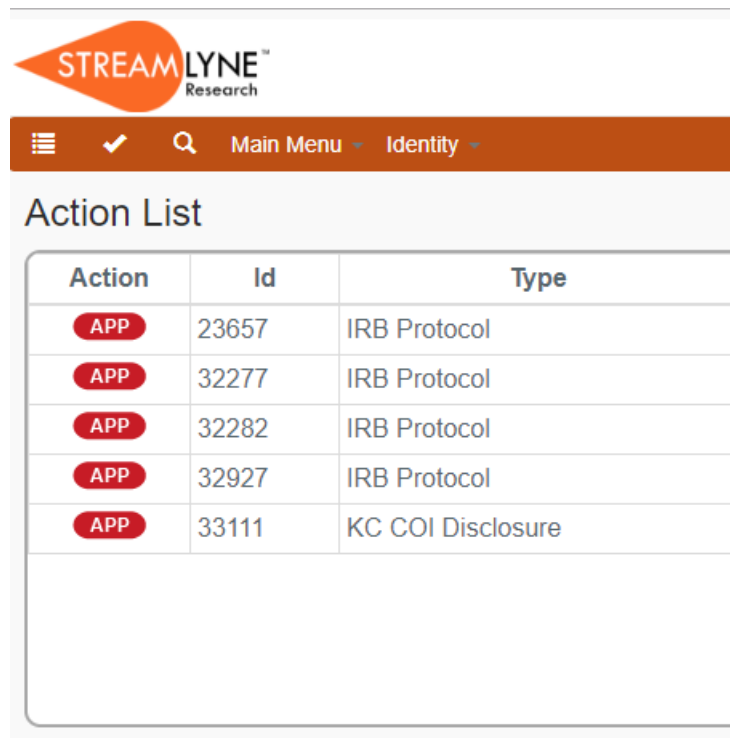
A typical approval progression might route a COI disclosure from the Department Administrator to the PI, the Department Chair, and perhaps even to the Dean before a COI Administrator will take action on the disclosure. Departmental reviews are configurable and optional. If your institution has chosen to route submitted COI disclosures through Chairs and Deans, follow the steps included in this section to complete those reviews.

Section III Contents

Reviewing and Approving Disclosures in Workflow

This section will describe the steps to review and approve a COI disclosure for departmental and other institutional reviewers and approvers. These users will typically have read-only access to the disclosure to enable them to review the information before taking approval action.
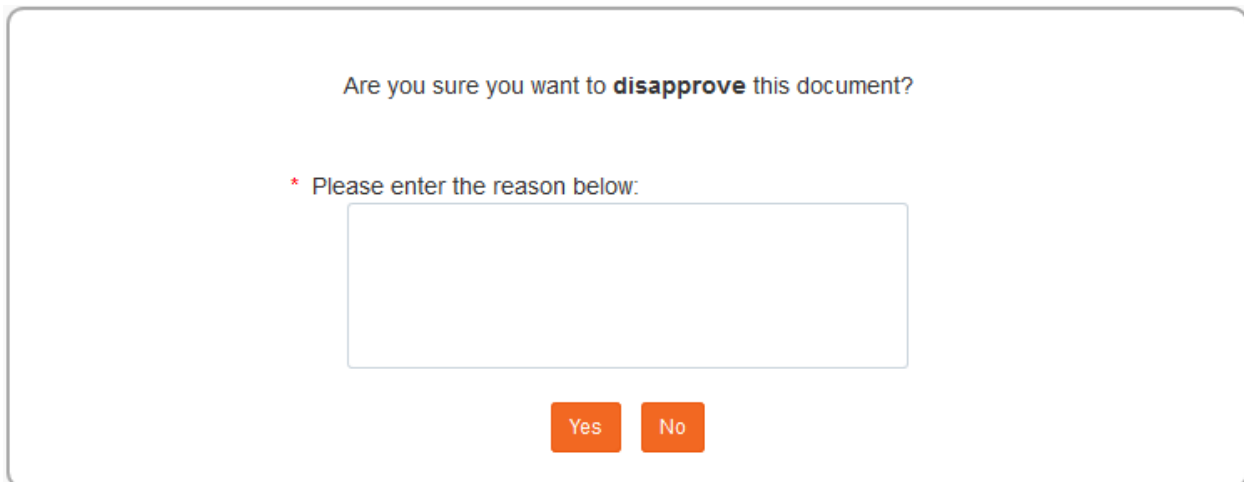
1.   Access your Action List by clicking the Action List button ▤ on the Menu Bar.

2.   Documents requiring your approval will be noted with the Approval symbol in the Action column.

      Click the hyperlinked Document ID number in the Id column to open the document in a new browser tab.

3.   Drill into as many tabs and sections as necessary to fully review the document according to your institution's procedures. You may want to familiarize yourself with COI disclosure documents and how a Reporter prepares and submits a new disclosure by referencing the For COI Reporters section.

4. When you are ready to execute an action, click the Disclosure tab header.

`Disclosure`

5. If you wish to approve submission to the COI Office, click the Approve button located at the bottom of the page. Otherwise, skip to the next Step.

`Approve`

Result If you have selected Approve, the document will be routed to the next user in the workflow.

6. If you wish to disapprove submission to the COI Office, click the Disapprove button located at the bottom of the page.

`Disapprove`

Are you sure you want to **disapprove** this document?

* Please enter the reason below:

`Yes` `No`

7. If you are sure you want to disapprove, enter explanatory comments in the field provided and continue to the next Step. Otherwise skip to Step 9.

8. Click the Yes button.

`Yes`

9. Click the No button to return to the protocol without disapproving.

`No`

10. If you are ready to approve the protocol, click the Approve button located at the bottom of `Approve` the page.

Result If you have selected Approve, the document will be routed to the next user in the workflow.

IV. For COI Reviewers

The fourth section provides a step-by-step guide for reviewers to prepare, review, and submit assigned disclosure reviews online.

Section IV Contents

Completing an Assigned COI Review

When the COI Administrator assigns a Disclosure to a designated COI Reviewer, Streamlyne Research notifies the assignee that he or she has a Disclosure Review to complete.

Follow the instructions in this section to complete a review of a Disclosure that has been assigned to you by the COI Administrator.

Accessing an Assigned Review

Follow these steps to access a Disclosure assigned to you for review:

1.   Working from your Action List, find the FYI Notification with a **Title** of Reviewer Assigned and click the Show button.

2.   Click the hyperlinked Document ID number within the message content.

> **Title:** Reviewer Assigned
> **Content:**
> You have been Assigned as a reviewer for disclosure number 1000016593

Result   Streamlyne Research displays the document open to the Disclosure tab.

Performing an Online Review

Follow these steps to begin an online review:

1.   Working from the Disclosure tab, review all Project/Event and Financial Entities data. Drill into as many tabs and sections as necessary to fully review the document according to your institution's procedures. You may want to familiarize yourself with COI disclosure documents and how a Reporter prepares and submits a new disclosure by referencing the For COI Reporters section.

2. When you are ready to record your findings, click the tab header on the left-hand menu to access the Disclosure Actions tab.

Disclosure Actions

3. Click the header to expand the Reviewer Actions section.

❯ Reviewer Actions

Adding Reviewer Notes

❯ Reviewer Actions
    Notes (1) ⓘ

Add
* Note Topic
[   ] 🔲

Note Type
[Reviewer Comment ▾]

Project Name
[Alicia's Demo ▾]

Financial Entity
[select   ▾]

Restricted View
☐

* Comments
[   ] ✏️

[Add]

Follow these steps to add a Reviewer note associated with the Disclosure:

1. Enter a short description of the note in the **Note Topic** field.

2. The **Note Type** defaults to Reviewer Comment. If this is not correct for any reason, click the arrow next to the **Note Type** field and select the appropriate option from the dropdown list.

[Reviewer Comment ▾]
select
PI Entry
Reviewer Comment
COI Officer

3. If the note refers to a specific project, identify this project by clicking the arrow next to the **Project Name** field and selecting the appropriate project from the dropdown list.

4. If the note refers to a specific **Financial Entity,** identify the entity by clicking the arrow next to the field and selecting the entity name from the dropdown list.

5. Enter the note itself in the **Comments** field.

You may do this by hand keying the text directly into the freeform text field, by copying and pasting from a source document, or by clicking the pencil icon ✏️ to open a text editor in a pop-up window.

6. If only COI Administrators should be allowed to view the note, click the **Restricted View** checkbox.

7. Click the Add button to attach the note. [Add]

Result Once you have attached a note, the contents will be displayed in the Notes subsection and the total number of notes attached to the document will be reflected in the subheader title bar within parentheses.

Notes (1) ⓘ

Editing or Deleting an Existing Note

Follow these steps to edit a note:

1. Working from the Reviewer Actions section, click the Edit button that corresponds to the note you wish to edit. Edit

Note Unless you also have COI Administrator privileges, you will not be able to edit a note that you did not create.

2. The system will open all the note fields for you to change.

Make any changes as necessary.

3. Click the Save button at the bottom of the page to save the changes. Save

Result Once saved, the fields will return to read-only status and the Updated By information will reflect the username and the date/timestamp of the change.

Follow these steps to delete a note:

1. Working from the Reviewer Actions section, click the Delete button that corresponds to the note you wish to delete. Delete

Note Unless you also have COI Administrator privileges, you will not be able to delete a note that you did not create.

2. The system will prompt you to confirm the action.

Click the Yes button to proceed or click the No button to cancel.

Are you sure you would like to delete this note?

Yes No

Accessing Other Reviewer's Notes

When the COI Administrator assigns more than one reviewer to a Disclosure document, each reviewer has access to the content of the other reviews as they are completed. If another reviewer has added Notes, you will be able to find these listed in the Notes section of your

Reviewer Actions panel. The notes will display in chronological order based on their creation date, with the username of the creator clearly indicated, as shown in the screenshot:

Uploading a New Review Attachment

Follow these steps to upload a new attachment to the Disclosure Review:

1.   Working in the New Attachment subsection of the Reviewer Action section, click the arrow next to the **Attachment Type** field and select the appropriate option from the dropdown list.

2.   Enter the name of the person uploading the attachment in the Contact Name field, if other than yourself.

3.   Click the arrow next to the Project field to select the project name from the dropdown list, if applicable.

4.   Click the arrow next to the Financial Entity field to select the entity's name from the dropdown list, if applicable.

5.   Enter contact information in the Email and/or Phone fields, if someone other than you uploaded the attachment.

6.   Enter optional **Comments** to be preserved for future reference.

7.   Enter a summary or description of the attachment's contents in the **Description** field.

8.   To upload the file, click the Choose File button next to **File Name.** Complete this action by following your operating system's prompts.

9.   Click the Add button to attach the file to the Disclosure Review.   `Add`

Result   The system will append an Attached Items subsection with the total number of attachments reflected within parentheses on the title bar.

`Attached Items (1) ⊚`

Filtering, Viewing, Editing, Replacing and Deleting Attachments
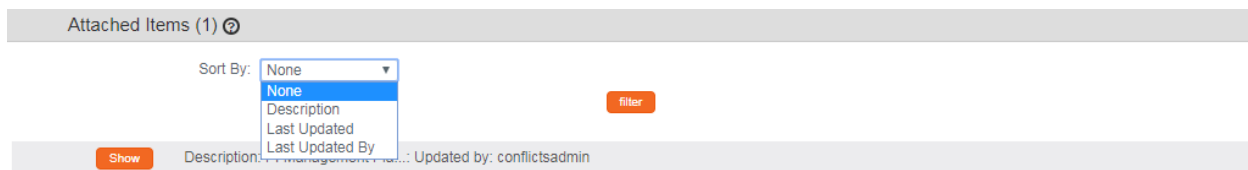
Streamlyne Research provides filtering options to manage the way attachments are displayed.

Follow these steps to filter the attachment list:

1.   Working within the Attached Items subsection, click the arrow next to the **Sort By** fields and select the filtering option from the dropdown list.

2.   Click the Filter button to sort the list of attachments according to your selection.   `filter`

Note   Streamlyne Research displays each attachment's details as a collapsed subsection with the attachment's details displayed in the title bar according to the following naming convention: Description: File Name: Updated By: username.

* Attachment Type :	Management Plan ▼		
Contact Name :	Conflicts Administrator	Project: Alicia's Demo	Financial Entity: Apple Computer
Uploaded By :	conflictsadmin	Email :	
Posted Timestamp :	07/09/2018 06:25 AM	Phone :	
Comments :		* Description : Description	
* File Name :	PI Management Plan.docx		

view   replace   delete

Follow these steps to view an attachment:

1. Click the Show button that corresponds to the attachment you wish to view. `Show`

2. Streamlyne Research displays the attachment's details. These fields may or may not be editable based on your permissions.

Click the View button. `view`

3. Save or open the download by following your browser's prompts.

Follow these steps to edit the details of an attachment file:

1. If you haven't already done do, click the Show button that corresponds to the attachment you wish to edit. `Show`

Note Unless you also have COI Administrator privileges, you will not be able to edit the details for an attachment that you did not upload.

2. Streamlyne Research displays the attachment's details. These fields may or may not be editable based on your permissions.

If these fields are editable, make changes as necessary.

3. Click the Save button at the bottom of the page to save the changes. `Save`

Follow these steps to replace an attached file with a new version:

1. If you haven't already done do, click the Show button that corresponds to the attachment you wish to replace. `Show`

Note Unless you also have COI Administrator privileges, you will not be able to replace an attachment that you did not upload.

2. Streamlyne Research displays the attachment's details.

Click the Replace button. `replace`

Note   Clicking the Replace button effectively deletes the existing attachment without warning. Take care not to click the Replace button without preserving the existing attachment if necessary.

3.   Streamlyne Research makes the Choose File button available next to the **File Name** field.

4.   To upload the file, click the Choose File button next to **File Name.** Complete this action by following your operating system's prompts.

5.   Click the Save button at the very bottom of the page to save the replacement file to the existing attachment record.   Save

Follow these steps to delete an attachment:

1.   If you haven't already done so, click the Show button that corresponds to the attachment you wish to replace.   Show

Note   Unless you also have COI Administrator privileges, you will not be able to delete an attachment that you did not upload.

2.   Streamlyne Research displays the attachment's details.

Click the Delete button.   Delete

3.   The system will prompt you to confirm the action.

Click the Yes button to proceed or click the No button to cancel.   Yes No

Accessing Other Reviewer's Attachments

When the COI Administrator assigns more than one reviewer to a Disclosure document, each reviewer has access to the content of the other reviews as they are completed. If another reviewer has added attachments, you will be able to find these listed in the Attachments section of your Reviewer Actions panel.

Unless you have COI Administrator privileges, you will not be able to alter the content of other reviewer's attachment, but you will be able to view the content of the attachments. Use the steps outlined here to view an attachment uploaded by another reviewer:

1.   Click the Show button that corresponds to the attachment you wish to view.   Show

2.   Streamlyne Research displays the attachment's details. These fields may or may not be editable based on your permissions.

Click the View button.   view

3.   Save or open the download by following your browser's prompts.

Recommending an Action

	Complete Review ⓘ				
	Full Name	**Reviewer Type**	**Lead Unit**	**Date Assigned**	**Recommended Action**
1	Mary Reviewer	Assigned Reviewer (RVW)	Criminal Justice (102010)	2015-09-23	select ▾
2	Randy Reviewer	Assigned Reviewer (RVW)	Medicine (105020)	2016-12-20	select ▾

submit

To complete your review of the disclosure, follow these steps to recommend an action to the COI Administrator:

Note   All Recommended Actions submitted using the steps below will be visible to any other reviewers assigned to this Disclosure, as well as to the COI Administrator.

1.   Working from the Complete Review subsection of the Reviewer Actions section, click the arrow beneath the **Recommended Action** field and select your recommendation from the dropdown list.

select
Recommend Approve - No Conflict
Recommend Further Review
Recommend Management Plan

2.   Click the Submit button to finalize your review.   Submit

Result   If you are the only reviewer, or if all other reviews are also complete, the Disclosure's Review Status is updated to Assigned Review Complete and the document becomes read-only for all users except the COI Administrator.

An FYI Notification will be sent to the COI Administrator notifying him or her that you have completed your review, as shown here:

	FYI	26447	Streamlyne Research Notification	Assiged Review Complete	FINAL	06:33 AM 07/09/2018	NONE ▾
Hide							

Id: 2810
From: conflictsadmin
Recipients: conflictsadmin , conflictsadmin2 , conflictsdirector
Channel: Notification Channel
Producer: Notification System
Type: FYI
Priority: Normal
Send Date: 2018-07-09T06:33:40.000-07:00
Removal Date: none

Title: Assiged Review Complete
Content:

The disclosure status has been changed to "Assigned Review Complete" for:
Disclosure Number: 1000014481
Disclosure Status: Routed for Review
Disclosure By: Conflicts Administrator
Thank you

FYI

V. For COI Administrators

This section reviews the various administrative functions delivered with the Streamlyne Research Conflict of Interest module. The processes documented in this section require that the COI Administrator role be included in a user's Streamlyne Research permissions.

Section V Contents

Administering Financial Entities

A reporter can document significant financial interests (SFIs) on a new Financial Entities document at any time. Generally, these records are not of interest to a COI Administrator until the SFI is evaluated for conflicts relative to research projects, travel events, or other types of Manual Disclosures. Given this, new Financial Entities documents need not be reviewed or approved by COI Administrators until they are linked to Disclosure documents.

The system does deliver notification functionality that generates an FYI Notification to COI Administrators each time a new Financial Entities document is submitted. These notifications are optional.

A sample notification is included here:

Administering Disclosures

Administrative features for Disclosures fall into two main categories: pre-submission and post-submission. Pre-submission features help COI Administrators to be sure that all triggered disclosures are completed. The Unsubmitted Project Disclosures Lookup provides administrators with a snapshot of all reporters who have yet to submit triggered Project Disclosure documents. The administrator can then choose to escalate some or all the Disclosures via an internally defined process, depending on each reporter's circumstances. For more information on the Unsubmitted Project Disclosures Lookup, refer to [Unsubmitted Project Disclosures](#).
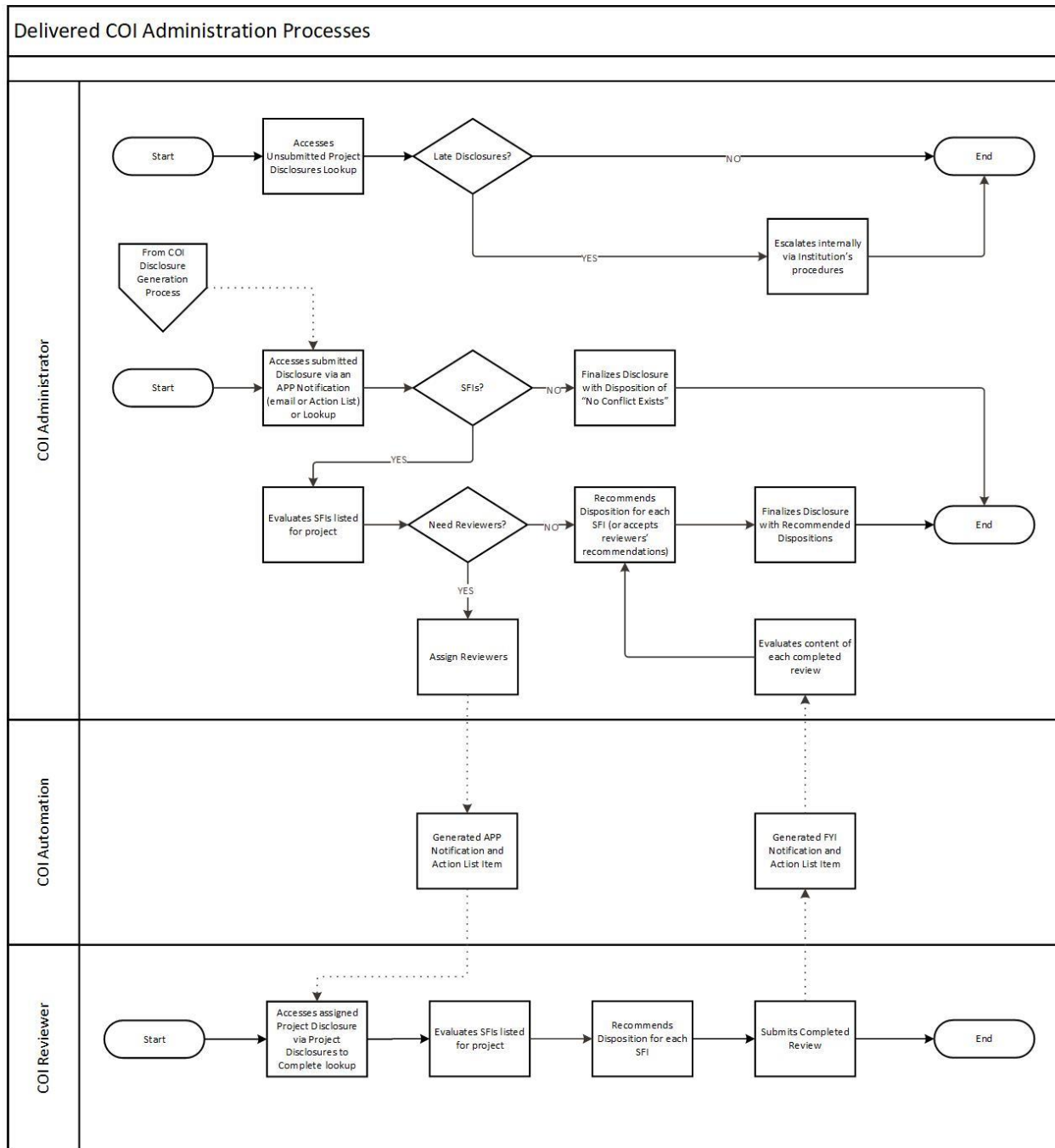
Post-submission administrative features facilitate the review and finalization processes for Disclosure documents. Disclosures with no SFIs can be quickly reviewed and finalized by the COI Administrator, while more complex cases can be optionally assigned to one or more reviewers by the COI Administrator. In fact, one nice feature that adds efficiency to the COI review process is Streamlyne's Auto-Approval functionality. At many institutions, most investigators either have no significant financial interests to report or they have no conflicts of interest to disclose. In these cases, Streamlyne can Auto-Approve these COI Disclosures where No Conflict Exists so that the COI Administrators do not have thousands of COI Disclosures to approve when there are really no concerns. Note that with Streamlyne Reporting, these Auto-Approved COI Disclosures can be readily audited on a periodic basis.

Reviewers are notified via email and an Action List Item that a Disclosure has been assigned to them for review. Both options contain hyperlinks that will take the reviewer directly to the disclosure. Reviewers have access to all Disclosure data for which they are assigned to review. Notes, attachments, and recommended dispositions logged during reviews are available in read-only form to all other reviewers to facilitate collaboration. When a reviewer indicates that a review is complete, the COI Administrator is notified via email and an Action List Item. Instructions for completing COI Reviews will be covered in Completing an Assigned Review.

The COI Administrator can edit or change any submitted review in order to correct administrative errors or move the Disclosure along when a reviewer is unable to complete the work. Whether the reviews were completed with or without intervention, the COI Administrator will review the content of the reviews and render a final disposition for each SFI relative to the project. If more than one SFI is listed on the Disclosure, the most severe disposition logged becomes the overall disposition for the Disclosure document at the point that the COI Administrator finalizes the Disclosure.

Regardless of the severity of the Disclosure's disposition, the decision to withdraw any related project falls exclusively under the purview of the institution's internal guidelines and procedures. Streamlyne Research does not automatically enforce any business rules after the Disclosure is initially created.

Process Diagram

Delivered COI Administration Processes

COI Administrator

Start → Accesses Unsubmitted Project Disclosures Lookup → Late Disclosures? → NO → End

Late Disclosures? → YES → Escalates internally via Institution's procedures → End

From COI Disclosure Generation Process

Start → Accesses submitted Disclosure via an APP Notification (email or Action List) or Lookup → SFIs? → NO → Finalizes Disclosure with Disposition of "No Conflict Exists" → End

SFIs? → YES → Evaluates SFIs listed for project → Need Reviewers? → NO → Recommends Disposition for each SFI (or accepts reviewers' recommendations) → Finalizes Disclosure with Recommended Dispositions → End

Need Reviewers? → YES → Assign Reviewers

Evaluates content of each completed review → Recommends Disposition for each SFI

COI Automation

Generated APP Notification and Action List Item

Generated FYI Notification and Action List Item

COI Reviewer

Start → Accesses assigned Project Disclosure via Project Disclosures to Complete lookup → Evaluates SFIs listed for project → Recommends Disposition for each SFI → Submits Completed Review → End

Accessing Submitted Disclosures

There are multiple ways for a COI Administrator to access Disclosure documents submitted for review.

Follow these steps to access a submitted disclosure from your Action List:

| APP | 5900 | COI Disclosure | COI Disclosure - new | ENROUTE | 10:58 PM 11/21/2014 |

1.   Find the APP item on your Action List with a **Type** of COI Disclosure.

2.   Click the hyperlinked Document Id.

Result   Streamlyne Research will display the Disclosure document open to the Disclosure tab.

Follow these steps to access a submitted Disclosure using a Lookup:

1.   Navigate to Main Menu > Conflict of Interest > Submitted Disclosures.

2.   Streamlyne Research displays the COI Submitted Disclosure Lookup.

Enter criteria to narrow your search and click the Search button. ▩

3.   From the list of search results, click the open hyperlink associated with the submitted disclosure you wish to access.

Result   Streamlyne Research will display the Disclosure document open to the Disclosure tab.

Using Administrator Actions

Accessing the Administrator Action Section

The Administrator Action section of the Disclosure Actions tab houses everything an administrator needs to make decisions and/or take action on any given Disclosure.

Follow these steps to access this section:

1. From within a submitted Disclosure, click on the tab header on the left-hand menu to access the Disclosure Actions tab.

2. Click on the header to access the Administrator Actions section.

Reviewing Disclosures from the Administrator Action Section

Follow these steps to review the reported data from the Administrator Action section:

1. Working from the Financial Entity Status Review subsection of the Administrators Actions section, click the Show button to expand the Details subsection for the first project.

Note If you are reviewing a Manual or Project Disclosure, there will only be one project listed in the Financial Entity Status Review subsection.

If you are reviewing a Master or Annual Disclosure, there will very likely be multiple projects listed here. If you prefer to view this information grouped by linked Financial Entities, click the Group by Financial Entity button.

Once here, if you would prefer to return to the defaulted page view, click the Group by Projects button.

2. Review the details of the project or event.

3. Click the Show button next to the Financial Entities section to review the reported financial interests that may conflict with this project or event.

	Active Entities	Last Updated	Updated By	Recommended Status
1	Amgen, Inc.	2018-07-03 08:17:34.138	conflictsadmin	No Conflict Exists ▾
2	GlaxoSmithKline	2018-07-03 08:17:34.138	conflictsadmin	Potential Relationship ▾

Note Streamlyne Research displays all the Financial Entities linked to the project or event along with the Recommended Statuses suggested by the Reporter.

In many cases, a reporter will have no SFIs to disclose, so no financial entities will be listed in this section. In this case, it is easy to render a decision. More complicated cases may be assigned to a reviewer and/or a committee for an in-depth review.

4. For the first Financial Entity listed, click the arrow next to the **Recommended Status** field and select the most appropriate option from the dropdown list, whether it is the same or different from what the Reporter recommended.

Note that COI Administrator has more status options available to label a reporter's financial relationship than an assigned reviewer does. In addition, the status options on the dropdown are configurable and may be changed per your institution's language and business practices.

```
select
In progress
Exempt
Project Level Approval
No Conflict Exists
No Further Action
Best Practices Memo
Disclosed Interests Eliminated
Disclosed Interests Reduced
Disclosed Interests Managed
Submitted for Review
Under Review by COI Reviewer
Under COI Office Review
Under COI Committee Review
Awaiting Additional Information
Potential Relationship
Relationship Identified
Reviewer Identified Conflict
Unresolved
Disclosed Interests Unmanageable
```

5. Repeat Step 4 for any additional Financial Entities associated with the project.

6. Repeat Steps 1 through 5 for all remaining projects or events on the Disclosure.

7. Click the Save button at the bottom of the page to save the changes.

Result The overall disposition of the Disclosure document will be updated by the system to be the most severe disposition indicated in Step 4 for any single Financial Entity.

Disposition: Relationship Identified

This overall disposition will be updated in both the Document Header and in the Approval Action subsection of the Administrator Actions panel.

Disclosure Status is set to ' Relationship Identified ' based on the Project-Financial Entity conflict status.

Approve

Assigning a Disclosure to a Reviewer

	* User Name	Full Name	Reviewer Type	Lead Unit	Date Assigned	Actions
Add:			Assigned Reviewer ▼			Add Reset
1	conflictsadmin	Conflicts Administrator	Assigned Reviewer (RVW)	Conflict of Interest Office (106040)	2018-07-03	Delete

Administrator Actions
Add Reviewers Action ⓘ

Disclosures may also be assigned to one or more individuals or groups for review. Follow these steps to assign a document to a Reviewer:

1. Working with in the Add Reviewers Action subsection of the Administrator Actions section, enter the Reviewer's **User Name** on the **Add:** line. Alternatively, you may click the magnifying glass 🔍 to search for and select return value next to the corresponding **User Name**.

2. Click the arrow next to the **Reviewer Type** field and select the appropriate value from the dropdown list.

3. Click the Add button to assign the Disclosure to the Reviewer. Add

4. Repeat these steps until all Reviewers are assigned to the Disclosure.

Result The system will generate an FYI Notification to display on each Reviewer's Action List.

Making Changes to Reviews On Behalf of Assignees

It is important to note that any user with COI Administrator privileges can, at any time, complete a review on behalf of an assignee or make changes to any portion of a review already submitted by an assignee. This option is most often employed when errors are made by a reviewer, or when a reviewer is unable to complete any portion of the assigned review online.

For this reason it is necessary for the COI Administrator to be familiar with the instructions in [Completing an Assigned COI Review](#).

Updating the Disclosure's Review Status

Updating the Review Status to reflect the current state of the Disclosure helps to ensure organization and transparency in the review process for all interested parties. The field is anecdotal only and must be updated manually in all cases.

Follow these steps to update the Review Status:

1. Working in the Review Status subsection, click the arrow next to the **Review Status** field and select the appropriate status based on the current state of the Disclosure.

2. Click the Submit button to update the Disclosure's Review Status.

Result   The **Disclosure Status: Review Status** field in the Disclosure's Document Header will be updated with the Review Status you selected.

Disclosure Status is set to ' Relationship Identified ' based on the Project-Financial Entity conflict status.

Approve

Finalizing the Disclosure

A Disclosure is ready to be finalized after all reviews and due diligence has been completed to the satisfaction of the COI Administrator. This is an approval step signifying that the COI Administrator approves of the status or statuses selected for each Financial Entity relationship listed on the Disclosure document.

Disclosure Status is set to ' Relationship Identified ' based on the Project-Financial Entity conflict status.

Approve

1.   Working from the Approval Action subsection of the Administrator Actions panel, confirm that the Disclosure Status affirmed in this section is the correct and final status.

2.   Click the Approve button to update the Document Status to FINAL.   Approve