

NIH Ethics Management Information System (EMIS)

Substantially Affected Organizations (SAO) Review

The NIH Ethics Management Information System (EMIS) is maintained by the NIH Ethics Office (NEO) to track employee ethics actions and non-employee based actions, termed “administrative actions.” The **Substantially Affected Organizations (SAO) Review** module will track the review of SAO status of entities.

The module is named **SAO Review** and is listed with the other administrative modules on the users’ home page, on the left side of the screen (see Figure 1, below). EMIS users with any access role may view, add, or edit data, and may create custom reports using the SAO Reviews data table.

Background: The HHS Supplemental Standards of Ethics Conduct prohibit certain activities involving organizations which meet the definition of an SAO, and prohibit certain employees from holding financial interests above the specified level in entities determined to be SAOs. The NIH Ethics Office (NEO) has a mechanism in place to obtain names of entities identified as SAOs based on their business classification. Other organizations which meet the criteria but which are not listed are reviewed and a determination made regarding their SAO status. This module tracks that review and determination process. See the NIH Ethics Program web site for additional information regarding SAOs. <http://ethics.od.nih.gov/topics/sao/sao-intro.htm>

Search Function: When the EMIS user chooses **SAO Review**, the search function will permit searching the data table on one or more of the following fields:

- ID Number The internal EMIS ID number for the record
- Ticker Symbol Field # 4, see description of fields, below
- Entity Name Field # 3, see description of fields, below

Search for SAO

ID Number

Ticker Symbol

Entity Name

Please select a record to Edit, or click 'Add New' to create a new record

Add New

1					
ID	Ticker	Entity Name	NEO Decision	NEO Decision Date	Attachments
Edit	2	DST	Discovery Therapeutics		0
1					

Figure 1: SAO Search and Pending SAO Determination List

Records which match the search criteria will be displayed in table format as shown at the bottom of Figure 1, above. Users are presented with the options to **Add New** entity being reviewed, or **Edit** a record shown in the list. The list of records within the SAO module contains entities pending the final determination. Records will be automatically removed from the pending list once the NEO Action is entered. The EMIS record may retrieved when searching for the SAO using the search function.

Data Fields: Data will be entered into each field according to the instructions in the table following the view of the data entry screen below (Figure 2).

Add SAO

* = required field

* Request Date * Initiator

* Entity/Fund Name

* Ticker Symbol

Entity Type To NEO

NEO Receipt NEO Decision

NEO Decision Date Notify IC

Post On Web

Notes

Choose Your File To Upload

File Description

Figure 2: Add SAO

	Field Name	Type	Contents
	EMIS ID		The internal EMIS ID number for the record is visible, not editable.
1	Request Date*	Date	Date the determination is requested, regardless of who requests it.
2	Initiator*	drop down	IC or NEO, all ICs and NEO are included in the drop down list.
3	Entity/Fund Name*	Text	Full name of the entity or fund. Limit 100 characters.
4	Ticker Symbol*	Text	The ticker symbol for publicly-traded companies. Note: If the company is private (not publicly-traded) enter NA in this field.
5	Entity Type	drop down	Choose the correct option from the drop down list: <ul style="list-style-type: none"> • SAO • Sector Fund • Non SAO
6	To NEO	Date	Date request sent to NEO. Mm/dd/yy or mmddyyyy
7	Notes	Text	Enter additional relevant information. Be succinct.
8	Upload file		A pdf file of the final email or paper review information will be uploaded, named as follows: Entity-Name-NEO-Action-Date.pdf. <ul style="list-style-type: none"> • Truncate the entity name is necessary, omitting articles (i.e., the, a, an, of). Use standard abbreviations where possible, but keep the entity name recognizable. • Dates shall be designated in the yyyyymmdd format. Use hyphens between words, not blank spaces. Example: The entity named Mallinckroft Pharmaceuticals with an NEO determination made on January 24, 2015 would be named: Mallinckroft-Pharma-20150124.pdf
Data entry into the remaining fields is limited to NEO Users.			
9	NEO Receipt	Date	Date received in NEO. mm/dd/yy or mmddyyyy

	Field Name	Type	Contents
			Choose the appropriate NEO Action from the drop down list, which includes: Concur Do Not Concur None
11	Notify IC	Date	Date the IC is notified. Enter the actual date that this field is completed because when the record is saved the first time with this field complete, an email notification will be automatically sent to the ethics community (see below).
12	Post on Web	Date	Date the entity is added to the appropriate list on the NIH Ethics Program web site, i.e., additional SAOs or entities which are not SAOs.

Upload Files: This function permits you to upload files and attach them to the open record. At the bottom of the screen, click on *Browse*; locate the desired file; double click the file name; add a description if desired. PDF files are the best attachments because they can be opened by all users.

Files for SAO Review record shall be named using the entity's name, date of review, and determination. Use hyphens between words/sections; do not use spaces.

Example: Discovery Therapeutics was reviewed on June 15, 2015, and determined to be an SAO. The file containing notes and/or emails and confirmation of status, with the most recent document on top, will be scanned or printed to pdf, and named as follows: DiscoveryTherapeutics-2015-06-15-SAO.pdf

Document History:

File Name: Q:\EMIS\SOPs\Admin-Functions\SAO-Review.doc

- 12/20/12 Draft document for review.
- 3/22/13 Document finalized, format consistent with other SOPs. FEPLYler
- 6/6/14 Updated field instructions and NIH logo. NEO (C. Galvin-Combet)Re