

NATIONAL INSTITUTES OF HEALTH SAO Determination Job Aid

PURPOSE and BACKGROUND:

The NIH's ethics program is administered to help ensure that decisions made by NIH employees are not, nor appear to be, tainted by any question of conflict of interest. The ethics laws and regulations were established to promote and strengthen the public's confidence in the integrity of the Federal Government.

On August 31, 2005, the Department of Health and Human Services (HHS) published the revised HHS Supplemental Standards of Ethical Conduct ([5 CFR 5501](#)) and the new Supplemental Financial Disclosure Requirements ([5 CFR 5502](#)). Together, these regulations limit senior NIH employees financial interests in certain outside organizations, called a "[substantially affected organization](#)" (SAO), and require certain categories of employees to report their holdings in SAOs so a conflicts analysis can be completed.

When an entity's SAO status is unclear, NEO determines if the entity is or is not an SAO and then records the determination on the NIH Ethics Program website. Ethics officials will use the steps outlined below and the [SAO Determination Request form](#) to request an SAO determination.

1. Consult the list of [Substantially Affected Organizations](#) available on the NIH Ethics Program web site. This list is not definitive and may include some organizations that are not SAOs for the purpose of NIH. (also see the [List of Non-SAOs](#) and [SAOs - NOT Included on Dun & Bradstreet List](#)) **Absence of a company from the list does not automatically indicate that it is not an SAO or an SAO sector fund.**
2. Check the EMIS SAO determination module to see if NEO is currently working on a determination or if a determination has already been made but NEO website update is pending.
3. Review the definition of an SAO ([5 CFR 5501.109\(b\)\(10\)](#))
 - a. a biotechnology or pharmaceutical company; a medical device manufacturer; or a corporation, partnership, or other enterprise or entity significantly involved, directly or through subsidiaries, in the research, development, or manufacture of biotechnological, biostatistical, pharmaceutical, or medical devices, equipment, preparations, treatments, or products;
 - b. any organization, a majority of whose members are these types of entities; and
 - c. any other organization determined by the agency to be substantially affected by the programs, policies, or operations of the NIH.
4. Analyze the entity in question with respect to the SAO definition described above.
Note: If a company itself does not meet our SAO definition but includes subsidiaries, include subsidiary information regarding value of the company -- if 10% of the value of the company comes from biotech, pharmaceutical products or medical devices, then the company may be a substantially affected organization.
5. Conduct your research, gather information using a research tool (i.e., [Hoover's](#), [Yahoo](#) or [Google](#) Finance)
 - a. Check the industry
 - i. Does it fall under our SAO definition?
 - b. Check the competitors
 - i. If the entity's top competitors are SAOs, the entity is likely to be an SAO
6. After you have gathered sufficient data about the entity,
 - a. If the organization **is** on the SAO list but you feel it's not an SAO, or
 - b. If the organization is **not** on the SAO list but you feel it is an SAO,
 - c. Complete and submit, via upload to the [EMIS SAO module](#), an [SAO Determination Request form](#)
7. **Send an email to the NEO Action Coordinator with the subject line format: "SAO Determination Request EMIS ID# 123."**
Note: For this task, the NEO Action Coordinator will be using a rotation chart to assign the request to the next NEO Specialist on the list, you no longer need to copy your NEO Specialist.
8. NEO will notify you of its determination, upload the SAO Determination Request form to the SAO EMIS Module, and update the appropriate SAO list on the NEO Website.