



Current Status: *Active*

PolicyStat ID: 9139988



Origination: 02/2016

Effective: 01/2021

Last Approved: 01/2021

Last Revised: 01/2021

Next Review: 01/2022

Owner: *Patricia Gregory: Interim Chief Compliance and Privacy Officer*

Area: *Administration*

References:

Conflict of Interest

Policy Sections

- A. Policy Statement
- B. Scope
- C. Definitions
- D. General Principles
- E. Disclosure Requirements
- F. Review and Management
- G. Consulting and Other External Activities
- H. Continuing Education
- I. Institutional Conflicts of Interest
- J. Training

A. Policy Statement

Conflicts of Interest refer to situations in which financial or other personal interests, including secondary employment, may bias or otherwise compromise, or have the appearance of biasing or compromising, one's professional judgment relative to clinical, research, leadership, business, purchasing, or other actions taken by an individual. It is Shirley Ryan AbilityLab's ("SRALab") policy that individuals promptly and fully disclose all known and/or potential Conflicts of Interest to SRALab. SRALab does not prohibit all relationships that create, or may create, a Conflict of Interest, but SRALab **does** require that **all** such relationships be disclosed and that approved Conflicts of Interest be managed.

It is SRALab policy to post this policy publicly; therefore, when this policy is updated, it shall also be updated on our website.

B. Scope

This Conflict of Interest Policy applies to all SRALab employees, researchers and contractors.

C. Definitions

Conflicts of Interest: External Interests or situations in which financial or other personal interests, including

.

COPY

Receiving royalties on an invention/technology that You prescribe to SRAlab patients or use on a Sponsored Research study. If You have an External Interest related to diagnostic or treatment products

COPY

the Conflict of Interest requires additional review as set forth in Section F below.

Research Disclosure Requirements

In addition to disclosure of any External Interests as outlined above, SRAlab Researchers must also disclose External Interests related to their Institutional Responsibilities and/or any proposed Sponsored Research. If funding is proposed through an outside institution, such as Northwestern University, the Researcher should disclose any External Interest to that institution **and** to SRAlab.

Research disclosures to SRAlab must first be made on SRAlab's internal *Proposal Routing Form*, which are submitted to the Office of Research Administration with the proposal submission. The Corporate Compliance Department will subsequently facilitate the Researcher's completion of an *SRAlab Conflict of Interest Disclosure Form*, to provide more detail about the disclosed External Interests.

Researchers must disclose External Interests to the sponsor in their grant proposals and/or biosketches, whether or not it is requested by the research sponsor.

F. Review and Management

Conflict of Interest disclosures are reviewed and determinations (including rare, justifiable exceptions) are made on a case-by-case basis. All Conflicts are reviewed by the Office of Research Administration (Department of Research Administration) and the Corporate Compliance Department (Department of Corporate Compliance).
r136dictcue4MCID 24>i o(of R/P 4MCID 16>BDCBT684623224387d[Departm

COPY

with SRAlab's Conflict of Interest disclosure requirements, Conflict of Interest Management Plans, and/or any part of this Policy. Researchers may also be required to disclose Conflicts of Interest or request an addendum to previously published presentations in the event that a Conflict of Interest is identified that was not previously reported or managed in a timely manner. Failure to comply with SRAlab policies may necessitate for-cause compliance review and investigation, which may result in disciplinary action.

An annual independent data review may be conducted as an element of a Researcher's Conflict of Interest Management Plan to confirm whether or not inconsistencies between the project's research design, data collection and analysis and data reported exists that would potentially create cause for concern.

REPORT	CONTENT	REQUIRED WHEN?
New FCOI Report (Initial submission)	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	(1) Prior to expenditure of funds (2) Within sixty (60) days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when SRAlab is required to submit annual progress report, multi-year progress report, or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	When bias is found as a result of a retrospective review.

G. Consulting and Other External Activities

Consulting relationships and other external activities have the potential to increase the knowledge and experience of individuals, to broaden their exposure to external experts in their fields, and to advance public interest. Nevertheless, these relationships also have the potential to conflict with the obligations of an individual's obligations to SRAlab, including to SRAlab patients and research subjects. Examples include

other external activities. SRAlab employees, including physicians (subsequent to Physician Council approval),

H. Continuing Education

Continuing Medical Education (CME)

Other Continuing Education

I. Institutional Conflicts of Interest

J. Training

Attachments

[Conflict of Interest Acknowledgement Agreement \(12.04.20\).pdf](#)

Approval Signatures

COPY