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## Conflict of Interest

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### 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

secondary employment, may bias or compromise, or have the appearance of biasing or compromising, one's professional judgment relative to clinical, research, leadership, business, purchasing, or other actions. Conflicts of Interest may prioritize (or give the appearance of prioritizing) the personal interests of an individual over the individual's obligations to SRAlab, SRAlab's mission, and the public interest.

**Conflict of Interest Management Plan:** A plan of action approved by SRAlab that provides a detailed description of how the risks associated with a Conflict of Interest will be handled in light of an individual's Conflict of Interest. Not all approved Conflicts of Interest will require a Management Plan.

**Entity:** Any company or organization in which an individual holds an External Interest. Entity, for the purposes of this policy, also includes any of the Entity's affiliates or subsidiaries.

**External Interest:** Any of the following that You (as defined in this Policy) and/or your spouse and/or dependent children possessed, received or conducted in the past twelve (12) months from the date of disclosure:

- Direct or indirect compensation arrangements or other payments for service (e.g., salary, loans, gifts, consulting, advisory and/or lecturing fees, paid authorship, honoraria, and reimbursement of travel, lodging, meals, and out-of-pocket expenses);
- Equity interests (e.g., stock, stock options, securities, partnership interests, or other ownership interests); *NOTE: interests in publicly-traded entities that do not exceed five percent (5%) of any class of shares or other publicly-traded securities and stock ownership through personal retirement accounts and mutual funds are **excluded** from the definition of External Interest. Researchers must disclose equity interests exceeding \$5,000.00.*
- Intellectual property rights and interests (e.g., patents, copyrights, licensing agreements, and royalties or expected royalties from such rights); and
- A position as an officer, director, manager, general partner, employee, independent contractor, consultant, trustee, or member of a policy-making committee of an Entity.

**Finance and Audit Committee:** A committee of the Board of Directors of the SRAlab which oversees compliance with applicable legal and regulatory requirements, including conflict of interest, industry standards and SRAlab's Corporate Compliance Program.

**Financial Conflict of Interest:** A Financial Conflict of Interest ("FCOI") exists when SRAlab, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest (as defined by law) is related to an NIH or other government funded research project and could directly and significantly affect the design, conduct, or reporting of the NIH or other government funded research. For purposes of this policy, Investigator and Researcher are used interchangeably.

**Institutional Responsibilities:** A Researcher's professional responsibilities on behalf of SRAlab such as clinical, administration, teaching, research, research consultation, SRAlab committee memberships, and service on panels on behalf of SRAlab, such as Institutional Review Boards or Data and Safety Monitoring Boards.

**Researcher:** Any individual responsible for the design, conduct, or reporting of SRAlab research, regardless of position or job title (e.g., including but not limited to the Principal Investigator, Co-Investigator, Research Coordinator, Research Assistant, Post-Doctoral Fellow, Biostatistician, etc.)

**Research Conflict of Interest Committee:** Consists of member(s) of SRAlab's Executive Leadership Team, Research Leadership and the Office of Research Administration.

**Sponsored Research:** Any externally-funded research project in which SRAlab is the recipient, regardless of

funding source.

**You:** Individual and Related Party (which includes (i) a spouse or domestic partner, child (including a legally adopted child), grandchild, sibling, parent, and/or grandparent; and/or (ii) any person with whom the individual is living and/or who is claimed as an exemption on their most recently completed federal tax return).

## D. General Principles

The following are examples of circumstances that may give rise to a Conflict of Interest and are generally prohibited:

- **SRAIab Information**

Obtaining, disclosing, or using SRAIab information:

- i. For direct or indirect personal interest, profit, or advantage of individuals within the scope of this policy;
- ii. For any purpose that may be detrimental to SRAIab; or
- iii. Without authorization.

- **Solicitation**

Soliciting or assisting others in soliciting SRAIab employees, contractors, Researchers, or patients to:

- i. Cease or limit their relationship with SRAIab;
- ii. Compete with SRAIab, or to enter into an employment or other contractual relationship with a person or entity that competes with SRAIab; or
- iii. Treat a current or discharged SRAIab patient privately for one year after the patient is discharged from SRAIab unless an exception is requested from, and approved by, the appropriate member of the Executive Leadership Team or his/her designee. If approved, the employee receiving the exception must complete and forward an *Exception Acknowledgement Form* (see attachment to this policy) to the Chief Privacy and Compliance Officer. This one-year prohibition on treating a current or discharged SRAIab patient applies even if (1) the patient was seen by another clinician at SRAIab; and (2) the treatment is different than what was provided at SRAIab. (For example, a physical therapist cannot provide personal training services).

- **Diversion of Corporate Opportunity**

Appropriating or diverting, for personal advantage, a business or financial opportunity with knowledge that SRAIab is pursuing, intends to pursue, or would have an interest in pursuing if it were aware of the opportunity.

- **Fundraising**

Acting in any fundraising capacity for any organization other than SRAIab, except a local elementary/secondary type school or religious organization, if You are a member of the SRAIab Advancement Department or your position at SRAIab is at or above the level of Executive Director. Regardless of your role at SRAIab, You of course may make your own personal donations to any organization of your choice.

You are not allowed to solicit any SRAIab employee, board member, volunteer, outside vendor, contractor or any other individual or entity that provides goods or services to or on behalf of SRAIab. You are not allowed to use SRAIab property or materials in any way to fundraise for non-SRAIab activities.

- **Royalties**

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 that the Entity prescribes. You must disclose the nature of this External Interest to the patient or subject, including that the Entity receives no royalties or other payments when SRAlab purchases the product.

- **Purchasing**

All SRAlab purchases must adhere to SRAlab purchasing policies and, where applicable, be subject to review and approval by the New Product Evaluation Committee. You may be required to recuse yourself from being involved in and/or leading the purchase of the product that You have an External Interest in.

If You are using, prescribing, or referring a product to a SRAlab patient or subject and You have an External Interest in the Entity that manufactures or sells the product, including intellectual property rights in the product, then you must disclose the External Interest and a Conflict of Interest Management Plan may be implemented. Furthermore, if the product is being used in a Sponsored Research study, the product will be purchased by SRAlab at cost unless an exception is made.

- **Gifts**

Individuals may not accept gifts, favors, services, entertainment, or other things of value to the extent that decision-making or actions affecting SRAlab might be influenced. Similarly, the offer or giving of money, services, or other things of value with the expectation of influencing the judgment or decision-making process of any purchaser, supplier, customer, government official or other person is absolutely prohibited.

Individuals may accept gifts of nominal value from vendors, suppliers, contractors, or other persons (for example, holiday cookies). To the extent possible, these gifts should be shared with others at SRAlab. Individuals may NOT accept or solicit excessive gifts, meals, expensive entertainment or other offers of goods or services that have more than a nominal value.

## E. Disclosure Requirements

Any External Interests shall be disclosed: (1) upon hire or contract date; (2) during the annual competency process; and (3) as new External Interests arise.

Individuals at SRAlab with a faculty appointment in the Northwestern University Feinberg School of Medicine will complete one annual online Conflict of Interest disclosure survey, which will meet both Northwestern University's and SRAlab's *annual* Conflict of Interest disclosure requirements. This survey is typically administered by Northwestern University in collaboration with SRAlab.

New External Interests that arise after an initial and/or annual disclosure must be submitted to SRAlab's Corporate Compliance Department using the *SRAlab Conflict of Interest Disclosure Form* (see attachment to this policy) within ten (10) business days of learning of the new External Interest(s). SRAlab reserves the right to approve any professional or non-professional activity that may have a bearing on an individual's SRAlab responsibilities and role. When an individual discloses that they have External Interests that may conflict with SRAlab's interests (e.g., therapist who has a private practice), the individual will be required to complete and sign a *Conflict of Interest Acknowledgement Agreement* (see attachment to this policy) in which the individual agrees not to compromise SRAlab's interests in favor of their own separate External Interests, among other requirements. The Conflict of Interest Acknowledgment Agreement only needs to be filled out once for each Conflict of Interest, and must be signed by the individual's supervisor before being submitted to the Corporate Compliance Department. The supervisor will indicate whether they believe the Conflict of Interest should be approved; however, approval by a supervisor does not serve as approval of the Conflict of Interest. Approval of

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 of Interest deemed material will be reported to the Compliance Committee and the Finance and Audit Committee of the Board of Directors.

Any potential or actual Conflict of Interest will be reviewed, at a minimum, by a member of the Corporate Compliance Department and the individual's supervisor and/or Director. The Vice President of the individual's area, an attorney in the Office of General Counsel, a member(s) of the Compliance Committee, and/or others deemed appropriate may also be involved in the review. The nature of the External Interest, the nature of the individual's role and responsibilities, and the potential for the External Interest to affect, bias, or compromise the integrity of the individual's responsibilities at SRAlab will be considered.

It may be determined that a Conflict of Interest Management Plan is required to eliminate, reduce, or manage the Conflict of Interest. A member(s) of the Compliance Committee may also determine that as a result of the disclosed Conflict of Interest, the individual's relationship with SRAlab may need to be changed (e.g., termination of continued employment or service with SRAlab). In that event, SRAlab may give the individual the option of eliminating the conflicted relationship. These discussions will occur with the individual, their immediate supervisor, Human Resources, an attorney in the Office of General Counsel, member(s) of the Compliance Committee, and others as deemed appropriate.

External Interests related to a Researcher's Institutional Responsibilities will be reviewed by SRAlab's Chief Scientific Officer, Chief Research Officer, and the relevant supervisors or their designees for each applicable sponsored research activity. The nature of the External Interest, the nature of the research, the individual's role in the research, and the potential for the External Interest to affect or bias the research will be considered. The Chief Scientific Officer and the Chief Research Officer may determine that: (a) the Researcher be given the option of eliminating the conflicted relationship; (b) the Researcher is allowed to participate in the research with a documented and monitored Conflict of Interest Management Plan; or (c) the Researcher is not allowed to be involved in the research.

A Researcher's Conflicts of Interest must be eliminated, reduced, or managed before the relevant research activity is initiated and before Sponsored Research funding is accessed. As required, SRAlab will report information regarding research-specific Conflicts of Interest to external sponsors and/or federal regulatory agencies. SRAlab will also handle and report, as required and described in the chart below, non-compliance

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 engagements to serve as: (i) a member of a scientific advisory board or data safety monitoring board; (ii) a speaker or moderator at a company-sponsored event; or (iii) as a consultant to a company in connection with its research or products.

SRAlab employees may not participate in or conduct a presentation at any event in which the event sponsor directs or alters specific content to promote a particular product, process, technology, or activity. Participation in such activities must be to **educate** and **not** to promote. If the SRAlab employee has an External Interest with the Entity sponsoring the event, the individual must disclose the relationship in the presentation materials to the audience. If an Entity reimburses expenses related to continuing education activities (e.g., travel and lodging), or if an Entity pays for such expenses directly, the actual or estimated amount of remuneration must be disclosed.

Physicians must also go through the Physician Council disclosure and review process for any consulting or

other external activities. SRALab employees, including physicians (subsequent to Physician Council approval), must go through SRALab's Office of General Counsel prior to engaging in any contractual agreement with a commercially-sponsored entity.

## H. Continuing Education

### Continuing Medical Education (CME)

SRALab employees are strongly encouraged to participate only in CME activities sponsored by not-for-profit academic institutions or commercially-sponsored educational programs offered through ACCME (Accreditation Council for Continuing Medical Education) accredited providers, which abide by standards to ensure independence in CME Activities.

If an Entity reimburses expenses related to CME activities (e.g., travel and lodging), or if an Entity pays for such expenses directly, the actual or estimated amount of remuneration must be disclosed to SRALab.

### Other Continuing Education

SRALab employees are strongly encouraged to participate only in continuing education activities offered through or by sanctioned bodies that abide by standards to ensure quality and integrity in continuing education activities (including, but not limited to, the American Nurses Credentialing Center, the American Occupational Therapy Association, the American Physical Therapy Association, the American Speech-Language-Hearing Association, and the State of Illinois Department of Financial and Professional Regulation).

## I. Institutional Conflicts of Interest

An institutional Conflict of Interest is a situation in which the interests of an institution or an institutional official, acting within their authority on behalf of the institution, may affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution. For example, an institutional Conflict of Interest may exist if SRALab receives royalties from the sale of a product that is either part of or the subject of the research, or a product that is prescribed or used at SRALab for its patients.

Institutional Conflicts of Interest will be reviewed by the Finance and Audit Committee of the Board of Directors. If the institutional Conflict of Interest is considered to be significant, the Conflict of Interest may be eliminated or a Conflict of Interest Management Plan may be instituted.

## J. Training

New SRALab employees, Researchers, and applicable contractors will receive training on Conflict of Interest at new hire orientation and annually. Additional Conflict of Interest education is required for certain Researchers prior to engaging in research activities. Periodic training sessions may be scheduled at the discretion of the Chief Compliance and Privacy Officer to address policy changes, department or specialty-specific needs, or to provide additional training for those who fail to demonstrate the requisite knowledge of the Corporate Compliance Program.

### Attachments

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

## Approval Signatures

Approver	Date
Nancy Paridy: SVP Chief Administrative Officer	01/2021
Tanya Dworkin	01/2021
Stephanie Snarskis: Manager Business Support	01/2021
Patricia Gregory: Interim Chief Compliance and Privacy Officer	01/2021

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