

## Research Financial Conflicts of Interest Disclosure Form

At initial IRB Review, please assure that all entries are complete and submit Electronically to https://www.irbnet.org

Yearly disclosures or a change in disclosure should be emailed to the Director of Research Administration

For assistance, you may contact the Director of Research Administration

#### FINANCIAL DISCLOSURE INTRUCTIONS

For purposes of this Financial Disclosure form, the following definitions apply:

#### Covered Individual (CI):

- 1. Any employee, contractor or medical staff member of a Sheppard Pratt Entity who has the authority to make independent decisions related to the design, conduct, or reporting of a Sheppard Pratt research project, but not including individuals who perform only incidental or isolated tasks, related to the project. Examples of a CI include a principal investigator, sub-investigator, research nurse, associate, personnel whose resume is provided to a sponsor, personnel listed on study budgets or on an FDA 1572 Form, or individuals who are likely to be authors on publications of research findings;
  - Members of a Sheppard Pratt research review-related committee (e.g., IRB members, Local Research Review Committee members, Privacy Board members, Data Safety Monitoring Board members for investigator-initiated studies and/or members of other research review committees); or
- 3. Staff who negotiate or execute research agreements on behalf of Sheppard Pratt.

Covered Family Member: An individual who is the spouse or dependent child of a CI.

<u>Significant Financial Interest (SFI)</u>: A financial interest consisting of one or more of the following interests of a CI or Covered Family Member that reasonably appears to be related to the CI's Institutional Responsibilities:

- Publicly Traded Entity
  - a) The value of stock or other equity interest in a publicly traded company that, in aggregate, exceeds \$5,000 as of the date of disclosure and represents more than a five percent ownership interest in any single entity
  - b) Income from a publicly traded company that, in aggregate, exceeds \$5,000 in the 12 months preceding disclosure (includes salary and payment for other services, e.g. consulting fees, honoraria [payment granted in recognition of a special service or distinguished achievement, such as for a presentation or lecture on behalf of a sponsor or company that may or may not be related to a project], paid authorship)
- 2. Non-Publicly Traded Entity
  - a) Any stock or other equity/ownership interest of any value
  - b) Income from a private company that, when aggregated, exceeds \$5,000 in the 12 months preceding disclosure (includes salary and payment for other services, e.g. consulting fees, honoraria, paid authorship)
- 3. Intellectual Property Rights and Interest
  - a) Income related to intellectual property rights or interests that exceeds \$5,000 (e.g., patents, copyrights and royalties from such rights)
- 4. Travel
  - a) Reimbursed travel that exceeds \$1,500 in the 12 months preceding disclosure related to their institutional responsibilities
  - b) Sponsored travel estimated as exceeding \$1,500 (i.e., that which is paid on behalf of the CI and not reimbursed to the CI so that the exact monetary value may not be readily available) in the 12 months preceding disclosure, related to their institutional responsibilities The following information must be provided for all applicable reimbursed or sponsored travel:
    - (1) Purpose of the trip
    - (2) Identity of the sponsor/organizer
    - (3) Destination of the trip
    - (4) Duration of the trip
    - (5) Estimate of the monetary value
- 5. Gifts
  - a) The value and source of a single gift that exceeds \$250 in value, or multiple gifts from a single entity that in aggregate exceed \$250 in value, received in the 12 months preceding disclosure
- 6. Fiduciary Positions
  - a) A fiduciary position (e.g. member, officer, director, committee member) held in a for-profit or nonprofit entity in the 12 months preceding disclosure, for which the individual received any form of remuneration or reimbursement for expenses exceeding \$5,000
- 7. Other
  - a) Any other financial interest that the CI or the COI Official believes conflicts with the CI's ability to protect research subjects

<u>Financial Conflict of Interest (FCOI)</u>: An SFI that could directly and significantly affect the design, conduct, or reporting of research.



THIS SUBMITTAL IS FOR:   NEW DISC PROTOCOL TITLE: PROTOCOL NUMBER (IF APPLICABLE):	CLOSURE 🗆 ANNUAL DISC	:LOSURE □UF	PDATED DISCLOSURE	
INVESTIGATOR'S NAME FIRST NAME:	MIDDLE INITIAL:	LAST NA	ME:	SUFFIX:
PRINCIPAL INVESTIGATOR'S NAME (	F DIFFERENT FROM INVESTIG	GATOR) 🗆 N/A		
FIRST NAME:	MIDDLE INITIAL:	LAST NA	ME:	SUFFIX:
INSTITUTIONAL RESPONSIBILITIES	ı	I		
☐ Research ☐ Research Consultation ☐ Professional Practice ☐ Institutional Committee comment:  SIGNIFICANT FINANCIAL INTEREST	Teaching e/Panel Membership (such as	s IRB, FCOI-R, DS	SMB) Other - Please spec	ify by adding a
To your knowledge, do you or a Covered interest in a <b>Publicly Traded Entity</b> relate aggregate, exceeds \$5,000? (Equity does such as mutual funds and retirement account directly control the investment decisions)	d to your <b>Institutional Responsi</b> NOT include income from inves ounts as long as the CI or Family	<b>bilities<sup>1</sup></b> that, in tment vehicles	□NO □YES * If Yes, please Disclosure Form [A-1].	e complete SFI
To your knowledge, have you or a Covere months from a <b>Publicly Traded Entity</b> rel in aggregate, exceeds \$5,000?			□NO □YES * If Yes, please Disclosure Form [A-2].	e complete SFI
To your knowledge, do you or a Covered interest in a <b>Non- Publicly Traded Entity</b> (Any stock or other equity/ownership inte	related to your <b>Institutional Res</b>		□NO □YES * If Yes, please Disclosure Form [B-1].	e complete SFI
To your knowledge, have you or a Covere months from a <b>Non-Publicly Traded Enti</b> <b>Responsibilities<sup>1</sup></b> that, in aggregate, exce	ty related to your Institutional	ne in the last 12	□NO □YES *If Yes, please Disclosure Form [B-2].	e complete SFI

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<sup>&</sup>lt;sup>1</sup> Pharmaceutical/biotechnology companies, device/medical equipment manufacturers, or other healthcare suppliers are examples of entities related to Sheppard Pratt Research Institutional Responsibilities.



Date: .

To your knowledge, do you or any Covered Family Member receive income, have patent ownership, or have any other Intellectual Property agreements, (e.g., copyrights and royalties from such rights) with a <b>Publicly Traded Entity</b> or a <b>Non-Publicly Traded Entity</b> related to your <b>Institutional Responsibilities¹</b> that in aggregate, exceeds \$5,000? (This does not include royalties or other remuneration paid by a Sheppard Pratt entity to the CI if the CI is employed or otherwise appointed by the Sheppard Pratt entity, including intellectual property rights assigned to the Sheppard Pratt entity and agreements to share royalties related to such rights).	□NO □YES *If Yes, please complete SFI Disclosure Form [C].
To your knowledge, have you or a Covered Family Member been reimbursed for <b>Travel</b> or received sponsored Travel by a <b>Publicly Traded Entity</b> or a <b>Non-Publicly Traded Entity</b> related to your <b>Institutional Responsibilities</b> <sup>1</sup> that in aggregate exceeds \$1,500?	□NO □YES *If Yes, please complete SFI Disclosure Form [D] and provide explanation.
To your knowledge, have you or a Covered Family Member received a single <b>Gift</b> that exceeds \$250 in value, or multiple Gifts that, in aggregate, exceeds \$250 in value from a single <b>Publicly Traded Entity</b> or a <b>Non-Publicly Traded Entity</b> related to your <b>Institutional Responsibilities</b> <sup>1</sup> ?	
To your knowledge, have you or a Covered Family Member held a <b>Fiduciary Position (e.g., member, officer, director, committee member, etc.)</b> in a for-profit or nonprofit entity <b>(e.g., pharmaceutical/biotechnology company, device/medical equipment manufacturer, or other healthcare supplier)</b> for which the individual received any form of remuneration or reimbursement for expenses that in aggregate exceeds \$5,000?	□NO □YES *If Yes, please complete SFI Disclosure Form [F].
To your knowledge, do you or a Covered Family Member have any <b>other</b> Financial Interests that potentially conflict with the protection of human research subjects?	□NO □YES *If Yes, please complete SFI Disclosure Form [G].

#### **COVERED INDIVIDUAL STATEMENT**

By submitting this form, I confirm:

- I have reviewed and understand the Sheppard Pratt FCOI policy
- The information on this form is complete and accurate to the best of myknowledge.
- I will disclose changes to my Institutional Responsibilities within 30 days of occurrence.
- I will disclose additional SFIs or changes to previously reported SFIs within 30 days of occurrence.

Covered Individual Signature:
If you answered "no" to all the questions above, take one of the following actions:

- If this is a NEW DISCLOSURE, submit your completed form in IRBNet with your IRB Submission
- If this is an ANNUAL or UPDATED DISCLOSURE send to the Director of Research Administration

If you answered "yes" to any of the questions above, please complete the appropriate form below and take one of the following options listed above.



### FORM A-1 EQUITY INTERESTS IN A PUBLICLY TRADED ENTITY

Covered Individual or Family Member The SFI(s) on this form pertain to (select one from the following):				
□ Covered Individual □ Spouse: □ Child:				
Use this form to disclose <i>equity interests</i> aggregate, exceeds \$5,000 as of the date single entity.	<i>in any Publicly Traded</i> entity related to your Institutional of disclosure and/or represents more than a five percent	Responsibilities¹ that in t ownership interest in any		
Name of Publicly Traded Entity	Nature of Public Equity Interest	Total Value of Public Equity Interest		
	□ Warrants □ Stock □ Stock Options □ Other:	\$		
	☐ Warrants ☐ Stock ☐ Stock Options ☐ Other:	\$		
	☐ Warrants ☐ Stock ☐ Stock Options ☐ Other:	\$		
	☐ Warrants ☐ Stock ☐ Stock Options ☐ Other:	\$		

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<sup>&</sup>lt;sup>1</sup> Pharmaceutical/biotechnology companies, device/medical equipment manufacturers, or other healthcare suppliers are examples of entities related to Sheppard Pratt Research Institutional Responsibilities.



### FORM A-2 INCOME (PUBLICLY TRADED ENTITIES)

<u>Covered Individual or Family Member</u> The SFI(s) on this form pertain to (select one from the following):				
□ Covered Individual □ Spouse: □ Child:  Use this form to disclose <i>income from any Publicly Traded</i> entity related to your Institutional Responsibilities¹ that in aggregate, exceeds \$5,000 in the last 12 months.				
Name of Publicly Traded Entity	Nature of Publicly Traded Income	Please provide the total value of the income <u>received</u> from the <b>Publicly Traded Entity</b> over the <u>PAST</u> 12 months.	total value of the income <u>expected</u> from the <b>Publicly</b>	
	□ Consulting □ Honoraria □ Paid Authorship □ Other:	\$	\$	
	□ Consulting □ Honoraria □ Paid Authorship □ Other:	\$	\$	
	□ Consulting □ Honoraria □ Paid Authorship □ Other:	<b>*</b>	\$	
	☐ Consulting ☐ Honoraria ☐ Paid Authorship ☐ Other:	*	\$	

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### FORM B-1 EQUITY INTERESTS (NON-PUBLICLY TRADED ENTITIES)

Covered Individual or Family Member The SFI(s) on this form pertain to (select or	ne from the following):	
□ Covered Individual □ Spouse: □ Child:		
Use this form to disclose <i>equity interests</i> and Responsibilities <sup>1</sup> .	<i>in any Non-Publicly Traded</i> entity of any value related to	your Institutional
Name of Non-Publicly Traded Entity	Nature of Non-Publicly Traded Equity	Total Value of Non-Publicly Traded Equity Interest
	□ Warrants □ Stock □ Stock Options □ Partnership □ Other:	\$
	□ Warrants □ Stock □ Stock Options □ Partnership □ Other:	\$
	□ Warrants □ Stock □ Stock Options □ Partnership □ Other:	\$

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#### FORM B-2 INCOME (NON-PUBLICLY TRADED ENTITIES)

Covered Individual or Family Member The SFI(s) on this form pertain to (select one from the following):				
□ Covered Individual □ Spouse: □ Child:  Use this form to disclose <i>income from any Non-Publicly Traded</i> entity related to your Institutional Responsibilities¹ that in aggregate, exceeds \$5,000 in the last 12 months.				
Name of Non-Publicly Traded Entity	Nature of Non-Publicly Traded Income	Please provide the total value of the income <u>received</u> from the Non- Publicly Traded Entity over the <u>PAST</u> 12 months.	Please provide the total value of the income <u>expected</u> from the Non-Publicly Traded Entity over the <u>NEXT</u> 12 months.	
	☐ Consulting			
	☐ Honoraria			
	□ Paid Authorship	\$	\$	
	□ Partnership			
	□ Other:			
	☐ Consulting			
	☐ Honoraria			
	□ Paid Authorship	\$	\$	
	□ Partnership			
	□ Other:			
	☐ Consulting			
	☐ Honoraria			
	□ Paid Authorship	\$	\$	
	□ Partnership			
	□ Other:			

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<sup>&</sup>lt;sup>1</sup> Pharmaceutical/biotechnology companies, device/medical equipment manufacturers, or other healthcare suppliers are examples of entities related to Sheppard Pratt Research Institutional Responsibilities.



### FORM C INTELLECTUAL PROPERTY RIGHTS AND INTEREST

<b>Covered Individual or Family Member</b> The SFI(s) on this form pertain to (select one fro	om the following):		
☐ Covered Individual ☐ Spouse: ☐ Child:			
Use this form to disclose patent ownership o and Interest in any Publicly Traded or Non- aggregate, exceeds \$5,000 (e.g., patents, cop	Publicly Traded entity rel	lated to your Institutional F	ual Property Rights Responsibilities¹ that in
Company	Total Income <u>Received</u> Over <u>PAST</u> 12 months	Total Income <u>Expected</u> Over <u>NEXT</u> 12 months	Is the intellectual property under study in your research at Sheppard Pratt?
	\$	<b>\$</b>	□ Yes □ No
	\$	\$	□ Yes □ No
	\$	\$	□ Yes
	\$	\$	□ Yes

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#### FORM D SPONSORED TRAVEL/REIMBURSEMENT

Covered Individual or Family Member The SFI(s) on this form pertain to (select one from the following):				
□ Covered Individual □ Spouse: □ Child:				
		reviously reported <i>Travel</i> e or medical equipment r		<del>-</del>
Purpose	Company	Destination	Duration	Sponsorship/ Reimbursement Amount
				\$
				\$
				\$
				\$

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<sup>&</sup>lt;sup>1</sup> Pharmaceutical/biotechnology companies, device/medical equipment manufacturers, or other healthcare suppliers are examples of entities related to Sheppard Pratt Research Institutional Responsibilities.



FORM E GIFTS EXCEEDING \$250.00

The SFI(s) on this form pertain to (select one from the following):

Covered Individual or Family Member

□ Covered Individual □ Spouse: □ Child:				
Please disclose new, unreported, or change: pharmaceutical or biotechnology company,	Please disclose new, unreported, or changes to previously reported <i>Gifts that in aggregate exceed \$250 in value from any</i> charmaceutical or biotechnology company, device or medical equipment manufacturer, or other healthcare suppliers.			
Company	Description of Gift	Value		
		\$		
		\$		
		\$		
		\$		
		\$		

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<sup>&</sup>lt;sup>1</sup> Pharmaceutical/biotechnology companies, device/medical equipment manufacturers, or other healthcare suppliers are examples of entities related to Sheppard Pratt Research Institutional Responsibilities.



#### FORM F FIDUCIARY POSITIONS

Covered Individual or Family Member The SFI(s) on this form pertain to (select one from the following):				
□ Covered Individual □ Spouse: □ Child:				
	ove) in any pharmaceutical	y reported <i>Fiduciary Positions (he</i> or biotechnology company, device	-	
Company	Position Title	Relationship Between Sheppard Pratt Research Operations and Company Position Activities	Total value of the remuneration or reimbursements received in the PAST 12 months for this Fiduciary Position	
			\$	
			\$	
			\$	
			\$	

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<sup>&</sup>lt;sup>1</sup> Pharmaceutical/biotechnology companies, device/medical equipment manufacturers, or other healthcare suppliers are examples of entities related to Sheppard Pratt Research Institutional Responsibilities.



#### FORM G OTHER ACTIVITIES

The SFI(s) on this form pertain to (select one from the following):

Covered Individual or Family Member

□ Covered Individual □ Spouse: □ Child:				
Other Activities Please disclose new, unreported, o categories described in Forms A equipment manufacturer, or other	<i>through F) in any</i> pharmaceu			
Company	Description of Activity and Relationship with Sheppard Pratt (if any)	Total Compensation <u>Received</u> Over <u>PAST</u> 12 Months	Total Compensation <u>Expected</u> Over <u>NEXT</u> 12 Months	Expected Time Commitment Associated with Other Activity (average % of activity over the year)
		\$	\$	%
		\$	\$	%
		\$	\$	%
		\$	\$	%

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