

**Study Identifier (IRB# or Study Title):**

**Study Principal Investigator:**

**Study Sponsor:**

**Study team member completing this form:**

**Instructions:**

- All members of the study team must disclose financial interests that require disclosure under regulation, including financial interests related to the research as defined below.
- **Where the word ‘you’ is used below, it is meant to also include, as applicable: Your Spouse/Domesticpartner and dependent children.**
- Definitions may be found on page 2.

a) Within the last 12 months, have you **performed any work** (not directly related to the costs of conducting research) for **any** entity whose financial interests could reasonably appear to be affected by the conduct or outcome of this research project?  Yes  No

b) Within the last 12 months, have you **received compensation** (not directly related to the costs of conducting research) from **any** entity whose financial interests could reasonably appear to be affected by the conduct or outcome of this research project? Please answer Yes for paid/reimbursed travel (see definitions below).  Yes  No

c) Do you maintain **any board or executive relationship related to this research, regardless of compensation?**  Yes  No

d) Within the next 12 months, do you anticipate **performing any work and/or receiving any compensation (not directly related to the costs of conducting research)** from **any** entity whose financial interests could reasonably appear to be affected by the conduct or outcome of this research project? Please answer Yes for paid/reimbursed travel (see definitions below).  Yes  No

e) Do you **own stock, stock options or other forms of ownership** in **any** entity whose financial interests could reasonably appear to be affected by the conduct or outcome of this research project?  Yes  No

f) Do you have any **intellectual property related to the proposed research** (e.g., named as an inventor in an issued patent or patent application, license fees, technology transfers, current or future royalties from patents and copyrights)?  Yes  No

g) Do you want to voluntarily disclose anything else?  Yes  No

**For any YES answers to the above, complete EXHIBIT A.**

**I certify that the above information is accurate and complete. I will report any change to the above responses within 30 days to the NJH HRPP.**

**Signature:**

**Date (mm/dd/yyyy):** \_\_\_\_\_

## HUMAN SUBJECT RESEARCH STUDY-SPECIFIC FINANCIAL DISCLOSURE FORM

### **Definitions:**

**“Financial Interest Related to the Research” – A financial interest in the sponsor, product, or service being tested, or anything of monetary value from a financially interested company, including but not limited to:**

- **Officer’s/Director’s fees**
- **Consulting fees**
- **Compensation for service on an Advisory Board (including scientific advisory boards)**
- **Honoraria**
- **Gifts**
- **Other emoluments or "in kind" compensation such as travel and entertainment from a financially interested company (including those from a third party if the original source is a financially interested company), for any services not directly related to the reasonable costs of conducting the research as specified in the research agreement**
- **Compensation related to the research whose amount might be affected by the outcome of the research**
- **Equity interest of any kind and in any amount in a non-publicly or publicly traded Financially Interested Company (e.g., stocks, stock options, convertible notes, other ownership interests), including those for which the value cannot be determined through reference to publicly available prices, those for which the value may be affected by the outcome of the research, and those which represent a 5% or more interest in any one single entity**
- **Intellectual property related to the proposed research**
- **License fees, technology transfers, and/or current and future royalties from patents and copyrights**
- **Board or executive relationships related to the research (regardless of compensation)**
- **Paid/reimbursed travel for research funded or supported by an HHS agency, meaning the occurrence and value of any paid/sponsored (i.e., sponsored travel is that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), and/or reimbursed travel, whether in connection with an outside position or for consulting, lecturing, or service on a scientific advisory board, data safety monitoring board, steering committee for a clinical trial, executive committee for a clinical trial, or other committee for an outside entity, or for any other purpose including the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration**

**The term “Financial Interest” does not include:**

- **Salary, royalties, or other remuneration received from National Jewish Health**
- **Grant support for salaries from the institution/organization**
- **Interests held in a diversified, independently managed mutual fund**
- **Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, or a research institute affiliated with an Institution or higher education**
- **Income from service on an advisory committee or review panel sponsored by a federal, state, or local government agency, or a research institute affiliated with an Institution of higher education.**

## EXHIBIT A

*Only complete this form if you answered YES to any question in part one.*

**Study Identifier (IRB# or Study Title):**

**Study Principal Investigator:**

**Study team member completing this form:**

**Study Sponsor:**

**Are you making a disclosure for yourself, or on behalf of a spouse, domestic partner, or dependent children?**

Self  
 Related Party (e.g., spouse, domestic partner etc.); Please identify: \_\_\_\_\_  
 Both; Briefly explain: \_\_\_\_\_

**Complete the questions below as they relate to the (a) study sponsor or (b) any entity whose financial interests could reasonably appear to be affected by the conduct or outcome of the current research project.**

**a) Work performed within the last 12 months (not directly related to the costs of conducting research):**

<i>Check all that apply:</i>	<i>Sponsor/entity name:</i>	<i>Check all that apply:</i>	<i>Sponsor/entity name:</i>
<input type="checkbox"/> Consultant/advisor	_____	<input type="checkbox"/> Officer/Director	_____
<input type="checkbox"/> Employee	_____	<input type="checkbox"/> Fiduciary Role	_____
<input type="checkbox"/> Independent contractor	_____	<input type="checkbox"/> Other (Specify): _____	_____

**b) Compensation received within the last 12 months (not directly related to the costs of conducting research) (check all that apply):**

<input type="checkbox"/> Consulting fees	Value: \$_____	Sponsor/entity name: _____
<input type="checkbox"/> Honoraria	Value: \$_____	Sponsor/entity name: _____
<input type="checkbox"/> Salaries	Value: \$_____	Sponsor/entity name: _____
<input type="checkbox"/> Officer's / Director's fees	Value: \$_____	Sponsor/entity name: _____
<input type="checkbox"/> Gifts / gratuities	Value: \$_____	Sponsor/entity name: _____
<input type="checkbox"/> Compensation for service on advisory board	Value: \$_____	Sponsor/entity name: _____
<input type="checkbox"/> Royalty payments	Value: \$_____	Sponsor/entity name: _____
<input type="checkbox"/> Paid/reimbursed travel for research funded or supported by an HHS agency	Value: \$_____	Sponsor/entity name: _____
<input type="checkbox"/> Other (specify): _____	Value: \$_____	Sponsor/entity name: _____

**EXHIBIT A (CONTINUED)**

**c) Board or executive relationship related to the research, regardless of compensation:**  
*Check all that apply:*

<input type="checkbox"/> Board member	Value: \$ _____	Sponsor/entity name: _____
<input type="checkbox"/> Director	Value: \$ _____	Sponsor/entity name: _____
<input type="checkbox"/> Trustee	Value: \$ _____	Sponsor/entity name: _____
<input type="checkbox"/> Other (specify): _____	Value: \$ _____	Sponsor/entity name: _____

**d) Describe anticipated work and/or receipt of compensation (within the next 12 months) not directly related to the costs of conducting research (specify any anticipated paid/reimbursed travel for research funded or supported by an HHS agency here):**  
 Sponsor/entity name: \_\_\_\_\_ In what capacity? \_\_\_\_\_ Value: \$ \_\_\_\_\_

**e) Stock, stock options or other forms of ownership:** Please respond to the following for each entity:

<b>PUBLICLY TRADED</b>			<b>NON PUBLICLY TRADED</b>			
	# shares	Entity name:		Value	% share	Entity name:
<input type="checkbox"/> Stock	_____	_____	<input type="checkbox"/> Stock	\$ _____	_____	_____
<input type="checkbox"/> Stock options	_____	_____	<input type="checkbox"/> Stock options	\$ _____	_____	_____
<input type="checkbox"/> Other (specify): _____	_____	_____	<input type="checkbox"/> Other (specify): _____	\$ _____	_____	_____

**f) Intellectual Property Related to the Proposed Research** (e.g., named as an inventor in an issued patent or patent application, license fees, technology transfers, current or future royalties from patents and copyrights):  
 Intellectual property: \_\_\_\_\_ Explain: \_\_\_\_\_ Value (if known): \$ \_\_\_\_\_

**g) Department/NJH's financial interest** in the agent under investigation or in a company that could benefit from the study findings, or receipt of **significant financial support** from such a company:  
 Describe financial interest or support (include amount/\$ value if applicable): \_\_\_\_\_

**h) Do you want to voluntarily disclose anything else?**  
 No  
 Yes – describe: \_\_\_\_\_

**i) Comments** (optional): \_\_\_\_\_

***I certify that the above disclosure is accurate and complete. I will report any change to the above responses within 30 days to the NJH HRPP.***

Printed Name \_\_\_\_\_ Signature \_\_\_\_\_ Date (mm/dd/yyyy) \_\_\_\_\_