

Human Research Protection Program

RESEARCH CONFLICT OF INTEREST DISCLOSURE FORM

When To Use This Form

Refer to [Children's Wisconsin HRPP SOP Manual](#) found on the HRPP website for details.

When submitting a study in eBridge that engages Children's Wisconsin (CW), this supplemental form will capture whether you have a financial interest and/or personal relationship with a company, foundation, organization, etc. ("entity") that is associated with this research (e.g., sponsor, licensee, donor, provider of reagents/equipment/services, etc.) or with the technology to be studied. The Principal Investigator is responsible for identifying whether any members of the study team have a potential conflict of interest to disclose, and if so, to make sure a separate disclosure form is submitted by each individual with the potential interest. If there are no conflicts, then this form should indicate that there are no interests to disclose for the PI or any members of the study team.

Instructions For Submission

Complete this form ELECTRONICALLY and upload it in eBridge in Section 52 (or Section 98 for amendments). It will be reviewed by the HRPP analyst and forwarded to the CW COI review committee if appropriate.

Project Information

Project (PRO) Title:

Principal Investigator:

Study team name disclosing interest (if different than PI):

Contact Email:

Organization and department:

Sponsor (or indicate if not applicable):

Section 1: Your Financial Interests And/Or Relationships

A. After reviewing this Disclosure Form and COI section of CW HRPP SOP manual, if no disclosure is applicable, **STOP HERE**, select the statement and upload in the appropriate section of the eBridge application.

If there are interests to disclose, continue on and complete this form for each individual who has an interest.

B. Indicate the name of the entity with which the interest is based:

C. Briefly describe the entity's business and its relationship to this research:

D. Indicate your financial interests and relationships that are related to the entity and/or to this research. Check all that apply:

<u>Financial Interests and Relationships</u> ¹	<u>Reporting for?</u>		<u>\$ Value in Prior 12 months?</u>	<u>Anticipated \$ Value in Next 12 Months?</u>
	<u>Yourself</u>	<u>Family Member²</u>		
Lectures, Speakers Bureau				
Consulting, Advising				
Scientific Advisor, Scientific Advisory Board				
Data Safety Monitoring Board/Event Adjudication Committee				
Management or Executive Position				

Human Research Protection Program Request for Engagement Determination

Board Member, Officer, Director				
Provide Education, CME, develop educational materials				
Employment, Independent Contractor				
Intellectual Property Rights (personal ownership)				
Royalties				
Gifts >\$250 in Value				
Sponsored or Reimbursed Travel				
Stock Ownership, Business Ownership				
Stock Options				
Other:				
*For stock, stock options, and/or business ownership, provide your aggregated interests:				
# Stock Shares:	# Stock Options:	% Business Ownership:		

¹ Even if the value is zero at this time or anticipated to be zero in the next 12 months or ever, the relationship should still be reported.

² A family member is defined here as: (1) spouse; (2) dependent child or stepchild; (3) any individual financially dependent on you; and (4) any person with whom you have joint financial interests such that an objective third party could reasonably conclude that your decisions or other exercise of professional responsibilities at Children's Wisconsin could be influenced by the effect of the action on your financial interest.

E. Describe how your financial interests and/or relationships might have the potential to affect, or be affected by, this proposed research:

Section 2: Other Financial Interests

Do any employees or trainees who will work on this project AND report to you have any financial interests or personal relationships that are related to this entity or to the research?

If **YES**, a disclosure form must be completed and submitted for each individual with a potential COI.

Section 3: Intellectual Property

A. Does this research involve the use, study, or validation of any intellectual property (e.g., patents or patent applications, inventions, discoveries, devices, licenses, copyrights of software or educational materials)?

B. If YES, who holds the rights and/or licenses to the intellectual property?

I am uncertain who holds the rights and/or licenses.

I and/or a family member² personally own the intellectual property rights.

The entity described in this disclosure.

Another commercial entity (describe):

MCW/CW

Another institution of higher education (describe):

Section 4: Manufacture Or Commercialization Of Research Related Items

Will the entity manufacture and/or commercialize any drug, device, procedure, software, educational material, or other item associated with this research or that will result from this research?

If **YES**, please describe:

Section 5: Qualifications

Human Research Protection Program Request for Engagement Determination

Describe why you believe you should participate in the study given your potential financial conflict of interest and your specific unique qualifications (e.g., investigator expertise, institutional resources, access to particular patient populations, nature of the science, level of risk in the study):

Section 6: Your Role(s) In The Research

A. Did you design the research?

If **YES**, describe:

B. Will you collect the data?

If **YES**, describe:

C. Will you analyze and/or interpret the data?

If **YES**, describe:

D. Will you write reports?

If **YES**, describe:

E. Will you publish or present the research?

If **YES**, describe:

F. Will you identify and/or adjudicate adverse events?

If **YES**, describe:

G. Will you participate in any portion of the informed consent process?

If **YES**, describe:

Section 7: Existing Management Plan

H. Do you have an existing Management Plan for your financial interests indicated in this disclosure?

If **YES**, please review your Management Plan and describe how the research represented in this disclosure could be managed by your existing plan, or if you feel additional safeguards might be required to ensure objectivity in the design, conduct, or reporting of the research:

Certification

By submitting this form into eBridge, I certify the following:

- I understand that I am responsible for complying with the *CW Research - Conflict of Interest Policy* found on the Children's Wisconsin Connect under Practice and Policy.
- If this is a new disclosure of a financial interests and/or personal relationship, I understand that Children's Wisconsin may implement a Management Plan to eliminate or manage actual or perceived conflicts of interest in the research, and I must comply with any such Plan. This may be in addition to any MCW Management Plan imposed.
- I agree to notify the Children's Wisconsin HRPP within 30 days of any changes in this disclosure.
- I understand that this research may not be initiated, nor may any funds be expended on this research until the Children's Wisconsin COI review committee determines that either no conflict of interest exists or approves a Management Plan.
- The information provided in this disclosure is true and correct to the best of my knowledge.