SAMPLE MANAGEMENT PLAN (FOR REFERENCE ONLY)

Scenario: The Investigator in this sample management plan is participating in a NIH-funded study on outcomes of the use of telemedicine in the initial assessment of pediatric mass lesions. They have equity in an ultrasound company and act as an ultrasound consultant.

NIH FCOI Management Plan

You need to complete this form if you:

(1) have an identified Financial Conflict of Interest (FCOI) that needs to be managed; **and**

(2) you have or are applying for National Institutes of Health (NIH) funding.

A management plan for FCOIs is required, pursuant to the US NIH *Regulation on the Responsibility of Applicants for Promoting Objectivity in Research and Responsible Prospective Contractors* (42. CFR, Part 50, Subpart F and 45. CFR, Part 94 Final Rule). Your NIH awards and related patent applications, issued patents, trademarks, and/or copyrights are subject to this Management Plan.

This Management Plan will need to be updated on an annual basis, or sooner if mandated by the Institutional Official and/or anytime your FCOI-related circumstances change. When you renew your PHSA conflict of interest declaration, if there are no changes in the plan, indicate so at the bottom of the form.

Once you have developed your Management Plan, upload it into your PHSA Conflict of Interest declaration form (http://coi.phsa.ca) for final approval. For additional information on PHSA's Conflict of Interest process and to see a sample NIH Management Plan, visit PHSA Research & Academic Services NIH FCOI webpage.

LAST NAME:	FIRST NAME:	MIDDLE NAME(S):
Doe	Chris	Paige
PROJECT TITLE:		
Outcomes on the Use of Telemedicine in the Assessment of Pediatric Mass Lesions		
PRINCIPAL INVESTIGATOR:		
Marianne Williams		

Your Role and Principal Duties on NIH Project

Co-Investigator: will be acting as a pediatric oncologist at one of the 8 hospitals involved. I will be reading the ultrasounds live and providing recommendations on treatment.

Management Plan Conditions

Check as many boxes as appropriate for you, your spouse, and/or your dependent child.

NO.	MANAGEMENT PLAN CONDITIONS
	INTERACTIONS WITH STUDENTS, STAFF, AND COLLEAGUES
1	☐ Disclose my FCOIs in writing to students, staff and/or colleagues who are part of the study. ☐ I have, or will, provide this information on an annual basis and to all new hires/students. ☐ In this FCOI disclosure I will provide/have provided instruction to students, staff and/or colleagues that if they have concern about the influence of the FCOI on potential research outcomes or findings, they may inform PHSA's Research & Academic Services (researchadministration@phsa.ca) without repercussion.
2	☒ I will notify the following, in writing (see PHSA Research & Academic Services website for example declarations) of my FCOIs: ☒ Co-Investigators at PHSA ☒ Subrecipients ☒ Direct recipients
	PUBLICATIONS/PRESENTATIONS/PUBLIC DISCLOSURE
3	☐ I have posted information on my website/faculty page/etc. pertaining to my FCOI ☐ This information outlines the value, type, etc. of the FCOI and how it creates a FCOI ☐ This information includes my participation in a company as a founder, consultant, etc. ☐ This information includes a summary of my reimbursed/sponsored travel
4	☒ I have an obligation to my employer (PHSA or university) to publish all findings, even if they would damage my potential financial benefit
5	☒ Publicly disclose FCOI when presenting and/or publishing (see PHSA Research & Academic Services website for wording examples)
	DISCLOSURE/MONITORING AT PHSA
6	☒ Disclose FCOI to Research Ethics Board
7	☐ Disclose FCOI, and the entire Management Plan, to intellectual property development offices (e.g., PHSA Technology Development Office [TDO], UBC University Industry Liaison Office [UILO], etc.) ☐ My FCOI has been discussed with and documented by the PHSA TDO staff
8	☐ Appoint of an Oversight Monitor (someone at PHSA who is familiar with the field) ☐ Oversight Monitor will advise and consent on all major research decisions ☐ Oversight Monitor will review the research and results every [Click or tap to enter text. Enter a time interval, should not exceed 6 months.]
9	☐ Continuous updates on research to PHSA Research Leadership, including the option to provide access to research findings and/or have a delegate of PHSA Research Leadership sit in on research study meetings ☐ I will provide, every 6 months, a written summary regarding data analysis and interpretation ☐ I will provide access to the raw data involved in research, including instrument output and notebooks
	MODIFICATION OF ROLES/SIGNIFICANT FINANCIAL INTEREST

NO.	MANAGEMENT PLAN CONDITIONS
10	☐ Change of my responsibilities: ☐ On NIH study ☐ At PHSA (or other institution) ☐ Other: Click or tap here to enter text.
11	☐ Reduction of significant financial interest
12	☐ Elimination of significant financial interest
13	☐ End of relationships that create the FCOI
14	☐ Refrain from participating in any licensing discussions between PHSA and outside entity except as I would in my normal inventor role
15	☒ I will recuse myself from the final approval or authorization of any financial transaction or relationship between PHSA and any other organization in which I have a significant financial interest
16	☐ PHSA TDO and/or UBC UILO will be assigned all intellectual property developed from this grant
17	☐ I will change my role/relationship with the start-up company that creates the FCOI
18	☒ I will remove myself from related procurement processes
OVERSIGHT AND REPORTING	
19	☐ Appointment of an Independent Monitor (i.e., has no direct employment/affiliation relationship with PHSA or any subrecipient institutions) ☐ Independent Monitor will advise and consent on all major research decisions ☐ Independent Monitor will review the research and results every [Click or tap to enter text. Enter a time interval, should not exceed 6 months.]
20	☐ Analyst of data will be blinded. Analysis will be conducted by a non-conflicted member of the research team.
HUMAN SUBJECTS	
21	☐ Conflict will be disclosed to all potential research participants in the consent process and in the consent documents when human participants are involved
22	☐ I will not be involved in the recruitment of human subjects or the consenting of human subjects
23	☐ I will include detailed information, as the Research Ethics Board consent form template outlines, to all human subjects on my FCOI
OTHER	
24	☐ Other items, actions, etc. that have not been listed above. Please include details below: Click or tap here to enter text.

Updates [*if needed*]

CONDITION NO. (FROM ABOVE)	REVISIONS TO PLAN	NOTES	NOTES FROM REVIEWER
			[Complete if Reviewer]
			[Complete if Reviewer]
			[Complete if Reviewer]
			[Complete if Reviewer]
			[Complete if Reviewer]

Other Information as Needed

ITEM

Conclusions/Recommendations

Click or tap here to enter text. To be completed by the Reviewer, if necessary.

Certification That There Has Been No Change

☐ There are no changes to my last year's Management Plan, and therefore, the above is the same as submitted last year.

Certification of Acceptance/Consent Form

By uploading this Management Plan into the online PHSA Conflict of Interest declaration form (http://coi.phsa.ca), you are accepting the conditions of this Management Plan and agree to comply with all of its elements. You understand that this Plan will be effective upon the Institutional Official's online acceptance. Indication of the Institutional Official's approval will be online when they indicate "Approve" of your PHSA Conflict of Interest declaration form.

I certify that the information disclosed in the attached declaration form on significant financial interests related to institutional responsibilities is complete and accurate and true to the best of my knowledge.

I understand that the personal information in the attached form is collected under the authority of Section 26(c) of British Columbia's *Freedom of Information and Protection of Privacy Act* and will be protected under Part 3 of the Act.

In the event that the Institutional Official finds that a FCOI exists, I voluntarily authorize PHSA to disclose information related to that FCOI to PHSA administrative units as required by PHSA's Research Conflict of Interest Policy and to the NIH for the purposes of grant reporting as required under the NIH Regulations. I understand that the information will be disclosed outside of Canada as required by the Regulations.

In the event that a member of the public provides a written request for information on the FCOI identified by the Institutional Office, I voluntarily authorize PHSA to disclose my personal information pertaining to the request to the member of the public making the request, as required by the NIH Regulations.

I understand that I may withdraw consent at any time by notifying PHSA by email at researchadministration@phsa.ca. I understand that this withdrawal of consent may result in the suspension or termination of NIH funding for the related project.

I understand that if I have any questions, I may contact PHSA Research & Academic Services at researchadministration@phsa.ca.

This consent will automatically expire **three (3) years** from the date of consent.

Signature

(Signature) (Date)