



THIS IS A SAMPLE MANAGEMENT PLAN FOR REFERENCE ONLY

The Investigator in this management plan is participating in a NIH-funded study on outcomes of the use of telemedicine in the initial assessment of pediatric mass lesions. He also has equity in an Ultrasound company and acts as a consultant for ultrasound.

NIH 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. This 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](#)).

This Management Plan (the “Plan”) will need to be updated on an annual basis, or sooner if mandated by the Institutional Official (IO) and/or due to changes in circumstances. When you renew your declaration, if there are no changes in the plan, indicate so at the bottom of the form.

Your NIH awards and related patent applications, issued patents, trademarks, and/or copyrights are subject to this Plan.

Once you have filled out the form, upload it into your PHSA COI declaration form (<http://coi.phsa.ca>) for final approval. For additional information on the process and to see a sample Management Plan, visit PHSA Research & Academic Services NIH FCOI [webpage](#).

PROJECT SUMMARY

LAST NAME:

Doe

FIRST NAME:

Chris

MIDDLE NAME:

PROJECT TITLE:

Outcomes Of Use of Telemedicine in The Assessment Of Pediatric Mass Lesions

PRINCIPAL INVESTIGATOR:

Douglas 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.

CONDITIONS OF MANAGEMENT PLAN

Check as many boxes as appropriate for you, your Spouse, and/or your Dependent Child.

NO.

CONDITIONS OF PLAN

INTERACTIONS WITH STUDENTS, STAFF, AND COLLEAGUES

- 1 Disclose in writing (see [Informing Students and Colleagues of COIs](#) for example declarations) my FCOIs 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.
 - Included in this document 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 findings, they may inform the BCCA VP of Research (or Office of Research Facilitation) 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 of FCOI when presenting and/or publishing (see PHSA Research & Academic Services [website](#) for wording examples)

DISCLOSURE/MONITORING AT BCCA

- 6 Disclose of FCOI to Research Ethics Board
- 7 Disclose of FCOI, and the entire 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 who is at PHSA and 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 [enter interval] not to 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 the 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/SFI

- 10 Change of my responsibilities:
- On NIH study
 - At PHSA (or other institution)

Other [specify]

- 11 Reduction of SFI
- 12 Elimination of SFI
- 13 End of relationships that create the FCOI
- 14 Will refrain from participating in any licensing discussions between PHSA and outside entity except as they would in their 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 SFI
- 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 (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 [enter interval]
- 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:

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

[To be completed by reviewer if needed]

CERTIFICATION THAT THERE HAS BEEN NO CHANGE

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

CERTIFICATION OF ACCEPTANCE/CONSENT FORM

By uploading this template in the online PHSA COI Declaration Form (<http://coi.phsa.ca>), you are accepting the conditions of this 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 COI declaration form.

I certify that the information disclosed in the attached declaration form on significant financial interests (SFIs) 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 policy and to the NIH for the purposes of grant reporting as required under the 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 requests in writing 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 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 Aditi Bhardwaj, Manager Research Policy, PHSA, at 604-675-7498, researchadministration@phsa.ca.

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

Signature

(Signature)

(Date)