Unity Health Toronto
Office of Research Administration

**Addendum #2 – Non-Human Subjects Research**

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| **Section 1: Conflict of Interest** |
| Does the Unity Health Toronto Investigator or his/her family member(s) have one or more of the following interests? Please note that if you select yes, this information will be used for review under the [Research Conflicts of Interest Policy.](http://cpps/Default.aspx?cid=888&lang=1)[ ]  No [ ]  Yes, please contact Marianna Betro at x45521 for details and check all that apply:[ ]  Employment, consulting, ownership, or other financial interest in any entity that could benefit from the results of the study (including the funder, sponsor, owner of the study product, or entity that supplies products/materials for the study)[ ]  Member of the senior management (e.g. CEO or VP) or an officer or director of any entity that could benefit from the results of the study (including the funder, sponsor, owner of the study product, or entity that supplies products/materials for the study)[ ]  Inventorship, copyright or other ownership interest in the study product or a competitor product[ ]  Endorsement of the study product or a competitor product (i.e. my name, or my family member’s name, is associated in endorsing the product)The Unity Health Toronto Investigator is responsible for asking all members of the research team (including co-investigators, coordinators, managers, research, administrative staff, etc.) if they have any of the interests listed above.  |
| Are there any disclosures to be made by other members of the research team? [ ]  No [ ]  Yes, please contact  Marianna Betro at x45521  |
| **Section 2: Project Details** |
| Type of Research:[ ]  Wet bench (laboratory research that does not involve animal models, e.g., biochemical assays, microbiology research on Petri dishes, or molecular biology research, etc.) [ ]  Dry bench (research that does not involve animal models, e.g., literature review and analysis)[ ]  Animal study (research involving animals) [ ]  Other:       |
| Are any of the following involved in this project:Human subjectsPersonal or Personal health informationHuman biological samplesIf yes to any of the above, this addendum 2 is not applicable, please complete addendum 1 or addendum 4 as required. For assistance, please contact Researchcontracts@smh.ca | [ ] Yes [ ] No[ ] Yes [ ] No[ ] Yes [ ] No |
| Are there any other agencies/companies involved in the Project that are not listed in the agreement? If yes, please describe each of their involvement (e.g., Contract Research Organizations, Academic Research Organizations, Data Capture Management, etc.):       | [ ] Yes [ ] No |
| Are there pre-existing agreements related to the Project? (e.g., Funding Agreement, Licensing Agreement, Service Provider Agreement, other Sub-Site Agreements etc.)If yes, please provide contract ID(s)#       or attach a copy of the agreement(s).  | [ ] Yes [ ] No |
| Briefly describe the Project:       |
| Please provide any other factors that need to be taken into account in developing or reviewing the agreement (e.g., unique context, precedents/other agreements with source, timing, etc).       |
| Will confidential (proprietary) information be transferred to or from an external party (e.g., documents, research methods etc.)? If yes, by whom?       What information is being transferred?       | [ ] Yes [ ] No |
| Are there any students participating in this study? If yes, will it form part of their thesis work? *(U o fT guidelines require reduced publication delays for student thesis work. There may be questions about insurance coverage for non-employee students.)* | [ ] Yes [ ] No[ ] Yes [ ] No |
| Do you have adequate space and facilities to undertake this project to completion?If “no”, please discuss with your Department Head | [ ] Yes [ ] No |
| Please confirm that the protocol and informed consent form (pending versions accepted) are included in your contracts submission.If no, please explain:       | [ ] Yes [ ] No  |
| **Section 3: Project Certifications**  |
| *Animal Welfare*Are Animals involved in this Project? Location: If other, please name institution:       If Unity Health Toronto, do you have designated animal space for this Project at Unity Health Toronto?  | [ ] Yes [ ] No[ ] Unity [ ] Other[ ] Yes [ ] No |
| Will this Project require a new ACC approval? *(If in doubt, please check with the ACC Office before you answer this question.)*If yes, when will the protocol be submitted to the ACC?      For which review date?      If no, please provide ACC file number:       | [ ] Yes [ ] No |
| Are Biohazards involved in this Project at Unity Health Toronto? Will viral vectors be used/created? Does this Project involve the use of radioactive materials? *If yes, please contact the Research Biosafety Committee.* | [ ] Yes [ ] No[ ] Yes [ ] No[ ] Yes [ ] No |
| **Section 4: Contract Terms** |
| *I understand that I must comply with the confidentiality provisions in the agreement, and that I must ensure that the rest of my research team also complies.*  | [ ]  I confirm  |
| **Section 5: Budget Details- Please submit current copy of budget along with this form** |
| Is the budget still under negotiation? *Note: Investigator and study team are responsible for budget negotiations* | [ ] Yes [ ] No |
| Does the budget cover all the costs of the Project?If no, how will the other costs be funded?       | [ ] Yes [ ] No |
| Currency: $CAN [ ]  $US [ ]  Other [ ]  if other, please name:       | Period of funding:       to       |
| Sub-Total Amount of Funding (minus overhead): $     Overhead Rate:      %Total Overhead Amount: $     Total Amount of Funding: $     *Note regarding overhead (indirect costs) for non-industry funding: Unless the funding agency has a written policy disallowing overhead (indirect costs), the total costs must include overhead at the rates allowed by the funding agency (e.g., NIH rate is 8%).* |