Unity Health Toronto
Office of Research Administration

**Addendum #1 – 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  |
| If you answered yes to either of the above, has this information been disclosed in the REB application? [ ]  No [ ]  Yes |
| **Section 2: Study Details** |
| Are there any other agencies/companies involved in the Study that are not listed in the agreement? If yes, please describe each of their involvement (e.g., Contract Research Organizations; Academic Research Organizations; Lab Services; Data Capture Management; etc.):       | [ ]  Yes [ ] No  |
| Are there pre-existing agreements related to the Study? (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  |
| Is this a multi-site study? (If yes, also complete Section 7).  | [ ] Yes [ ] No  |
| Is Unity Health Toronto the Lead or Coordinating Institution? | [ ] Yes [ ] No  |
| If Unity Health Toronto is a sub-site/sub-grantee/sub-contractor, name Lead Institution:       and Lead PI:       |
| Briefly describe the Study intervention:        |
| 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: Privacy, REB and Study Certifications**  |
| Are human subjects involved in this Study at Unity Health Toronto (includes questionnaires, drugs, blood, tissue, DNA, excreta, tests or other procedures)?If yes, will their data/samples be sent out of Unity Health Toronto? | [ ] Yes [ ] No[ ] Yes [ ] No  |
| Will this project require a new REB approval?*(If in doubt, please check with the REB Office before you answer this question.)*If yes, when will the protocol be submitted to the REB?     For which review date?      If no, please provide REB file number:       | [ ] Yes [ ] No |
| Are human subjects involved in another location? If yes, will their data/samples be sent to Unity Health Toronto?  | [ ] Yes [ ] No[ ] Yes [ ] No |
| Is there any other transfer of personal and/or personal health information (e.g., identifiable data, human biological samples)?If yes, briefly explain:       | [ ] Yes [ ] No |
| Will confidential (proprietary) information be transferred to or from an external party (e.g., drug information, documents, research methods etc.)? If yes, by whom?       What information is being transferred?       | [ ] Yes [ ] No |
| Are Biohazards involved in this Study at Unity Health Toronto? Will viral vectors be used/created? Does this Study involve the use of radioactive materials? *If yes, please contact the Research Biosafety Committee.* | [ ] Yes [ ] No[ ] Yes [ ] No[ ] Yes [ ] No |
| Are there any students working on this Study? | [ ] Yes [ ] No |
| If yes, will it form part of their thesis work? (add UofT Guidelines language from addendum 2) | [ ] Yes [ ] No |
| Do you have adequate space and facilities to undertake this Study to completion? If “no”, please discuss with your Department Head.  | [ ] Yes [ ] No |
| **Section 4: Study Product or Equipment (if applicable)** |
| Will a drug, device, biologic or natural health product be used? If yes, please name and describe:       | [ ] Yes [ ] No  |
| Is equipment (not a study device as described above) being provided by an external entity? If yes, name or provide a description of the equipment:       | [ ] Yes [ ] No  |
| Who is providing the drug/device/biologic/natural health product or equipment?       |
| Is the product or equipment coming from another country (i.e. it needs to be imported)? If yes, who is listed as the importer?       | [ ] Yes [ ] No  |
| If a product will be provided by a company, do you want the company to supply the product free of charge after the end of the study (barring subject safety issues) until it is commercially available in Canada?  | [ ] Yes [ ] No  |
| Has a Clinical Trial Application been submitted to Health Canada for the Study products listed above? If yes, please provide a copy of the Health Canada regulatory approval. If no, please explain:       | [ ] Yes [ ] No  |
| **Section 5: 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 6: Budget- 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 |
| Number of subjects you are intending or anticipating to enroll:       |
| Does the budget cover all costs of the research? If no, how will the other costs be funded?       | [ ] Yes [ ] No  |
| Currency: $CAN [ ]  $US [ ]  Other [ ]  if other, please name:       |
| Period of funding:       to       |
| For industry/investigator initiated clinical research, have you included the following in the budget?Non-refundable REB Fee (If no, we will add it) Archiving Fee Audit FeeScreen Failure FeePharmacy FeeNon-refundable Start Up FeeLaboratory Start UpAdvertising Fee | [ ] Yes [ ] No [ ] Yes [ ] No [ ] N/A[ ] Yes [ ] No [ ] N/A[ ] Yes [ ] No [ ] N/A[ ] Yes [ ] No [ ] N/A[ ] Yes [ ] No [ ] N/A[ ] Yes [ ] No [ ] N/A[ ] Yes [ ] No [ ] N/A |
| Overhead Rate:       (If it is below our institutional OH rate of 35%, you must obtain a Waiver of OH).*Note: OH applies to everything except for REB review. 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%).*  |
| **Section 7: Multi-Site Involvement**  |
| In the event that this Study has multiple sites , please list all sites involved and provide the PI information for each site:

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| PI: |       | Institution: |       | Contact: |       |
| PI: |       | Institution: |       | Contact: |       |
| PI: |       | Institution: |       | Contact: |       |
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