Unity Health Toronto
Office of Research Administration

Version date Dec 23 2021

**Addendum #4 - Privacy (Data or Human Biological Samples Transfer)**

For Non-Human Biological Samples, please complete addendum 3 instead

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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** |
| What is being transferred under this agreement? Check all that applyPersonal and/or Personal Health Information (Identifiable) [ ] Personal and/or Personal Health Information (De-Identified) [ ] Human Biological Samples [ ] Whole genome/exome sequencing data or methylation sequencing data [ ] Is the transfer with Consent [ ] Is the transfer with Waiver of Consent [ ] What page in the Protocol is the Waiver/Consent for the transfer referred to?:      What page in the Protocol describes the description of the external transfer?      Please describe what is being transferred:      Please describe the quantity of what is being transferred:      What is the frequency of the transfer?      Is the data and/or samples being transferred to or from a databank/biobank, consortium, or restricted/controlled genomic database: [ ]  Yes [ ]  No Are the transferred human biological going to be sequenced by the Recipient? [ ]  Yes [ ]  No  |
| Provider Researcher: Recipient Researcher:[contact details] [contact details]Provider Institution: Recipient Institution: [contact details] [contact details] |
| Do the personal information/biological samples(s) originate from the European Union/European Economic Area?Do the personal information/biological samples(s) originate from the United Kingdom (Great Britain and Northern Ireland)?Is the personal information/biological sample(s) being transferred: * Out of UHT
* To UHT
* Both ways (e.g., Are both parties sending and receiving personal information/biological samples?) Please explain:
 | [ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  [ ] [ ]  |
| Is this a collaboration or joint research initiative? Is the personal information/biological sample(s) being returned to Provider or destroyed? If no, please explain (e.g.: added to Recipient’s databank or biobank):      If UHT is the Provider, are we receiving back a copy of the analysis or results?  If no, please explain:       If yes, do we: Intend to use a copy of the analysis or results in our own research? Require ownership of the analyzed data? | [ ]  Yes [ ]  No [ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No[ ]  Yes [ ]  No |
| 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 contracts related to the study? (e.g., funding agreement)If yes, please provide contract(s) and/or contract ID number(s)        | [ ]  Yes [ ]  No |
| Will the Recipient be further transferring the personal information and/or biological samples to a third party (e.g., consortium, service provider, or collaborator)?If yes, please provide the name of the third party and explain       | [ ]  Yes [ ]  No  |
| Will the Recipient, or third party, use the personal information/biological sample(s), including derivatives from the biological sample(s), for a commercial purpose\* (see next page for definition)?If yes, please give a brief description:\*”Commercial purpose” includes the sale, lease, license, or transfer of the data/material by the Recipient to a for-profit organization; using data/material to perform contract research, screen compound libraries, or produce or manufacture products for general sale; conducting research that results in any sale, lease, license or transfer of the data/material to a for-profit organization; and any other commercial exploitation of the data/material. Industry sponsored academic research will not be considered a “commercial purpose” unless it also constitutes one of the above scenarios. | [ ]  Yes [ ]  No  |
| 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 other confidential information be provided (e.g., proprietary information)? If yes, by whom?       What might it be?       | [ ]  Yes [ ]  No  |
| Are there any students participating in this study? If yes, will it form part of their thesis work? *(U of T guidelines require reduced publication delays for student thesis work. There may be questions about insurance coverage for non-employee students.)* | [ ]  Yes [ ]  No [ ]  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: Privacy, REB and Study Certifications**  |
| 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? ***Oct 4, 2021.***For which review date? ***This can be a delegated review.*** If no, please provide REB file number:       | [ ]  Yes [ ]  No  |
| ***Biohazards***Are Biohazards involved in this project at Unity Health Toronto? Will viral vectors be used/created?  | [ ]  Yes [ ]  No [ ]  Yes [ ]  No |
| ***Radioactive Materials***Does this project involve the use of radioactive materials? *If yes, please contact the Research Biosafety Committee.* | [ ]  Yes [ ]  No  |
| **Section 4: Budget** |
| Is funding provided or to be paid under this Agreement? (This includes invoicing for nominal fees associated with the transfer of data/samples) If yes, is the budget still under negotiation? Please attach the budget for this Study, if applicable.       | [ ]  N/A [ ]  Yes [ ]  No[ ]  Yes [ ]  No  |