MATERIAL AND INFORMATION TRANSFER AGREEMENT (MITA)

This Material and Information Transfer Agreement ("Agreement") is entered into this [Date] ("Effective Date")

BETWEEN:

MCMASTER UNIVERSITY ("Provider Institution"), a corporation incorporated under the laws of the Province of Ontario, Canada, and having an office at 175 Longwood Road S., MIP-305, Hamilton, Ontario, L8P 0A1**,** Attention: McMaster Industry Liaison Office, Telephone: 905-525-9140, Facsimile: 905-546-1372, on behalf of Dr. Padmaja Subbarao ("Provider Scientist"), telephone: 416-813-6247; e-mail: Padmaja.subbarao@sickkids.ca.

(together, the Provider Institution and the Provider Scientist will be known as the "**Provider**")

AND:

_____, ("The Recipient Institution") a corporation incorporated under the *ABC University Act* of ABC and having offices at 123 ABC Road, ABC, ABC, Canada ABC, Attention: University-Industry Liaison Office, Telephone: 123, Facsimile: 6123, on behalf of ("The Recipient Scientist"); e-mail:_____.

(together, the Recipient Institution and the Recipient Scientist will be known as the the **"Recipient**")

WHEREAS:

The Provider will provide the Recipient certain proprietary information and/or biological materials on the terms and conditions set out in this Agreement.

NOW THEREFORE, the Provider and Recipient agree as follows:

1. **DEFINITIONS**

a. "The CHILD Study" means the Canadian Healthy Infant Longitudinal Development (CHILD) Study, an academic consortium of 40+ Canadian researchers, who recruited 3,624 infants and their families to uncover the root causes of asthma, allergies, and other chronic diseases.

b. "Material" means the Original Material and all Progeny and Unmodified Derivatives. Material may include biological samples derived from human subjects, including blood, stool, urine, milk, nasal swabs, saliva and tissue, as well as samples of environmental nature, including but not limited to dust samples that have been collected for the CHILD Study. Material may include information or Data collected for the CHILD Study.

I. "Original Material" means the original material being transferred to the Recipient as described in Appendix A of this Agreement.

II. "Progeny" means unmodified descendant from the Material, such as virus from virus, cell from cell or cells from tissue.

III. “Unmodified Derivatives” means substances created by the Recipient, which constitute an unmodified functional or structural sub-unit or product expressed by the Original Material or derived from Progeny. Some examples include sub-clones of unmodified cell lines; purified or fractionated subsets of the Original Material; proteins expressed by DNA/RNA supplied by the Provider; monoclonal antibodies secreted by a hybridoma cell line; or sub-sets of the Original Material, such as novel plasmids or vectors.

IV. “Modifications” means substances created by the Recipient which contain/incorporate any form of the Material.

c. “Data” means the data collected for the CHILD Study as more fully described in Appendix B attached;

d. "Information" means any and all information, know-how, techniques or practices that the Provider discloses to the Recipient either orally or in writing and identified as CONFIDENTIAL at the time of disclosure, relating to the Material or its use, and includes all research, data, specifications, plans, drawings, prototypes, recordings, instructions, manuals, papers or other materials in whatever form, but excludes any Information that:

I. was already in the possession of the Recipient and evidenced by written documents existing prior to the date of disclosure of the Information by the Provider to the Recipient;

II. is publicly known at the time of the disclosure;

III. must be disclosed under applicable laws, regulations or orders of any governmental authority;

IV. is furnished by the Provider to others without restrictions on its use or disclosure; or

V. is independently developed by the Recipient without use of the Information.

Information disclosed orally or visually shall be reduced to writing within thirty (30) days.

e. “Commercial Purposes” means the sale, lease, license or other exploitation of the Material, Information or Modifications to a person or organization for profit, including, but not limited to, use of the Material, Information or Modifications by the Recipient or any individual or organization to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license or other exploitation of the Material, Information or Modifications to any individual or organization for profit. For greater certainty, academic research sponsored by government or industry does not fall within the definition of Commercial Purposes unless the sponsor retains rights, title or interests in and to the Material, Information or Modifications; or unless the research activities result in any sale, lease, license or other exploitation of the Material, Information or Modifications to any individual or organization for profit.

f. “The Recipient’s Research Project” means the Recipient Scientist’s research project described in Appendix A for access to materials, or Appendix B for access to Data.

2. **PERMITTED USES & USERS OF MATERIAL AND INFORMATION**

Subject to the terms and conditions of this Agreement, the Provider hereby grants to the Recipient a non-transferable non-exclusive license to use the Material and Information in the Research Project for academic research purposes only.

The Recipient must:

I. have received local Research Ethics Board (REB) approval for the Recipient's Research Project or an REB waiver, as applicable;

II. only use the Material and Information for academic research purposes as part of the approved study protocol set out in the Recipient's Research Project;

III. use the Material and Information only under the direction of the Recipient Scientist or others working under his/her direct supervision and control;

IV. use the Material and Information for analysis purposes only and must not undertake, directly or indirectly, any efforts to duplicate or reverse engineer the Material and Information;

V. ensure that current best practices are strictly observed for the preservation, examination, management, and analysis of the Material and Information to increase their sustainability and minimize the risk of Material and Information degradation;

VI. not use the Material and Information on human subjects, in clinical trials or for diagnostic purposes involving human subjects without the prior written consent of the Provider and confirmation of all regulatory and ethics approvals;

VII. not transfer the Material and Information to any person or entity other than laboratory personnel under the direct supervision or control of the Recipient Scientist without the Provider's prior written consent;

VIII. not use the Material and Information to identify any individuals;

IX. not make contact or attempt to make contact with an individual unless the Provider first obtains the individual's consent to be contacted;

X. will not attempt to link the Data (in whole or in part) with any other data held by or available to the Recipient, other Recipients or by the Recipient Institution, unless specified and agreed in the initial Data request in Appendix B.

3. **COMMERCIAL USE**

If the Recipient wishes to use or license the Material, Information or Modifications for Commercial Purposes, the Recipient must obtain a commercial license from the Provider. The Provider has no obligation to grant such a license to the Recipient. The Provider is free to grant exclusive or non-exclusive licenses to others or assign all or part of the rights in the Material and Information to any third party(ies), subject to any pre-existing rights held by others and any obligations to government agencies.

4. **COST & DELIVERY OF MATERIAL AND INFORMATION**

The Provider will review and negotiate with the Recipient the need for cost recovery in consideration of the Material and Information provided on a case-by-case basis, and the agreed upon costing will be documented prior to the Provider sending the Material and Information to the Recipient (see Appendix A.3 Cost recovery for Material and Information).

5. **OWNERSHIP**

The Provider retains all rights, title and interest in and to the Material, Information, including any Material contained in whole or in part in Modifications.

6. **PROGRESS AND FINAL REPORTS**

The Recipient will send to the Provider an annual written report on the progress and results of the Research Project, including any raw data, and analysis on or generated from the use of the Material within sixty (60) days of the end of each anniversary year of this Agreement, including its final year (see Appendix A.4 re Progress Reports). Subject to further discussion and the consent of the Recipient, the

Provider shall be entitled to use the report and raw data for further academic research and analysis activities only. Upon completion of the Research Project, the Recipient will provide an electronic copy of the original Data, the derived data and meta data generated by the Recipient Institution results and the syntax used to generate them within a period of six (6) months of completion of the Research Project for permanent archiving (see also Appendix A.5 re Data Sharing).

7. **WARRANTIES**

The Provider makes no representation or warranty of any kind, expressed or implied, with respect to the Material and Information, including but not limited to any representation or warranty with respect to the utility, efficacy, non-toxicity, safety, merchantability, title, or fitness for a particular purpose or that the use of the Material and Information will not infringe any patent, copyright or other proprietary rights of a third party.

8. **ASSUMPTION OF RISK**

The Recipient acknowledges that the Material is experimental in nature, that all of its characteristics, as well as hazards associated with its use, may not be known. The Recipient assumes all risk and responsibility for the use, storage or disposal of the Material as well as the risks of transport, loss or damage to or by the Material upon the Material leaving the custody and premises of the Provider.

9. **NO LICENSE TO PROPRIETARY RIGHTS**

The Recipient acknowledges that the Material is or may be the subject of a patent application, plant breeders' rights or other forms of proprietary rights. Except as provided in this Agreement, no express or implied licenses or other rights, including for profit-making or Commercial Purposes, are provided to the Recipient in respect of such rights, including any altered forms of the Material made by the Provider.

10. **NEW INTELLECTUAL PROPERTY/INVENTIONS**

If the Recipient's use of the Material and Information results in an invention or substance which he/she discloses to the Recipient Institution for commercialization purposes ('New Intellectual Property'), the Recipient will also promptly disclose the invention or substance to the Provider and notify the Provider of the role of the Material and Information, the Provider and any other person affiliated with the Provider in the creation of the New Intellectual Property.

The Provider will keep confidential any information provided by the Recipient relating to the New Intellectual Property. If the Recipient wishes to commercialize New Intellectual Property, the Recipient must negotiate in good faith with the Provider, and any other party having rights to benefit from the use of the Material and Information for Commercial Purposes, an agreement based on the respective parties' contributions in creating the invention or substance. Where the Recipient has created Modifications, the Recipient grants the Provider a non-exclusive, non-transferable, perpetual, royalty-free license to use the Modifications for teaching and academic research purposes.

11. **CONFIDENTIALITY**

Subject to Section 12 hereof, during the term of this Agreement and for a period of three (3) years after the termination of this Agreement, the Recipient will make reasonable efforts to maintain the confidentiality of the Material and Information (whether or not owned or developed by the Provider or disclosed to the Provider by a third party whose material or information the Provider is obligated to treat as confidential or proprietary) and to prevent any unauthorized access, reproduction, disclosure and/or use of the Material and Information.

12. **PUBLICATION**

If the Recipient wishes to present or publish the results of the research conducted using the Material or Information, the Recipient will submit a copy of the proposed presentation or publication to the Provider

at least thirty (30) days in advance of the presentation or publication submission date to allow the Provider time to review and identify any disclosure of its confidential or proprietary information. If the Provider responds within the thirty (30) day period and identifies such information, the Recipient shall remove such information before publication or presentation. If the Provider responds to the Recipient within the thirty (30) day period and identifies patentable subject matter of either the Provider or the Recipient for which the Provider desires to have patent applications filed, the Recipient shall delay publication for a maximum of ninety (90) days from date of original disclosure to allow the Provider an opportunity to file the required patent applications. The parties agree that any publication made pursuant to this agreement shall be made in accordance with the custom of scientific research and shall acknowledge the contribution of the parties' scientists, as appropriate.

13. **LIMITATION OF LIABILITY & INDEMNITY**

The Recipient assumes all liability for loss or damages arising from the use, storage or disposal of the Material or Information and further agrees to indemnify, defend and hold harmless the Provider and its officers, directors and employees from all claims, actions and damages whatsoever, including legal fees, resulting from or in connection with the use, storage or disposal of the Material, except insofar as such claims result directly from the gross negligence or willful misconduct of the Provider. In no circumstances will the Provider be liable for any special, direct, consequential, incidental or any other damages suffered by the Recipient or any others resulting from the use, storage or disposal of the Material or Information, and Modification or any product derived from use of the Material or any Modification.

14. **TERM & TERMINATION**

This Agreement will terminate on the earliest of the following dates:

I. Three (3) years from the date of the last signature;

II. When the Recipient notifies the Provider in writing that the Research Project has been completed or terminated;

III. When the Material or Information becomes generally and unconditionally available from third parties, for example, through reagent catalogues or public depositories;

IV. On thirty (30) days written notice by either party to the other of its intention to terminate this Agreement, in the absence of a breach of any of the provisions of this Agreement;

V. The Recipient becomes bankrupt or insolvent or a receiver is appointed to take possession of the Recipient's business or property or the Recipient has assigned its interest to creditors;

VI. The Recipient commits a breach of this agreement;

VII. The Recipient terminates the non-exclusive license granted to the Provider under section 10.

On the expiration or early termination of this Agreement, the Recipient will discuss and document with the Provider whether to return, retain or destroy any unused Materials and Information However, if the Provider has a request for any unused Material from a third party, the Recipient may retain unused Materials on site in an appropriate manner to preserve their value and with clear records indicating how they have been stored (*e.g.*, freeze thaw cycles, *etc*.) in order to transfer them to a new approved Recipient pursuant to Section 2 VI.

15. **CONSEQUENCES OF A BREACH**

Failure to comply with the terms of this Agreement may result, in addition to termination of this Agreement pursuant to Section 14, to the disqualification of the Recipient and/or the Recipient's Institution from receiving any additional Material and Information from the Provider.

16. **NOTICES**

All notices given under this Agreement must be in writing and delivered by courier or registered mail, return receipt requested, or facsimile, to the address of the party set out on page one of this Agreement. All notices to the Provider must be addressed to Gay Yuyitung, Executive Director, McMaster Industry Liaison Office, 305 – 175 Longwood Rd., S., Hamilton, Ontario L8P 0A1, email: yuyitun@mcmaster.a and all notices to the Recipient must be addressed to title / contact name for position. Notices will be deemed to have been received on the date of delivery, if delivered by courier, on the fifth business day following receipt, if delivered by registered mail, or on the first business day following the electronic confirmation of the successful transmission of the facsimile, if sent by facsimile or by email to the Recipient's last known email address on the day the email was sent.

17**. REMEDIES/NO WAIVER**

The Provider will be entitled to seek a temporary or permanent injunction or any other form of equitable relief to enforce the obligations contained in this Agreement. Failure of a party to enforce its rights on one occasion will not result in a waiver of those rights on any other occasion.

18**. ASSIGNMENT**

Neither party may assign any of its rights or obligations under this Agreement without the prior written consent of the other party.

19**. REGULATORY COMPLIANCE**

Each party must comply with all applicable laws, regulations and rules in its jurisdiction, including but not limited to those involving the use of animals or recombinant DNA. This Agreement is made in compliance with section 44(5) of the Personal Health Information Protection Act, 2004, S.O. 2004, c. 3 ("PHIPA").

20. **ENTIRE AGREEMENT/SEVERABILITY**

This Agreement represents the entire agreement between the parties with regard to the Material or Information and supersedes any previous understandings, commitments or agreements, whether written or oral. If any provision of this Agreement is wholly or partially unenforceable for any reason, all other provisions will continue in full force and effect.

21. **SURVIVAL**

The obligations contained in clauses 2, 5, 6, 7, 9, 10, 11, 12, 14 and 15 will survive termination or early expiration of this Agreement.

22. **AUTHORITY TO BIND/EXECUTION**

Each Party represents that it is permitted to enter into this Agreement and to consent to its conditions and that each has authority to sign this Agreement. This Agreement may be executed in one or more counterparts, each of which will be deemed an original, but all of which will constitute one and the same instrument. If delivered by facsimile, the party must also send promptly and without delay an executed original by courier to the other party. This Agreement may also be created as an electronic document and executed by electronic signature.

23. **GOVERNING LAW**

This Agreement will be governed and construed in accordance with the laws of the Province of Ontario and the laws of Canada and the parties submit to the exclusive jurisdiction of the courts of the Province of Ontario.

24**. FURTHER ASSURANCES**

Each party will execute and deliver such further agreements and other documents and do such further acts and things as the other parties reasonably request to evidence, carry out or give full force and effect to the intent of this Agreement.

The Parties have duly executed this Agreement by their duly authorized representatives as of the Effective Date.

PROVIDER	**THE RECIPIENT**
_____	_____
Gay Yuyitung	<First Name, Last Name>
Executive Director	<Title>
McMaster Industry Liaison Office	<Name of Institution>
_____	_____
Date	Date

Acknowledgment by the PROVIDER SCIENTIST and the RECIPIENT SCIENTIST

I have read and understood this Agreement and agree to act in accordance with all the terms and conditions of the Agreement. I further agree to ensure that all participants working under my supervision or otherwise involved in working with the Material and Information are aware of and abide by the terms of this Agreement.

_____	_____
Padmaja Subbarao, Director, CHILD Study	Name of the Recipient Scientist
_____	_____
Date	Date

Appendix A to CHILD MITA

NOTE: Appendix A may be updated from time to time if additional materials are required. However, any subsequent requests will be governed by the initial MITA dated _____ (insert date from page 1)

1. Description of the Materials:

1.1: The Provider reserves the right to request immediate feedback regarding the Material quality. If there are concerns with Material quality, the Recipient will contact the Provider with this information.

2. Description of the Recipient's Research Project:

3. Cost recovery for Material and Information.

The Recipient will make payment to the Provider Institution in the amount of $_____ CAD in consideration for the Material and Information. The Provider Institution shall be in receipt of the financial consideration within forty-five (45) days of the execution date of this Agreement. Should such consideration not be received by the Provider Institution from the Recipient during this forty-five (45) day period, and within fifteen (15) days after the Provider Institution notifies the Recipient of such non-payment, the Provider Institution shall have the right to terminate this Agreement.

4. Progress reports

The Provider retains the right to investigate the veracity of progress reports at the Provider's expense. These investigations may include a site visit with reasonable prior notice to the Recipient and at mutually acceptable times.

5. Data sharing

The Recipient will make available all results or analysis performed on or generated by the Material to the Provider for the purposes of data sharing. Given the many different types of potential data, the precise format for the data documentation, formatting, presentation, or transport mode may vary. With respect to data content and format, for this agreement, the following has been agreed upon:

Data sharing should occur in a timely fashion however, the specific time will be influenced by the nature of the data. It is expected that the Recipient may benefit from first and continuing use but not from prolonged exclusive use of this data. With respect to timing of data sharing, for this agreement, the following has been agreed upon:

Appendix B

REQUEST FOR DATA **Date: _____**

(NOTE: Appendix B may be updated from time to time if additional Data is required. However, any subsequent requests will be governed by the initial MITA dated _____(insert date from page 1).

Please complete fully and submit to Dr. Padmaja Subbarao (Padmaja.subbarao@sickkids.ca) and copy Dr. Diana Lefebvre, Research Manager (lefeb@mcmaster.ca).

The request will be reviewed at the National Coordinating Centre, and any queries that arise will be discussed with you. The request will then be forwarded to our Data Manager who will extract the requested data and again we will review this at NCC to ensure it is what you require. The Data Manager may communicate directly with you to clarify your needs.

1	***Person making request:***
2	***Purpose of request:*** (a) Data for grant application ☐ (b) Data for QA / QC only ☐ (c) Data for exploratory analysis ☐ (d) Data for definitive analysis ☐
3	***Data requested:***

Event	**Questionnaire or Data Form**	**Specific questions**	**Justification**
e.g., 18 Week Prenatal	*e.g., Q92HENV18W*	*e.g., Q1,2,3-5.9(indicate whether you want subquestions)*	*Looking at how many child sleep in carpeted bedrooms*

4	***Data requested from which sites and cohorts (check all that apply):*** ❑ **Vancouver** ❑ **Edmonton** ❑ **Winnipeg** ❑ **Toronto** ❑ **Vanguard cohort only** ❑ **General cohort only** ❑ **Vanguard + General**
5	***Outline of Analysis Plan:***
6	***Collaborators for this analysis:***
7	***Intended use of this analysis:***
8	***Has proposal for abstract or paper been submitted to the Publications Committee?*** Yes ☐ No ☐ Not applicable ☐
9	***What format do you want the data in?*** CSV ☐ Excel ☐

10	***Any further details regarding this data request?***